EthxWeb Search Results

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2=(RESEARCH+ AND ("15."+[PC])) NOT (LETTER+ OR (NA.PT.) OR NEWS)
3=2 AND 1 : "
Documents: 1 - 325 of 692

Document 1
McMurter, Britney; Parker, Louise; Fraser, Robert B; Magee, J Fergall; Kozancyzn, Christa; Fernandez, Conrad V
Parental views on tissue banking in pediatric oncology patients.
Pediatric blood & cancer 2011 Dec 15; 57(7): 1217-21
Abstract: Research using banked tissue is key to advancing risk-stratification and treatment of children with cancer. Knowledge of parental attitudes to ethical issues arising in tissue banking is very limited but essential in obtaining respectful consent.

Document 2
Holmes, David
Sound and fury after stem cell ruling.
Lancet 2011 Nov 5; 378(9803): 1617

Document 3
Katapodi, Maria C; Munro, Michelle L; Pierce, Penny F; Williams, Reg A
Psychometric testing of the decisional conflict scale: genetic testing hereditary breast and ovarian cancer.
Nursing research 2011 Nov-Dec; 60(6): 368-77
Abstract: Hereditary breast and ovarian cancer (HBOC) syndrome is attributed mostly to mutations in the Breast Cancer 1 and Breast Cancer 2 genes (BRCA1/2). Mutation carriers of BRCA1/2 genes have significantly higher risk for developing breast cancer compared with the general population (55%-85% vs. 12%) and for developing ovarian cancer (20%-60% vs. 1.5%). The availability of genetic testing enables mutation carriers to make informed decisions about managing their cancer risk (e.g., risk-reducing surgery). However, uptake of testing for HBOC among high-risk individuals is low, indicating the need to better understand and measure the decisional conflict associated with this process.

Document 4
Saha, Krishanu; Hurlbut, J Benjamin
Research ethics: Treat donors as partners in biobank research.
Nature 2011 October 19; 478(7369): 312-3
"Who owns your poop?: insights regarding the intersection of human microbiome research and the ELSI aspects of biobanking and related studies.

Abstract: While the social, ethical, and legal implications of biobanking and large scale data sharing are already complicated enough, they may be further compounded by research on the human microbiome.

European biobanks forge cross-border ties.

Bridging consent: from toll bridges to lift bridges?

Biobank research: who benefits from individual consent?

Gene and genetic diagnostic method patent claims: a comparison under current European and US patent law.

Abstract: The paper focuses on the fundamental debate that is going on in Europe and the United States about whether genes and genetic diagnostic methods are to be regarded as inventions or subject matter eligible for patent protection, or whether they are discoveries or principles of nature and thus excluded from patentability. The study further explores some possible scenarios of American influences on European patent applications with respect to genetic diagnostic methods. Our analysis points out that patent eligibility for genes and genetic diagnostic methods, as discussed in the United States in the Association of Molecular Pathology versus US Patent and Trademark
Office decision, is based on a different reasoning compared with the European Patent Convention.

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Document 10

Tonkens, Ryan

**Good parents would not fulfill their obligation to genetically enhance their unborn children.**
Journal of medical ethics 2011 Oct; 37(10): 606-10

**Abstract:** The purpose of this paper is to unveil the incompleteness of John Harris' view that parents have a moral obligation to genetically enhance their unborn children. Specifically, here two main conclusions are proposed: (1) at present there exist insufficient empirical data for determining whether prenatal genetic enhancement (PGE) is a moral obligation on prospective parents. Although the purpose of PGE research would be to determine the extent to which PGE is safe and effective, the task of determining the veracity of Harris' premises is impossible to achieve without begging the question; we would be forced to assume the moral permissibility of PGE in order to generate the data that are required for determining its moral standing. So, given this empirical blindness, consequence-based normative frameworks like that of Harris cannot determine the moral standing of PGE, but merely push the question of the moral standing of PGE back a step, without offering any plausible and morally endorsable recourse for how to answer it; (2) even if PGE research were legal, which it is not, parents nevertheless have good reason not to consent to it for their children, especially as participants in the first wave(s) of such research.

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Document 11

Arnason, Vilhjálmur

**Database research: public and private interests.**

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Document 12

Karlsen, Jan Reinert; Solbakk, Jan Helge; Holm, Søren

**Ethical endgames: broad consent for narrow interests; open consent for closed minds.**

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Document 13

Fullerton, Stephanie M; Lee, Sandra S-J

**Secondary uses and the governance of de-identified data: lessons from the human genome diversity panel.**
BMC medical ethics 2011 September 26; 12: 16

**Abstract:** Recent changes to regulatory guidance in the US and Europe have complicated oversight of secondary research by rendering most uses of de-identified data exempt from human subjects oversight. To identify the implications of such guidelines for harms to participants and communities, this paper explores the secondary uses of one de-identified DNA sample collection with limited oversight: the Human Genome Diversity Project (HGDP)-Centre d'Etude du Polymorphisme Humain, Fondation Jean Dausset (CEPH) Human Genome Diversity Panel.

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Document 14
Walsh, Pat; Elsabbagh, Mayada; Bolton, Patrick; Singh, Ilina
In search of biomarkers for autism: scientific, social and ethical challenges.
Abstract: There is widespread hope that the discovery of valid biomarkers for autism will both reveal the causes of autism and enable earlier and more targeted methods for diagnosis and intervention. However, growing enthusiasm about recent advances in this area of autism research needs to be tempered by an awareness of the major scientific challenges and the important social and ethical concerns arising from the development of biomarkers and their clinical application. Collaborative approaches involving scientists and other stakeholders must combine the search for valid, clinically useful autism biomarkers with efforts to ensure that individuals with autism and their families are treated with respect and understanding.

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Document 15
Renwick, Chris
From political economy to sociology: Francis Galton and the social-scientific origins of eugenics.
British journal for the history of science 2011 Sep; 44(162 Pt 3): 343-69
Abstract: Having coined the word 'eugenics' and inspired leading biologists and statisticians of the early twentieth century, Francis Galton is often studied for his contributions to modern statistical biology. However, whilst documenting this part of his work, historians have frequently neglected crucial aspects of what motivated Galton to establish his eugenics research programme. Arguing that his work was shaped more by social than by biological science, this paper addresses these oversights by tracing the development of Galton's programme, from its roots in a debate about political economy to his appeals for it to be taken up by sociologists. In so doing, the paper not only returns Galton's ideas to their original context but also provides a reason to reflect on the place of the social sciences in history-of-science scholarship.

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Document 16
Widdows, Heather; Cordell, Sean
The ethics of biobanking: key issues and controversies.

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Document 17
Levitt, Mairi
Relating to participants: how close do biobanks and donors really want to be?
Abstract: Modern biobanks typically rely on the public to freely donate genetic data, undergo physical measurements and tests, allow access to medical records and give other personal information by questionnaire or interview. Given the demands on participants it is not surprising that there has been extensive public consultation even before biobanks in the UK and elsewhere began to recruit. This paper considers the different ways in which biobanks have attempted to engage and appeal to their publics and the reaction of potential and actual donors. Whilst those organising biobanks presumably want to be as close to their publics as they need to be in order to successfully recruit and sustain participation in sufficient numbers, the closer the relationship the more obligations and expectations there are on both sides.

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Holm, Søren

Withdrawing from research: a rethink in the context of research biobanks.
Health care analysis: HCA: journal of health philosophy and policy 2011 Sep; 19(3): 269-81

Abstract: It is generally assumed in research ethics that research participants have an unconditional right to withdraw from research without any detriment or reprisal. This paper analyses this right in the context of biobank research and argues that the traditional shape of the right in clinical research can be modified in biobank research without incurring significant ethical cost. The paper falls in three parts. The first part is a brief explication of the philosophical justification of the right to withdraw. The second part presents a number of extant criticisms of the right. And the third and final part argues that although a right to withdraw is crucial in relation to biobank research, such a right has to be specified in a different way to the similar right in relation to clinical research.

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McHale, Jean V

Accountability, governance and biobanks: the ethics and governance committee as guardian or as toothless tiger?
Health care analysis: HCA: journal of health philosophy and policy 2011 Sep; 19(3): 231-46

Abstract: The huge potential of biobanks/genetic databases for the research community has been recognised across jurisdictions in both publicly funded and commercial sectors. But although there is tremendous potential there are likewise potential difficulties. The long-term storage of personal health information and samples poses major challenges. This is an area is fraught with ethical and legal uncertainties. Biobanks raise many questions of the control of rights, of consent, of privacy and confidentiality and of property in human material. It is thus unsurprising then that there has been a lively debate as to how biobanks should operate, the boundaries of participation and what governance structure, if any they should adopt, a debate which has been engaged in across the academic community and by funders and researchers alike. This paper asks despite the good intentions can ad hoc ethics and ethics and governance committees long term provide an effective solution to the legal and regulatory challenges arising from biobanks.

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Tassé, Anne Marie

Biobanking and deceased persons.
Human genetics 2011 Sep; 130(3): 415-23

Abstract: Early biomedical research focused primarily on the study of specific diseases or sets of diseases within small groups of living research participants. Accordingly, the first ethical frameworks governing biomedical research addressed short-term, limited-scope research involving living research participants. Due to recent interest in longitudinal population studies and biobanking, research is increasingly long term. This shift raises several ethical and legal issues concerning the impact of a participant's death on research. This paper offers an overview of these issues in the context of longitudinal biobanking genetic research. Our first part outlines the legal and ethical frameworks that govern the effect of the participants' death on consent. This will be followed by an analysis of the legal and ethical frameworks that govern the secondary use of deceased participants' data and samples and the return of deceased participants' individual research results to biological family members. In our second part, we will review the current literature and discuss the above mentioned issues using the bioethics "principlism" theory before concluding.

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**Genomic databases access agreements: legal validity and possible sanctions.**

Human genetics 2011 Sep; 130(3): 441-9

**Abstract:** Large-scale, public genomic databases have greatly improved the capacity of researchers to do genomic research. In order to ensure that the scientific community uses data from these public resources properly, data access agreements have been developed to complement already existing legal and ethical norms. Sanctions to address cases of data misuse constitute an essential part of this compliance framework meant to protect stakeholders in genomic research. Yet very little research and community debate has been done on this most important topic. This paper presents a review of different sanctions that could be invoked in cases of non-compliance from data users. They have been identified through comprehensive research and analysis of over 450 documents (journal articles, policy, guidelines, access policies, etc.) related to this topic. Given the considerable impact on users of even the milder sanctions considered in our paper, it is essential that stakeholders strive to achieve the highest degree of standardization and transparency when designing controlled-access agreements. It is only fair, after all, that users be able to expect that the border between acceptable and unacceptable conduct is clearly delineated and predictable in controlled-access policies. This suggests the importance for researchers to undertake additional empirical studies on the clarity and accessibility of existing database access agreements and related policies in the near future.

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**Identifiability in biobanks: models, measures, and mitigation strategies.**

Human genetics 2011 Sep; 130(3): 383-92

**Abstract:** The collection and sharing of person-specific biospecimens has raised significant questions regarding privacy. In particular, the question of identifiability, or the degree to which materials stored in biobanks can be linked to the name of the individuals from which they were derived, is under scrutiny. The goal of this paper is to review the extent to which biospecimens and affiliated data can be designated as identifiable. To achieve this goal, we summarize recent research in identifiability assessment for DNA sequence data, as well as associated demographic and clinical data, shared via biobanks. We demonstrate the variability of the degree of risk, the factors that contribute to this variation, and potential ways to mitigate and manage such risk. Finally, we discuss the policy implications of these findings, particularly as they pertain to biobank security and access policies. We situate our review in the context of real data sharing scenarios and biorepositories.

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**Biobanking and international interoperability: samples.**

Human genetics 2011 Sep; 130(3): 369-76

**Abstract:** In terms of sample exchange, international collaborations between biobanks, or between biobanks and their research partners, have two important aspects. First, the donors' consent usually implies that the scope and purpose of any sample transfer to third parties is subject to major constraints. Since the legal, ethical and political framework of biobanking may differ substantially, even between countries of comparable jurisdictional systems, general rules for the international sharing of biomaterial are difficult, if not impossible, to define. Issues of uncertainty include the right to transfer the material, the scope of research allowed, and intellectual property rights. Since suitable means of international law enforcement may not be available in the context of biobanking, collaborators are advised to clarify any residual uncertainty by means of bilateral contracts, for example, in the form of material transfer agreements. Second, biobank partners may rightly expect that the biomaterial they receive for further analysis attains a certain level of quality. This implies that a biobank has to implement stringent quality control measures covering, in addition to the material transfer itself, the whole process of material acquisition, transport, pre-analytical handling and storage. Again, it may be advisable for biobank partners to claim contractual warranties for the type and quality of the biomaterial they wish to acquire.

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**Document 24**
Meslin, Eric M; Garba, Ibrahim

**Biobanking and public health: is a human rights approach the tie that binds?**
Human genetics 2011 Sep; 130(3): 451-63

**Abstract:** Ethical principles guiding public health and genomic medicine are often at odds: whereas public health practice adopts collectivist principles that emphasize population-based benefits, recent advances in genomic and personalized medicine are grounded in an individualist ethic that privileges informed consent, and the balancing of individual risk and benefit. Indeed, the attraction of personalized medicine is the promise it holds out to help individuals get the "right medicine for the right problem at the right time." Research biobanks are an effective tool in the genomic medicine toolbox. Biobanking in public health presents a unique case study to unpack some of these issues in more detail. For example, there is a long history of using banked tissue obtained under clinical diagnostic conditions for later public health uses. But despite the collectivist approach of public health, the principles applied to the ethical challenges of biobanking (e.g. informed consent, autonomy, privacy) remain individualist. We demonstrate the value of using human rights as a public health ethics framework to address this tension in biobanking by applying it to two illustrative cases.

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**Document 25**
Laurie, Graeme

**Reflexive governance in biobanking: on the value of policy led approaches and the need to recognise the limits of law.**
Human genetics 2011 Sep; 130(3): 347-56

**Abstract:** Although a few jurisdictions around the world have legislated in response to the phenomenon of biobanking, the far more common response has been policy led with funders and other stakeholders initiating multi-level policy initiatives to guide biobanking practice. An example of this is UK Biobank which has developed and operates according to an Ethics and Governance Framework. Such an instrument has no basis in law and yet it has played a crucial role in the set up and ongoing management of the resource. It will continue to do so, as related policies emerge, such as access and intellectual property policies. Numerous biobanking initiatives have similar high-level policy documents that guide decisions and practice. These are often framed as a commitment to participants, researchers and society more broadly and invoke notions such as the public good and the public interest. As such, they serve as a benchmark against which to measure a biobank's performance. Moreover, policies become an important means by which biobankers are held accountable. This article critically analyses this policy-driven phenomenon asking how effectively policy--often as an alternative to law--serves to police and to promote biobanking. It argues that a policy of reflexive governance--defined and developed herein--can best meet the challenges faced by many biobanks and without the need for recourse to law.

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**Document 26**
Gottweis, Herbert; Chen, Haidan; Starkbaum, Johannes

**Biobanks and the phantom public.**
Human genetics 2011 Sep; 130(3): 433-40

**Abstract:** This paper surveys the current state of knowledge about the relationship between different national publics and biobanks, how different publics perceive biobanks, and which issues are identified as important by various stakeholders. We discuss existing studies and emerging governance strategies dealing with the biobank-publics interface and argue that the search for phantom (biobank) public(s) is on, but still much needs to be done. We argue that the existing data originate in a relatively few regions, among them Northern Europe, the United Kingdom, and in certain U.S. states and are often based on survey research with small samples and short questionnaires. Combined usage of qualitative and quantitative methodology in studies is still rare though of great importance in order to investigate distributions of public opinion and also to be able to explain these patterns. Many important questions in the relationship between publics and biobanks are unexplored, or the existing data are inconsistent.
Document 27
Bovenzi, Francesco Maria
[Praise for a conscious ethical choice]. = Elogio di una scelta etica responsabile.

Document 28
Schoonen, H M H J D; van Agt, H M E; Essink-Bot, M L; Wildschut, H I; Steegers, E A P; de Koning, H J
Informed decision-making in prenatal screening for Down's syndrome: what knowledge is relevant?
Patient education and counseling 2011 Aug; 84(2): 265-70
Abstract: To determine the content of decision-relevant knowledge needed for informed decision-making about (non-) participation in prenatal screening for Down's syndrome (DS), in order to develop a knowledge questionnaire for routine application in large-scale programme evaluations.

Document 29
Bredenoord, Annelien L; Onland-Moret, N Charlotte; Van Delden, Johannes J M
Feedback of individual genetic results to research participants: in favor of a qualified disclosure policy.
Human mutation 2011 Aug; 32(8): 861-7
Abstract: This article discusses whether and when researchers have a moral obligation to feedback individual genetic research results. This unsettled debate has rapidly gained in urgency in view of the emergence of biobanks and the advances in next-generation sequencing technology, which has the potential to generate unequaled amounts of genetic data. This implies that the generation of many known and unknown genetic variants in individual participants of genetics/genomics research as intentionally or collaterally obtained byproducts is unavoidable. As we conclude that valid reasons exist to adopt a duty to return genetic research results, a qualified disclosure policy is proposed. This policy contains a standard default package, possibly supplemented with (one or more of) three additional packages. Whereas the default package, containing life-saving information of immediate clinical utility, should be offered routinely and mandatory to all research participants, offering (one of) the three additional packages is context-specific. Such a qualified disclosure policy in our opinion best balances the potential benefits of disclosure with the potential risks for research participants and the harms of unduly hindering biomedical research. We appeal to the genetics community to make a joint effort to further refine the packages and set thresholds for result selection.

Document 30
O'Doherty, Kieran C; Burgess, Michael M; Edwards, Kelly; Gallagher, Richard P; Hawkins, Alice K; Kaye, Jane; McCaffrey, Veronica; Winickoff, David E
From consent to institutions: designing adaptive governance for genomic biobanks.
Abstract: Biobanks are increasingly hailed as powerful tools to advance health research. The social and ethical challenges associated with the implementation and operation of biobanks are equally well-documented. One of the proposed solutions to these challenges involves trading off a reduction in the specificity of informed consent protocols with an increased emphasis on governance. However, little work has gone into formulating what such governance might look like. In this paper, we suggest four general principles that should inform biobank governance and illustrate the enactment of these principles in a proposed governance model for a particular population-scale biobank, the British Columbia (BC) Generations Project. We begin by outlining four principles that we see as
necessary for informing sustainable and effective governance of biobanks: (1) recognition of research participants and publics as a collective body, (2) trustworthiness, (3) adaptive management, and (4) fit between the nature of a particular biobank and the specific structural elements of governance adopted. Using the BC Generations Project as a case study, we then offer as a working model for further discussion the outlines of a proposed governance structure enacting these principles. Ultimately, our goal is to design an adaptive governance approach that can protect participant interests as well as promote effective translational health sciences.

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Document 31

Tsouroufli, Maria

**Routinisation and constraints on informed choice in a one-stop clinic offering first trimester chromosomal antenatal screening for Down's syndrome.**

Midwifery 2011 Aug; 27(4): 431-6

**Abstract:** to explore routinisation and constraints on informed choice in a one-stop clinic offering first trimester antenatal chromosomal screening for Down's syndrome.

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Document 32

Wood, Fiona; Kowalczuk, Jenny; Elwyn, Glyn; Mitchell, Clive; Gallacher, John

**Achieving online consent to participation in large-scale gene-environment studies: a tangible destination.**


**Abstract:** Population based genetics studies are dependent on large numbers of individuals in the pursuit of small effect sizes. Recruiting and consenting a large number of participants is both costly and time consuming. We explored whether an online consent process for large-scale genetics studies is acceptable for prospective participants using an example online genetics study.

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Document 33

Knoppers, Bartha Maria; Harris, Jennifer R; Burton, Paul R; Murtagh, Madeleine; Cox, David; Deschênes, Mylène; Fortier, Isabel; Hudson, Thomas J; Kaye, Jane; Lindpaintner, Klaus

**From genomic databases to translation: a call to action.**


**Abstract:** The rapid rise of international collaborative science has enabled access to genomic data. In this article, it is argued that to move beyond mapping genomic variation to understanding its role in complex disease aetiology and treatment will require extending data sharing for the purposes of clinical research translation and implementation.

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Document 34

Schröder, Christina; Heidtke, Karsten R; Zacherl, Nikolaus; Zatloukal, Kurt; Taupitz, Jochen

**Safeguarding donors’ personal rights and biobank autonomy in biobank networks: the CRIP privacy regime.**


**Abstract:** Governance, underlying general ICT (Information and Communication Technology) architecture, and workflow of the Central Research Infrastructure for molecular Pathology (CRIP) are discussed as a model enabling biobank networks to form operational "meta biobanks" whilst respecting the donors' privacy, biobank autonomy and confidentiality, and the researchers' needs for appropriate biospecimens and information, as well as confidentiality. Tailored to these needs, CRIP efficiently accelerates and facilitates research with human biospecimens and data.
Glick, Shimon M

Some Jewish thoughts on genetic enhancement.

Abstract: The issues of the ethics of germ line modification in general and of enhancement by germ line modification in particular have been the subject of hundreds of articles in the bioethical literature. Both because the techniques are far from perfected and because the potential long term side effects are unknown, there is a widespread consensus that germ line modification for enhancement is absolutely unethical and beyond the pale at the present time. The author considers a thought experiment projecting into the future in which perhaps the safety and reversibility of germ line modification have been clearly demonstrated. Under such circumstances it is contended that the dividing line
between treatment and enhancement is difficult and indeed perhaps impossible to maintain. The Jewish tradition is examined and from the various sources cited it would seem that the benefits of certain kinds of genetic enhancements might well outweigh the objections to such manipulations.

**Document 41**

McGuire, Amy L; Basford, Melissa; Dressler, Lynn G; Fullerton, Stephanie M; Koenig, Barbara A; Li, Rongling; McCarty, Cathy A; Ramos, Erin; Smith, Maureen E; Somkin, Carol P; Waudby, Carol; Wolf, Wendy A; Clayton, Ellen Wright

**Ethical and practical challenges of sharing data from genome-wide association studies: the eMERGE Consortium experience.**

Genome research 2011 Jul; 21(7): 1001-7

**Abstract:** In 2007, the National Human Genome Research Institute (NHGRI) established the Electronic MEdical Records and GEnomics (eMERGE) Consortium (www.gwas.net) to develop, disseminate, and apply approaches to research that combine DNA biorepositories with electronic medical record (EMR) systems for large-scale, high-throughput genetic research. One of the major ethical and administrative challenges for the eMERGE Consortium has been complying with existing data-sharing policies. This paper discusses the challenges of sharing genomic data linked to health information in the electronic medical record (EMR) and explores the issues as they relate to sharing both within a large consortium and in compliance with the National Institutes of Health (NIH) data-sharing policy. We use the eMERGE Consortium experience to explore data-sharing challenges from the perspective of multiple stakeholders (i.e., research participants, investigators, and research institutions), provide recommendations for researchers and institutions, and call for clearer guidance from the NIH regarding ethical implementation of its data-sharing policy.

**Document 42**

Hens, Kristien; Cassiman, Jean-Jacques; Nys, Herman; Dierickx, Kris

**Children, biobanks and the scope of parental consent.**

European journal of human genetics : EJHG 2011 Jul; 19(7): 735-9

**Abstract:** The use of stored tissue samples from children for genetic research raises specific ethical questions that are not all analogous to those raised when adult participants are concerned. These include issues with regard to consent, as it is typically a parent who consents to the use of samples from children. In this paper, we discuss the scope of parental consent. This scope has a temporal dimension and one related to the content of consent. It is not questioned that the temporal scope of parental consent is limited and that young adults have the right to decide on the fate of their samples when they reach the age of maturity. With regard to the content of consent, the question remains whether parents are allowed to give full broad consent to any possible future research on the samples of their children. We argue that they should not be allowed to do so, based on two premises. First, it is generally acknowledged that children have a right to express their own values and that they should be given the opportunity to develop their own autonomy as they grow older. Second, research and science are not completely value-free and some types of research may be more sensitive than other types. Children should be given the opportunity to express their values also in this respect.

**Document 43**

Hayeems, Robin Zoe; Miller, Fiona Alice; Li, Li; Bytautas, Jessica Peace

**Not so simple: a quasi-experimental study of how researchers adjudicate genetic research results.**

European journal of human genetics : EJHG 2011 Jul; 19(7): 740-7

**Abstract:** Ethicists contend that researchers are obliged to report genetic research findings to individual study participants when they are clinically significant, that is, when they are clinically useful or personally meaningful to participants. Yet whether such standards are well understood and can be consistently applied remains unknown. We
conducted an international, cross-sectional survey of cystic fibrosis (CF) and autism genetics researchers using a quasi-experimental design to explore factors influencing researchers’ judgments. Eighty percent of researchers agreed, in principle, that clinically significant findings should be reported to individual participants. Yet judgments about when a specific finding was considered clinically significant or warranted reporting varied by scientific factors (replication, robustness, intentionality, and disease context), capacity of the research team to explain the results, and type of research ethics guidance. Further, judgments were influenced by the researchers' disease community (autism or CF), their primary role (clinical, molecular, statistical) and their beliefs regarding a general reporting obligation. In sum, judgments about the clinical significance of genetic research results, and about whether they should be reported, are influenced by scientific parameters as well as contextual factors related to the specific research project and the individual researcher. These findings call into question the assumption that the conditions under which an obligation to disclose arises are uniformly understood and actionable. Adjudicating the clinical readiness of provisional data may be a responsibility better suited to evaluative experts at arms' length of the provisional data in question, rather than a responsibility imposed upon researchers themselves.

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Document 44
Gutmann, Amy
The ethics of synthetic biology: guiding principles for emerging technologies.

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Document 45
Carlson, Rob
Staying sober about science.

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Document 46
Beyer, Christian; Distler, Jörg H W; Allanore, Yannick; Aringer, Martin; Avouac, Jérôme; Czirják, László; Cutolo, Maurizio; Damjanov, Nemanja; Del Galdo, Francesco; Fligelstone, Kim; Guiducci, Serena; Kowal-Bielecka, Otylia; van Laar, Jacob M; Martucci-Cerinic, Marco; Müller-Ladner, Ulf; Riemekasten, Gabriela; Tamer, Ingo H; Tyndall, Alan; Kennedy, Ann Tyrrell; Valentini, Gabriele; Vettori, Serena; Walker, Ulrich A; Denton, Christopher; Distler, Oliver; EUSTAR Biobanking Group
EUSTAR biobanking: recommendations for the collection, storage and distribution of biospecimens in scleroderma research.
Annals of the rheumatic diseases 2011 Jul; 70(7): 1178-82
Abstract: The European League Against Rheumatism Scleroderma Trials and Research Group (EUSTAR) has established an online database with clinical data of currently more than 8200 patients with systemic sclerosis (SSc). In addition to clinical research, EUSTAR fosters biomolecular studies to develop novel biomarkers and therapies for SSc. High-quality biospecimens are the basis for successful biomolecular studies. The EUSTAR biobanking group has therefore developed recommendations to standardise the collection, storage and distribution of SSc biospecimens at EUSTAR centres. These recommendations consider the scientific challenges associated with biomolecular research in SSc and the organisational requirements of EUSTAR. They were approved by the EUSTAR executive committee as well as the EUSTAR board. Once they become effective, these recommendations will be the basis for international EUSTAR studies with large numbers of SSc biospecimens. These recommendations might also be followed by other SSc consortia to enable exchange of biosamples between different SSc initiatives and might serve as a template for biobanking initiatives in other rheumatic diseases.

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Document 47
Ayuso, Carmen; Tellería, Juan José; Tejedor, Juan Carlos; Gracia, Diego

[Ethics in genetic research (2). Genetic susceptibility studies]. = Ética en investigación genética (2). Estudios de susceptibilidad.
Medicina clínica 2011 Jun 11; 137(1): 22-6

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Document 48
Michie, Marsha; Henderson, Gail; Garrett, Joanne; Corbie-Smith, Giselle

"If I could in a small way help": motivations for and beliefs about sample donation for genetic research.
Journal of empirical research on human research ethics : JERHRE 2011 Jun; 6(2): 57-70

Abstract: Human genome research depends upon participants who donate genetic samples, but few studies have explored in depth the motivations of genetic research donors. This mixed methods study examines telephone interviews with 752 sample donors in a U.S. genetic epidemiology study investigating colorectal cancer. Quantitative and qualitative results indicate that most participants wanted to help society, and that many also wanted information about their own health, even though such information was not promised. Qualitative analysis reveals that donors believed their samples contributed to a scientific "common good"; imagined samples as information rather than tissues; and often blurred distinctions between research and diagnostic testing of samples. Differences between African American and White perspectives were distinct from educational and other possible explanatory factors.

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Document 49
Budimir, Danijela; Polasek, Ozren; Marusi?, Ana; Kolci?, Ivana; Zemunik, Tatijana; Boraska, Vesna; Jeronci?, Ana; Boban, Mladen; Campbell, Harry; Rudan, Igor

Ethical aspects of human biobanks: a systematic review.
Croatian medical journal 2011 Jun; 52(3): 262-79

Abstract: To systematically assess the existing literature on ethical aspects of human biobanks.

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Document 50
Moran, Cassandra; Thornburg, Courtney D; Barfield, Raymond C

Ethical considerations for pharmacogenomic testing in pediatric clinical care and research.
Pharmacogenomics 2011 Jun; 12(6): 889-95

Abstract: The information gained from pharmacogenomic testing is becoming increasingly recognized as an opportunity to improve our current dosing strategies for children. The identification of gene polymorphisms that influence drug disposition and effect can be used to help predict a child's susceptibility to toxicity and/or response to a particular drug or therapeutic regimen. However, the potential consequences of performing genomic analysis in children raise important ethical considerations. Although the level of risk introduced remains partially hypothetical, awareness of the ethical concerns and protective legislation will be an important part of fully informing patients, families, clinicians, and researchers about the risks and benefits of pharmacogenomic testing in children. Where it can be done without loss of benefit, risk reduction is a moral imperative, and so the ethical complexities related to pharmacogenomics must be addressed in an ongoing way as we continue to learn more about the value of the technology to children.

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**Document 51**
Tonkens, Ryan

**Parental wisdom, empirical blindness, and normative evaluation of prenatal genetic enhancement.**
The Journal of medicine and philosophy 2011 Jun; 36(3): 274-95

**Abstract:** The purpose of this paper is to unveil one problem that surrounds the debate over the moral standing of prenatal genetic enhancement (PGE) and to outline a solution to it. The problem is that we have no way to test our speculations about the consequences of prenatal enhancement without begging the question about the moral permissibility of enhancing unborn children. The only way to empirically support our speculations about the consequences of prenatal enhancement is to resort to ethically worrisome (and radical) experimental genetic research. The suggested solution to this problem is to focus on the character of good parents. The virtue of parental wisdom is introduced and used as a basis for evaluating PGE. It is argued that good parents have good reason not to condone PGE for their children (in very many cases), especially as part of the first wave of genetically altered humans.

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**Document 52**
Yamamoto, Midori; Hata, Akira

**A commentary on for what am I participating? The need for communication after receiving consent from biobanking project participants: experience in Japan.**
Journal of human genetics 2011 Jun; 56(6): 405

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**Document 53**
Berg, Jonathan S; Khoury, Muin J; Evans, James P

**Deploying whole genome sequencing in clinical practice and public health: meeting the challenge one bin at a time.**
Genetics in medicine : official journal of the American College of Medical Genetics 2011 Jun; 13(6): 499-504

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**Document 54**
Cadigan, R Jean; Easter, Michele M; Dobson, Allison W; Davis, Arlene M; Rothschild, Barbra B; Zimmer, Catherine; Sterling, Rene; Henderson, Gail

**"That's a good question": university researchers' views on ownership and retention of human genetic specimens.**
Genetics in medicine : official journal of the American College of Medical Genetics 2011 Jun; 13(6): 569-75

**Abstract:** To explore the views of university-based investigators conducting genetic research with human specimens regarding ownership and retention of specimens, and knowledge of related institutional review board and university policies.

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**Document 55**
Geelen, Els; Van Hoyweghen, Ine; Horstman, Klasien

**Making genetics not so important: family work in dealing with familial hypertrophic cardiomyopathy.**

**Abstract:** The literature shows that genetic testing could stimulate solidarity among family members, but also lead to
major conflicts. To prevent negative effects, clinical geneticists and ethicists have stressed the importance of 'good communication' within families. In this qualitative study, we followed six extended families in the southern and eastern Netherlands involved in genetic testing for familial hypertrophic cardiomyopathy for three and a half years. In total 57 members of these families were interviewed in depth, most more than once. Our analysis shows that genetic testing does affect families, but that families perform a lot of 'balancing work' in order to prevent genetic testing from becoming too all-encompassing. There is much more continuity in family life than is often thought. Moreover, as these families demonstrate different styles of family work, establishing a single norm of 'good communication' in clinical genetics might in fact be more harmful for family life than genetic testing itself.

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**Document 56**

Howard, H C; Joly, Y; Avard, D; Laplante, N; Phillips, M; Tardif, J C

**Informed consent in the context of pharmacogenomic research: ethical considerations.**

The pharmacogenomics journal 2011 Jun; 11(3): 155-61

**Abstract:** Although the scientific research surrounding pharmacogenomics (PGx) has been relatively plentiful, the ethical research concerning this discipline has developed rather conservatively. Following investigation of the ethical, legal and social issues (ELSI) of PGx research, as well as consulting with key stakeholders, we identified six outstanding ethical issues raised by the informed consent process in PGx research: (1) scope of consent; (2) consent to 'add-on' studies; (3) protection of personal information; (4) commercialization; (5) data sharing; and (6) potential risks stemming from population-based research. In discussing these six areas as well as offering specific considerations, this article offers a solid base from which future practical guidelines for informed consent in PGx research can be constructed. As such, this effort works toward filling the ELSI gap and provides ethical support to the numerous PGx projects undertaken by researchers every year.

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**Document 57**

Skinner, Debra; Choudhury, Summer; Sideris, John; Guarda, Sonia; Buansi, Allen; Roche, Myra; Powell, Cynthia; Bailey, Donald B Jr.

**Parents' decisions to screen newborns for FMR1 gene expansions in a pilot research project.**


**Abstract:** The goal of this study was to document rates of parental consent in a pilot study of newborn screening for FMR1 gene expansions, examine demographic characteristics of mothers who consented or declined, describe the reasons for their decision, and discuss ethical and social aspects of the consent process.

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**Document 58**

Feldman, Robin

**Whose body is it anyway? Human cells and the strange effects of property and intellectual property law.**

Stanford law review 2011 Jun; 63(6): 1377-402

**Abstract:** Whatever else I might own in this world, it would seem intuitively obvious that I own the cells of my body. Where else could the notion of ownership begin, other than with the components of the tangible corpus that all would recognize as "me"? The law, however, does not view the issue so neatly and clearly, particularly when cells are no longer in my body. As so often happens in law, we have reached this point, not by design, but by the piecemeal development of disparate notions that, when gathered together, form a strange and disconcerting picture. This Article examines both property and intellectual property doctrines in relation to human cells that are no longer within the body. In particular, the Article discusses the Bilski decision, in the context of life science process patents, and the Molecular Pathology case, in the context of gene patents. For patent law, the Article concludes that the problem lies not with the fact that genes constitute patentable subject matter, but rather with the extent of the rights that are granted. For both property and intellectual property law, the Article concludes that a more careful application of basic legal principles would better reflect the interests of society as a whole and the interests of individual human subjects,
as well as the interests of those who innovate.

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Document 59

Kohane, Isaac S
Using electronic health records to drive discovery in disease genomics.

Abstract: If genomic studies are to be a clinically relevant and timely reflection of the relationship between genetics and health status—whether for common or rare variants—cost-effective ways must be found to measure both the genetic variation and the phenotypic characteristics of large populations, including the comprehensive and up-to-date record of their medical treatment. The adoption of electronic health records, used by clinicians to document clinical care, is becoming widespread and recent studies demonstrate that they can be effectively employed for genetic studies using the informational and biological 'by-products' of health-care delivery while maintaining patient privacy.

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Document 60

Ayuso, Carmen; Abad-Santos, Francisco; Dal-Ré, Rafael; Gracia, Diego
Medicina clínica 2011 May 28; 136(15): 678-82

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Document 61

Lunshof, Jeantine E; Chadwick, Ruth
Editorial: genetic and genomic research-changing patterns of accountability.
Accountability in research 2011 May; 18(3): 121-31

Abstract: Debates about genomic science have raised questions about the implications for ethics and accountability. Accountability has external and internal aspects. Whereas ethical review, including attention to appropriate consent procedures, has been central to 'giving an account' externally, there are also issues internal to the practice of science itself. The pursuit of truth is central to the scientific endeavour, but truths can sometimes be 'inconvenient', leading to complex questions of accountability that go beyond the issues of consent. This is illustrated by the case of the Havasupai.

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Document 62

Prainsack, Barbara
Voting with their mice: personal genome testing and the "participatory turn" in disease research.
Accountability in research 2011 May; 18(3): 132-47

Abstract: While the availability of genome tests on the internet has given rise to heated debates about the likely impact on personal genome information on test-takers, on insurance, and on healthcare systems, in this article I argue that a more tangible effect of personal genomics is that it has started to change how participation in disease research is conceived and enacted. I examine three models of research participation that personal genomics customers are encouraged to engage in. I conclude with an evaluation of the pitfalls and benefits of "crowdsourcing" genetic disease research in the context of personal genomics.

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Wieser, Bernhard

The microphysics of accountability.
Accountability in research 2011 May; 18(3): 163-80

Abstract: How is it possible to deploy the law to create and perform accountability? To answer this question, I address the argumentative function of the law in order to legitimize genetic medicine. Using interview data, I will in particular elaborate on how medical experts strive to convince interviewing social scientists that their own professional action is above all ethical reproach. For this purpose, medical experts capitalize on the law in specific ways. It is the aim of this article to expound exactly how this happens during qualitative research interviews. The analysis of the interview data is informed by the works of Sheila Jasanoff and Michel Foucault. The former provides an instructive conceptual background for demonstrating how the law serves as an important element of accountability practices. The latter is known for his plea not to understand the law in repressive terms. Accordingly, the law does not prohibit specific medical practices, but in a specific sense it rather makes medical practice socially robust. Based on qualitative analysis of interview data, I conclude that referring to the law allows experts of genetic medicine to evade engaging with ethical and social aspects of their work. The law was rhetorically utilized to bring a discussion on such issues to a communicative closure. For that purpose, the existence of the law was presented as proof that undesirable practices would not be possible and consequently further discussions of the matter would be unnecessary. The law allows medical experts to transfer ethical problems to other places and actors and also to promote their professional interests.

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Kosseim, Patricia; Chapman, Sheila

Science and society: some "made-in-Canada" options for improving integration.
Accountability in research 2011 May; 18(3): 194-216

Abstract: In this article, the authors describe relatively recent efforts by scientific research agencies to promote, through various funding programs, the integration of social sciences and humanities with the natural sciences. This "integrated" approach seeks to study science through a broader interdisciplinary lens in order to better anticipate, understand, and address its ethical, legal, and social implications. The authors review the origins and evolution of this trend, as well the arguments which have been formulated by both proponents and critics of integration. By using Genome Canada's "GE(3)LS" Research Program as a case study, the authors discuss the successes and continuing challenges of this model based on evaluation results available to date. The authors then go on to examine and compare three possible models for improving the future success of the GE(3)LS research program, including: 1) enhancing the current integrated research approach through incremental refinements based on concrete evidence and lessons learned; 2) promoting greater interaction and synergy across GE(3)LS research projects through a deliberate, systematic and coordinated "hub and spoke" approach; and 3) taking a broad programmatic approach to GE(3)LS research by creating a central resource of available expertise and advisory capacity.

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Zoglmeier, Christine; Martin, Silke; Weinauer, Franz

The Bavarian Red Cross Blood Donor BioBank: the first successful combination of blood donation and biobanking for medical research.
Transfusion 2011 May; 51(5): 1121-2

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Menzel, Paul T
That personal touch.
The Hastings Center report 2011 May-Jun; 41(3): 7; author reply 7-8

Document 67
Hens, Kristien; Nys, Herman; Cassiman, Jean-Jacques; Dierickx, Kris
Risks, benefits, solidarity: a framework for the participation of children in genetic biobank research.
The Journal of pediatrics 2011 May; 158(5): 842-8

Document 68
Hauskeller, Christine
Direct to consumer genetic testing.
BMJ (Clinical research ed.) 2011 April 21; 342: d2317

Document 69
Stafford, Ned
German parliament considers three bills on preimplantation genetic diagnosis.
BMJ (Clinical research ed.) 2011 April 15; 342: d2473

Document 70
Bergmann, Manuela M; Mathers, John C
Ethical challenges in human nutrigenomics research.
Maturitas 2011 Apr; 68(4): 297-8

Document 71
McCarty, Catherine A; Garber, Ann; Reeser, Jonathan C; Fost, Norman C; Personalized Medicine Research Project Community Advisory Group and Ethics and Security Advisory Board
Study newsletters, community and ethics advisory boards, and focus group discussions provide ongoing feedback for a large biobank.

Abstract: The Personalized Medicine Research Project (PMRP) is a population-based biobank with more than 20,000 adult participants in central Wisconsin. A Community Advisory Group (CAG) and Ethics and Security Advisory Board (ESAB) provide ongoing feedback. In addition, the study newsletter is used as a two-way communication tool with study participants. The aim of this study was to assess and compare feedback received from these communication/consultation strategies with results from focus group discussions in relation to protocol changes. In summer 2009, enrollee focus groups were held addressing these topics: newsletter format, readability, and content of three articles written to solicit PMRP subject feedback. The CAG and ESAB jointly reviewed focus group results, discussed protocol changes to access residual blood samples, and made recommendations about the general communication approach. Nearly everyone in three focus groups stated that they wanted more information
about PMRP. No focus group participant said that accessing stored samples would have changed their enrollment decision. Most said they wanted to be informed directly about changes affecting their original consent. For minimal-risk PMRP protocol changes, the community, CAG, and ESAB were comfortable with an opt-out model because of the initial broad consent. The planned duration of the biobank extends for decades; therefore regular, ongoing communication to enrollees is necessary to maintain awareness and trust, especially relating to protocol changes reflecting evolving science. The multi-faceted approach to communication including newsletters, external advisory boards, and focus group discussions has been successful for the PMRP biobank and may be a model for others to consider.

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**Document 72**

Richer, Julie; Ghebremichael, Musie S; Chudley, Albert E; Robinson, Walter M; Wilfond, Benjamin S; Solomon, Mildred Z

*Research use of leftover newborn bloodspots: attitudes of Canadian geneticists regarding storage and informed consent requirements.*

*Genetics in medicine : official journal of the American College of Medical Genetics* 2011 Apr; 13(4): 305-13

**Abstract:** Leftover newborn spots can provide a powerful research tool as a population-wide DNA bank. Some provinces/states store them for more than 20 years; however, parents are usually not informed of the retention of leftover newborn spots. To examine the opinions of Canadian geneticists regarding permission for leftover newborn spots storage for research purposes and the associated risks, a web-based survey was distributed to all members of the Canadian College of Medical Geneticists with a valid e-mail address (n = 209) and completed by 78 respondents (37%).

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**Document 73**

Pathmasiri, Saminda; Deschénes, Mylène; Joly, Yann; Mrejen, Tara; Hemmings, Francis; Knoppers, Bartha Maria

*Intellectual property rights in publicly funded biobanks: much ado about nothing?*

*Nature biotechnology* 2011 Apr; 29(4): 319-23

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**Document 74**

Lewis, Michelle H; Goldenberg, Aaron; Anderson, Rebecca; Rothwell, Erin; Botkin, Jeffrey

*State laws regarding the retention and use of residual newborn screening blood samples.*

*Pediatrics* 2011 Apr; 127(4): 703-12

**Abstract:** After newborn screening has been completed, many states retain residual newborn screening dried blood samples for various purposes, including program evaluation, quality assurance, and biomedical research. The extent to which states possess legal authority to retain residual dried blood samples (DBS) and use them for purposes unrelated to newborn screening is unclear.

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**Document 75**

Ricci, D S; Broderick, E D; Tchelet, A; Hong, F; Mayevsky, S; Mohr, D M; Schaffer, M E; Warner, A W; Hakkulinen, P; Snapir, A

*Global requirements for DNA sample collections: results of a survey of 204 ethics committees in 40 countries.*

*Clinical pharmacology and therapeutics* 2011 Apr; 89(4): 554-61

**Abstract:** The Industry Pharmacogenomics Working Group has an interest in attaining a better understanding of
global requirements for sample collections intended for pharmacogenetics research. To have adequately powered pharmacogenetics studies representative of the clinical trial population, it is important to collect DNA samples from a majority of consenting study participants under many institutional review board/ethics committee (IRB/EC) jurisdictions. A survey was distributed to gather information from local and central IRBs/ECs. The survey included questions related to the approval of pharmacogenetics studies, collection and banking of samples, and return of data to subjects. A total of 204 responses were received from global IRBs/ECs with pharmacogenetic experience. The data show that requirements for approval of pharmacogenetic research differ between IRBs/ECs within and between countries but not between regions of the United States. A better understanding of differing requirements should facilitate global sample collection of DNA for pharmacogenetics research and may provide the basis for harmonized regulations for collection of genetic samples in the future.

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**Document 76**

de Vries, Jantina; Bull, Susan J; Douombo, Ogobara; Ibrahim, Muntaser; Mercereau-Puijalon, Odile; Kwiatkowski, Dominic; Parker, Michael

**Ethical issues in human genomics research in developing countries.**

BMC medical ethics 2011 March 18; 12: 5

**Abstract:** Genome-wide association studies (GWAS) provide a powerful means of identifying genetic variants that play a role in common diseases. Such studies present important ethical challenges. An increasing number of GWAS is taking place in lower income countries and there is a pressing need to identify the particular ethical challenges arising in such contexts. In this paper, we draw upon the experiences of the MalariaGEN Consortium to identify specific ethical issues raised by such research in Africa, Asia and Oceania.

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**Document 77**

Abbott, Alison

**Europe rules against stem-cell patents.**

Nature 2011 Mar 17; 471(7338): 280

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**Document 78**

Tonti-Filippini, Nicholas; Zeps, Nikolajs

**Trade in human tissue products.**

The Medical journal of Australia 2011 Mar 7; 194(5): 263-5

**Abstract:** Trade in human tissue in Australia is prohibited by state law, and in ethical guidelines by the National Health and Medical Research Council: National statement on ethical conduct in human research; Organ and tissue donation by living donors: guidelines for ethical practice for health professionals. However, trade in human tissue products is a common practice especially for: reconstructive orthopaedic or plastic surgery; novel human tissue products such as a replacement trachea created by using human mesenchymal stem cells; biomedical research using cell lines, DNA and protein provided through biobanks. Cost pressures on these have forced consideration of commercial models to sustain their operations. Both the existing and novel activities require a robust framework to enable commercial uses of human tissue products while maintaining community acceptability of such practices, but to date no such framework exists. In this article, we propose a model ethical framework for ethical governance which identifies specific ethical issues such as: privacy; unique value of a person's tissue; commodification of the body; equity and benefit to the community; perverse incentives; and "attenuation" as a potentially useful concept to help deal with the broad range of subjective views relevant to whether it is acceptable to commercialise certain human tissue products.

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Ethical tensions in genetic counselling research.
Monash bioethics review 2011 Mar; 29(3): 07.1-12

Abstract: Ethical tensions are recognised as part of the everyday practice of conducting research and practising genetic counselling. What are the conceptual frameworks that can assist researchers and genetic counsellors to deal with ethical tensions when conducting research? How might the overlap that arises from being a researcher and clinical genetic counsellor be dealt with? This article uses a case study to consider the ethical tensions between conducting research in genetic counselling and maintaining a clinical practice as a genetic counsellor. It examines the reconciliation of the dual roles of researcher and genetic counsellor. It explores conceptual frameworks that can combine the needs of ethical research practice, while maintaining ethical clinical practice.

Disclosing individual CDKN2A research results to melanoma survivors: interest, impact, and demands on researchers.

Abstract: Whether to return individual research results from cancer genetics studies is widely debated, but little is known about how participants respond to results disclosure or about its time and cost burdens on investigators.

Current controversies in prenatal diagnosis 4: does industry-sponsorship accelerate or hinder the pace of research?
Prenatal diagnosis 2011 Mar; 31(3): 244-5

Something more is necessary: are genes and genetic diagnostic tests statutory subject matter for US patents?
Expert review of molecular diagnostics 2011 Mar; 11(2): 149-58

Abstract: In a recent decision (AMP v. USPTO) from the US District Court, patent claims directed at DNA sequences corresponding to human genes and to diagnostic tests based on such genes have been found to be invalid, primarily on the basis that the DNA molecules claimed, which included cDNA, primers and probes, are 'products of nature' and are thus unpatentable. If upheld, this decision will have considerable impact on the ability of biotechnical companies and universities to patent the results of their research. In this article, we will explain the basis for this decision and discuss the appropriateness of patenting discoveries and their (obvious) uses in the light of this fascinating case. While our focus will primarily be on the product claims, diagnostic method claims were also revoked in AMP v. USPTO on the basis that they were for mental acts or did not involve any 'transformation of matter'. This will be discussed in the light of the recent US Supreme Court decision in Bilski v. Kappos, which focused on the patent-eligibility of process claims.
Document 83
Hawkins, Alice K; Hayden, Michael R

**A grand challenge: providing benefits of clinical genetics to those in need.**

*Genetics in medicine* : official journal of the American College of Medical Genetics 2011 Mar; 13(3): 197-200

**Abstract:** Genetic research, techniques, and knowledge have rapidly expanded in the last two decades with the completion of the Human Genome Project and other major advances in discovery research and diagnostic technologies. Although these developments have obvious potential, they also raise significant challenges related to programs for the actual delivery of useful genetic testing and services. This challenge is particularly acute in rural and remote areas, where lack of access to genetic services is pervasive resulting in significant inequities in access and availability of services. Huntington disease, the classic example of an adult-onset hereditary disorder, is used to illustrate this concern and highlight the imperative of exploring novel mechanisms to improve access to effective genetic services. The components of an effective and practical solution strategy are outlined, including the development of innovative delivery systems such as telemedicine, web-based education tools, and cost-reduction mechanisms. A proactive approach is essential to ensure the potential benefits, and availability of clinical genetics is realized by those in need rather than just those in reach.

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Document 84
Sharp, Richard R

**Downsizing genomic medicine: approaching the ethical complexity of whole-genome sequencing by starting small.**

*Genetics in medicine* : official journal of the American College of Medical Genetics 2011 Mar; 13(3): 191-4

**Abstract:** As we look to a time when whole-genome sequencing is integrated into patient care, it is possible to anticipate a number of ethical challenges that will need to be addressed. The most intractable of these concern informed consent and the responsible management of very large amounts of genetic information. Given the range of possible findings, it remains unclear to what extent it will be possible to obtain meaningful patient consent to genomic testing. Equally unclear is how clinicians will disseminate the enormous volume of genetic information produced by whole-genome sequencing. Toward developing practical strategies for managing these ethical challenges, we propose a research agenda that approaches multiplexed forms of clinical genetic testing as natural laboratories in which to develop best practices for managing the ethical complexities of genomic medicine.

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Document 85
Bloss, Cinnamon S; Jeste, Dilip V; Schork, Nicholas J

**Genomics for disease treatment and prevention.**


**Abstract:** The enormous advances in genetics and genomics of the past decade have the potential to revolutionize health care, including mental health care, and bring about a system predominantly characterized by the practice of genomic and personalized medicine. This article briefly reviews the history of genetics and genomics and assesses the extent to which the results of genetic and genomic studies are currently being leveraged clinically for disease treatment and prevention. Relevant social, economic, and policy issues relevant to genomic medicine are also reviewed, and priority research areas in which further work is needed are identified.

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Document 86
Borovecki, Ana; Bradamante, Vlasta; Simonovic, Dubravka; Babic-Bosanac, Sanja

**Ethics of scientific research using patients’ archived biological material and their medical data.**

*Umetnička kulturna revija* 2011 Mar; 59(1): 43-60

**Abstract:** The ethical framework for handling patients' archived biological material and medical data is based on the principle that patients have a fundamental right to access and control their own medical records and archived biological samples. This involves the right to know about the research involving their data, the right to have their data used for research purposes, and the right to withdraw consent at any time. The ethical framework also includes the responsibility of researchers to ensure the confidentiality and security of patients' data, and to obtain informed consent from patients before using their data for research. These principles are important to ensure that research involving patients' archived biological material and medical data is conducted in an ethical and responsible manner.
Abstract: Informed consent represents the standard for adequate protection of all participants in biomedical research. This standard is affirmed in international legal documents concerning biomedical research, as well as in Croatian legislation. However, some questions regarding informed consent remain open. One of such questions that research ethics committees around the world and in the Republic of Croatia often deal with, is the question of whether to obtain informed consent for the research on archived material or previously collected research data taken from the patients during diagnostic or therapeutic procedures. This contribution provides an overview of both Croatian and international legal documents and guidelines that deal with this issue, together with an overview of the literature concerning this issue. Since in the Republic of Croatia there are no regulations regarding this type of research, the authors of this contribution are presenting conduct guidelines for researchers and ethics committees in such cases. The implementation of the proposed guidelines would facilitate scientific research and international cooperation for Croatian scientific institutions.
Bookman, Ebony B; Langehome, Aleisha A; Eckfeldt, John H; Glass, Kathleen C; Jarvik, Gail P; Klag, Michael; Koski, Greg; Motulsky, Arno; Wilfond, Benjamin; Manolio, Teë A; Fabats, Richard R; Luepker, Russell V

**Comment on "Multidimensional results reporting to participants in genomic studies: getting it right".**

Science translational medicine 2011 Feb 16; 3(70): 70le1

**Abstract:** Bookman et al. write to correct the impression given in the Commentary by Kohane and Taylor that the recommendations of the National Heart, Lung, and Blood Institute (NHLBI) Working Group "Reporting Genetic Results in Research Studies" included advice to return genetic information to research subjects only in cases where there is a proven or preventative intervention for the identified disorder. In fact, the report does recommend that genetic information be returned to subjects when there is an intervention available, but it does not recommend against giving this kind of information to subjects if there is no available intervention.

Nakaji, Peter; Nakaji, Nicole M

**Whose is it? A disagreement over DNA research may be the first of many.**

World neurosurgery 2011 Feb; 75(2): 180-1

Bradbury, A R; Patrick-Miller, L; Fetzer, D; Egleston, B; Cummings, S A; Forman, A; Bealin, L; Peterson, C; Corbman, M; O'Connell, J; Daly, M B

**Genetic counselor opinions of, and experiences with telephone communication of BRCA1/2 test results.**

Clinical genetics 2011 Feb; 79(2): 125-31

**Abstract:** BRCA1/2 test disclosure has, historically, been conducted in-person by genetics professionals. Given increasing demand for, and access to, genetic testing, interest in telephone and Internet genetic services, including disclosure of test results, has increased. Semi-structured interviews with genetic counselors were conducted to determine interest in, and experiences with telephone disclosure of BRCA1/2 test results. Descriptive data are summarized with response proportions. One hundred and ninety-four genetic counselors completed self-administered surveys via the web. Although 98% had provided BRCA1/2 results by telephone, 77% had never provided pre-test counseling by telephone. Genetic counselors reported perceived advantages and disadvantages to telephone disclosure. Thirty-two percent of participants described experiences that made them question this practice. Genetic counselors more frequently reported discomfort with telephone disclosure of a positive result or variant of uncertain significance (p < 0.01) than other results. Overall, 73% of participants reported interest in telephone disclosure. Many genetic counselors have provided telephone disclosure, however, most, infrequently. Genetic counselors identify potential advantages and disadvantages to telephone disclosure, and recognize the potential for testing and patient factors to impact patient outcomes. Further research evaluating the impact of testing and patient factors on cognitive, affective, social and behavioral outcomes of alternative models of communicating genetic information is warranted.

Holm, Søren
Access and use of human tissues from the developing world: ethical challenges and a way forward using a tissue trust.

Abstract: Scientists engaged in global health research are increasingly faced with barriers to access and use of human tissues from the developing world communities where much of their research is targeted. In part, the problem can be traced to distrust of researchers from affluent countries, given the history of 'scientific-imperialism' and 'biocolonialism' reflected in past well publicized cases of exploitation of research participants from low to middle income countries.

Consent for biobanking: assessing the understanding and views of cancer patients.

Abstract: Cancer patients were questioned about the consent process in a context in which they were routinely requested to donate tumor samples to research. After in-depth interviews of 19 patients, a 12-page questionnaire was designed and mailed to 745 patients who had been recently treated for colorectal cancer, breast cancer, or a hematological malignancy at a French Regional Cancer Center at which an opt-in biobanking system has existed since 2002. The response rate was 77.0% (N = 574). Among responding patients, 349 (60.8%) of the 574 were in favor of a formal and signed consent. Concordance was low (kappa = 0.23) between the number of patients who declared in the survey that they had given consent (213 of 574 [37.1%]) vs the number for whom registered consent had been recorded (267 of 574 [46.5%]). Only 2 (0.3%) of the 574 patients stated that they had signed a refusal, and only 88 (41.3%) of the 213 patients who remembered giving consent understood that their consent for biobanking also covered authorization to use their clinical data. We conclude that the opt-in consent procedure is positively perceived by most patients but should be improved for a better understanding and possibly an even better adherence to the consent process.

From 'beastly philosophy' to medical genetics: eugenics in Russia and the Soviet Union.

Abstract: This essay offers an overview of the three distinct periods in the development of Russian eugenics: Imperial (1900-1917), Bolshevik (1917-1929), and Stalinist (1930-1939). Began during the Imperial era as a particular discourse on the issues of human heredity, diversity, and evolution, in the early years of the Bolshevik rule eugenics was quickly institutionalized as a scientific discipline--complete with societies, research establishments, and periodicals--that aspired an extensive grassroots following, generated lively public debates, and exerted considerable influence on a range of medical, public health, and social policies. In the late 1920s, in the wake of Joseph Stalin's 'Great Break', eugenics came under intense critique as a 'bourgeois' science and its proponents quickly reconstituted their enterprise as 'medical genetics'. Yet, after a brief period of rapid growth during the early 1930s, medical genetics was dismantled as a 'fascist science' towards the end of the decade. Based on published and original research, this essay examines the factors that account for such an unusual--as compared to the development of eugenics in other locales during the same period--historical trajectory of Russian eugenics.
Document 97

Teman, Elly; Ivry, Tsipy; Bernhardt, Barbara A

Pregnancy as a proclamation of faith: Ultra-Orthodox Jewish women navigating the uncertainty of pregnancy and prenatal diagnosis.


Abstract: Research has suggested that religion and spirituality may inform individuals' interpretation of and responses to uncertainty during pregnancy including the possibility of genetic disorders. In this study, 25 qualitative interviews were undertaken with ultra-Orthodox [Haredi] Jewish women about their experiences with uncertainties related to pregnancy, prenatal care, and prenatal diagnosis. We found that women draw upon a particular set of faith-based concepts to cope with the uncertainties of pregnancy and to make decisions regarding prenatal testing. The women draw on the religious concepts of faith and certainty, which are based on trusting that God will not test them beyond what they can withstand. When prenatal screening indicates a possible fetal anomaly or when a disabled child is born, these women interpret the situation as a God-sent ordeal in which they are called upon to prove their trust and certainty in God's plan and to resist the uncertainties generated by the probability-based technologies. This research has implications for genetic service providers when discussing prenatal testing and fetal anomalies with Haredi women.

Document 98

Bombard, Yvonne; Palin, JoAnne; Friedman, Jan M; Veenstra, Gerry; Creighton, Susan; Paulsen, Jane S; Bottorff, Joan L; Hayden, Michael R; Canadian Respond-HD Collaborative Research Group

Factors associated with experiences of genetic discrimination among individuals at risk for Huntington disease.


Abstract: The purpose of this study was to identify factors that are associated with experiencing genetic discrimination (GD) among individuals at risk for Huntington disease (HD). Multivariable logistic regression analysis was used to examine factors associated with experiencing GD in data from a cross-sectional, self-report survey of 293 individuals at risk for HD. The study sample comprised 167 genetically tested respondents, and 66 who were not tested (80% response rate). Overall, individuals who learn they are at risk for HD at a younger age (OR?=3.1; 95% CI: 1.5-6.2; P?=0.002), are mutation-positive (OR?=2.8; 95% CI: 1.4-6.0; P?=0.006), or are highly educated (OR?=2.7; 95% CI: 1.4-5.1; P?=0.002) are more likely to experience GD, particularly in insurance, family, and social settings. Further, younger age was associated with discrimination in insurance (OR?=0.97; 95% CI: 0.94-1.00; P?=0.038). This study provides evidence that some people who are at risk for HD were more likely to experience GD than others. Individuals who learned they are at risk for HD at a younger age and those who are mutation-positive were more likely to experience GD, particularly in insurance, family, and social settings. Younger individuals were more likely to experience discrimination in the insurance setting. Overall, highly educated individuals were also more likely to report discrimination. These results provide direction for clinical and family discussions, counseling practice, and policy aimed at mitigating experiences of GD.

Document 99

McQuillan, Geraldine M; Porter, Kathryn S


IRB 2011 Jan-Feb; 33(1): 9-14
Document 100
Coggon, John
Confrontations in "genethics": rationalities, challenges, and methodological responses.

Georgetown users check [Georgetown Journal Finder](http://www.georgetownjournalfinder.com) for access to full text

Document 101
Montoya, Michael J.
MAKING THE MEXICAN DIABETIC: RACE, SCIENCE, AND THE GENETICS OF INEQUALITY
Call number: [RA645 .D5 M66 2011](http://wwwLibrary.net)

Document 102
Fraker, Mary and Mazza, Anne-Marie, rapporteurs
Institute of Medicine (United States) [and] National Research Council (United States). Committee on Science, Technology, and Law Policy and Global Affairs. Board on Life Sciences
DIRECT-TO-CONSUMER GENETIC TESTING: SUMMARY OF A WORKSHOP
Call number: [RB155.65 .D57 2011](http://wwwLibrary.net)

http://www.nap.edu (link may be outdated)

Document 103
Hongladarom, Soraj
GENOMICS AND BIOETHICS: INTERDISCIPLINARY PERSPECTIVES, TECHNOLOGIES, AND ADVANCEMENTS
Call number: [QH438.7 .G4615 2011](http://wwwLibrary.net)

Document 104
Matthews-Juarez, Pat; Juarez, Paul D
Cultural competency, human genomics, and the elimination of health disparities.
Social work in public health 2011; 26(4): 349-65
Abstract: It is unclear what impact human genomics research will have on the nation's efforts to close the gap in health disparities between and among racial/ethnic and disadvantaged groups. The literature suggests that understanding socio-economic and cultural factors are important for understanding the complex issues offer by genetic explanations of racial/ethnic differences. While this research will lead to tremendous improvements in health status of the overall population, its impact on reducing health disparities is likely to be minimal. Establishment of culturally competent systems of care, in contrast, offers great promise for reducing and eliminating health disparities.

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**Document 105**

Jones, Norma Gray; Harris, Jesse J

**African Americans and genetic research, risk versus benefit: implications for the profession of social work.**

Social work in public health 2011; 26(4): 380-91

**Abstract:** The Human Genome Project was a 13-year study with great potential for improving the health of the current generation and extending the life of future generations. Genetic research, though showing potential for good, may also result in societal problems. This article considers the implications of future genetic research for African Americans and other vulnerable groups with a retrospective view of medical research and the African Americans’ experience. In light of the growing health disparity between Whites and Blacks, this article argues for minority participation in clinical trials and other studies. It addresses the role of social workers as genetic counselors and encourages, especially social workers of color, involvement in the field of genetics as advocates, teachers, and as members of research teams.

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**Document 106**

Fuchs, Michael

**Ethical consideration.**


**Abstract:** The twofold distinction between interventions into the germ line and interventions into somatic cells on the one hand and between the treatment of diseases and enhancement on the other hand resulted in the concept of somatic gene therapy. There is a nearly unanimous agreement that somatic gene therapy has a high-ranking moral objective and uses methods that extend current techniques for treating diseases in a morally acceptable way. In its experimental phase principles of research ethics as the autonomy and the informed consent of the patient or the test person, a fair selection of test persons and a careful weighing of risks and benefits have to be taken into account and several specific points have to be considered. Experimental somatic gene therapy requires a positive vote of a competent and independent ethics committee.

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**Document 107**

Goldenberg, A J; Hull, S C; Wilfond, B S; Sharp, R R

**Patient perspectives on group benefits and harms in genetic research.**

Public health genomics 2011; 14(3): 135-42

**Abstract:** It is unclear how the possible effects of genetic research on socially identifiable groups may impact patient willingness to donate biological samples for future genetic studies.

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**Document 108**

Hens, K; Nys, H; Cassiman, J-J; Dierickx, K

**The storage and use of biological tissue samples from minors for research: a focus group study.**

Public health genomics 2011; 14(2): 68-76

**Abstract:** Genetic research on pediatric stored tissue samples raises specific ethical questions that differ from those raised when adults are the donors. To investigate opinions on this matter, we conducted 10 focus group discussions. Five focus groups were conducted with adult participants and 5 had teenage participants between 15 and 19 years old. The discussions were analyzed with NVIVO 8 (qualitative research software). We found the following recurrent categories: the requirement that research should not pose any burden on children and that it should benefit other children, the trust people had in the role of parents, the need for information and the growth towards autonomy. Both the adults and teenagers we interviewed thought that the inclusion of tissue samples from minors in research had ethical implications. A major concern was that nontherapeutic research would pose no extra burden on children,
which would assume the use of nonintrusive methods of gathering samples and the use of samples that were
gathered in a diagnostic context. Participants, however, also understood the necessity of such research. The overall
impression was that parents would be the best persons to make decisions on behalf of a small child and that the
same parents would engage their children in the decision-making when they grew older. People thought that there
was a duty to recontact minors when they reached the age of competence but on a best-effort basis.

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Document 109

With, Catherine M; Evers, David L; Mason, Jeffrey T

**Regulatory and ethical issues on the utilization of FFPE tissues in research.**

Methods in molecular biology (Clifton, N.J.) 2011; 724: 1-21

**Abstract:** Formalin-fixed, paraffin-embedded (FFPE) archival tissues and their associated diagnostic records
represent an invaluable source of information on diseases where the patient outcomes are already known. Older
archives contain many unique FFPE tissue specimens that would be impossible to replicate today due to changes in
medical practice and technology. Unfortunately, there is no single regulatory or bioethical standard that covers
research with FFPE tissue specimens. This makes it difficult for researchers to prepare protocols involving FFPE
tissues and equally difficult for Institutional Review Boards to evaluate them. In this review, focused on US
regulatory policy, the application of the Common Rule and the Privacy Rule of the Health Insurance Portability and
Accountability Act to research involving FFPE tissue specimens will be discussed. It will be shown that the difficulty
in applying regulatory and ethical standards to FFPE tissues results not from the tissues themselves, but from the
personally identifiable health information associated with the tissue specimens.

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Document 110

Heeney, C; Hawkins, N; de Vries, J; Boddington, P; Kaye, J

**Assessing the privacy risks of data sharing in genomics.**

Public health genomics 2011; 14(1): 17-25

**Abstract:** The protection of identity of participants in medical research has traditionally been guaranteed by the
maintenance of the confidentiality of health information through mechanisms such as only releasing data in an
aggregated form or after identifying variables have been removed. This protection of privacy is regarded as a
fundamental principle of research ethics, through which the support of research participants and the public is
maintained. Whilst this traditional model was adopted for genetics and genomics research, and was generally
considered broadly fit for purpose, we argue that this approach is increasingly untenable in genomics. Privacy risk
assessments need to have regard to the whole data environment, not merely the quality of the dataset to be
released in isolation. As sources of data proliferate, issues of privacy protection are increasingly problematic in
relation to the release of genomic data. However, we conclude that, by paying careful attention to potential pitfalls,
scientific funders and researchers can take an important part in attempts to safeguard the public and ensure the
continuation of potentially important scientific research.

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Document 111

Chalmers, Don

**Genetic research and biobanks.**

Methods in molecular biology (Clifton, N.J.) 2011; 675: 1-37

**Abstract:** Human biobanks, and genetic research databases, as referred to by the Organisation for Economic Co-
operation and Development (OECD), are essential tools for modern biomedical research. Biobanks may consist in
collections created in clinical diagnosis (such as pathology tissue samples in hospitals) or collections created for
large-scale longitudinal research (such as the UK Biobank). Human tissue collections are regulated by a patchwork
of national laws. However, there is an increasing international uniformity in national privacy laws based on 1980s
OECD standards. There are similar uniform standards developing in national research ethics guidelines. As biobanks
develop collaborations and linkages, international harmonisation of legislation and human research regulation will be required across jurisdictions. It is essential that international public trust is maintained in biobanking research.

**Document 112**

Hansson, Mats G

**The need to downregulate: a minimal ethical framework for biobank research.**


**Abstract:** There are currently multiple international bodies suggesting legal and ethical frameworks for regulating international biobank research. One will for obvious reasons find inconsistencies in terminology and differences in procedures suggested for biobank research among all those guidelines, emanating from many different moral and legal traditions. A central question is whether this constitutes a threat to making progress in international biobank research, as some have argued. In this book, Chapter 1 suggests that there are sufficient and well-established instruments and ethical principles available to guide research in this area. Basically I argue that there is no need for a top-down superstructure of detailed rules and guidelines to be imposed on biobank researchers. With the existing ethical review boards (ERBs) playing a central role guided by well-established ethical guidelines (e.g., the Helsinki Declaration) and solutions to specific ethical problems suggested in the literature, self-regulation by researchers providing arguments for balancing of interests in association with different research initiatives and protocols will be sufficient. Traditional information and consent procedures suffice and data protection implies a sovereign right of the individual citizen to grant the use of biobank material and personal data that is needed for biobank research. Clearly, there may still be inconsistencies in terminology when researchers of different nationalities meet in common enterprises, but both they and the ERBs are well equipped to sort out what is actually meant and propose different instruments for, for example, coding following recently established nomenclatures. The existing ERBs should play the key role, guided by the sound argumentation of the researchers in their applications to the board.

**Document 113**

Dillner, Joakim; Andersson, Kristin

**Biobanks collected for routine healthcare purposes: build-up and use for epidemiologic research.**

Methods in molecular biology (Clifton, N.J.) 2011; 675: 113-25

**Abstract:** The routine health services collect large amount of samples for biobanking, particularly in clinical laboratory medicine, mainly for clinical diagnostic purposes. These samples provide a large-scale and clinically relevant biobanking infrastructure that can be used for research if these conditions apply. There must be a system for database management that can obtain data on clinical endpoints, vital status, and additional required information via registry linkages. There must be an appropriate ethical system for handling consent for research use. There should be an active effort to optimize the usefulness of clinical biobanks also for research use. Major steps in this direction include measures to stop the ongoing discarding of old samples, reformatting to minimize pick-up times, external quality assurance and formal accreditation of biobanks, building of a dedicated high-quality database that is regularly used for registry linkages, and considerations on whether usefulness and accessibility for research can be optimized by extended saving or pre-treatment of samples. Systematic clinical biobanking could become a major asset for clinical research and public health if biobanking is considered as a routine part of everyday clinical practice, and the science of biobanking is considered an essential part of the science of laboratory medicine.

**Document 114**

Wjst, Matthias

**Caught you: threats to confidentiality due to the public release of large-scale genetic data sets.**

BMC medical ethics 2010 December 29; 11: 21

**Abstract:** Large-scale genetic data sets are frequently shared with other research groups and even released on the Internet to allow for secondary analysis. Study participants are usually not informed about such data sharing...
because data sets are assumed to be anonymous after stripping off personal identifiers.

Document 115

Fabsitz, Richard R; McGuire, Amy; Sharp, Richard R; Puggal, Mona; Beskow, Laura M; Biesecker, Leslie G; Bookman, Ebony; Burke, Wylie; Burchard, Esteban Gonzalez; Church, George; Clayton, Ellen Wright; Eckfeldt, John H; Fernandez, Conrad V; Fisher, Rebecca; Fullerton, Stephanie M; Gabriel, Stacey; Gachupin, Francine; James, Cynthia; Jarvik, Gail P; Kittles, Rick; Leib, Jennifer R; O'Donnell, Christopher; O'Rourke, P Pearl; Rodriguez, Laura Lyman; Scully, Sheri D; Shuldiner, Alan R; Sze, Rebecca K F; Thakuria, Joseph V; Wolf, Susan M; Burke, Gregory L

National Heart, Lung, and Blood Institute working group

Ethical and practical guidelines for reporting genetic research results to study participants: updated guidelines from a National Heart, Lung, and Blood Institute working group.

Circulation. Cardiovascular genetics 2010 Dec 1; 3(6): 574-80

Abstract: In January 2009, the National Heart, Lung, and Blood Institute convened a 28-member multidisciplinary Working Group to update the recommendations of a 2004 National Heart, Lung, and Blood Institute Working Group focused on Guidelines to the Return of Genetic Research Results. Changes in the genetic and societal landscape over the intervening 5 years raise multiple questions and challenges. The group noted the complex issues arising from the fact that technological and bioinformatic progress has made it possible to obtain considerable information on individuals that would not have been possible a decade ago. Although unable to reach consensus on a number of issues, the working group produced 5 recommendations. The working group offers 2 recommendations addressing the criteria necessary to determine when genetic results should and may be returned to study participants, respectively. In addition, it suggests that a time limit be established to limit the duration of obligation of investigators to return genetic research results. The group recommends the creation of a central body, or bodies, to provide guidance on when genetic research results are associated with sufficient risk and have established clinical utility to justify their return to study participants. The final recommendation urges investigators to engage the broader community when dealing with identifiable communities to advise them on the return of aggregate and individual research results. Creation of an entity charged to provide guidance to institutional review boards, investigators, research institutions, and research sponsors would provide rigorous review of available data, promote standardization of study policies regarding return of genetic research results, and enable investigators and study participants to clarify and share expectations for the handling of this increasingly valuable information with appropriate respect for the rights and needs of participants.

Document 116

Alici, Evren; Blomberg, Pontus

GMP facilities for manufacturing of advanced therapy medicinal products for clinical trials: an overview for clinical researchers.

Current gene therapy 2010 Dec; 10(6): 508-15

Abstract: To be able to produce advanced therapy medicinal products, compliance with regulatory standards while maintaining flexibility is mandatory. For this purpose, careful planning is vital in the design or upgrade of a facility. Similarly, extensive foresight is elemental to anticipate upcoming needs and requirements. Failing this may lead to the facility's inability to meet the demands. In this chapter we aimed to outline the current issues with regards to the European Union Directives (EUD) and the proposal for Advanced Therapies, which are of importance to cellular and gene therapy facilities in Europe. This chapter is an attempt to elucidate what the minimum requirements for GMP facilities for cell and gene therapy products are and what is considered necessary to comply with the regulations in Europe.

Document 117
Lorenz, H-M
[Biomarkers collections: the future or a waste of resources?]. = Biomarkerammlungen: Zukunft oder Ressourcenverschwendung?
Zeitschrift für Rheumatologie 2010 Dec; 69(10): 860-2
Abstract: Disease biomarkers would aim at a more specific definition of diagnosis or subtype of a certain disease, as well as prognosis definition, including efficacy and side effects of certain therapeutics. Biomarkers could lead to a prognostically optimized definition of remission in the individual patient and thus to a more objective definition of therapeutic efficacy. Is this possible and does it make sense? Or would an extensive analysis of biomarkers to date lead to a costly overestimation of as yet not well established biologic parameters? Although we are currently unable to answer this question, many colleagues argue in favour of more in depth research for a better evaluation of biomarkers in many diseases. This could save money if we were able to predict the efficacy of expensive drugs such as immunobiologics. Biomarkers comprise cytometric information, data on protein expression and secretion, mRNA, microRNA or DNA, including epigenetic variants. Although much of these data already exist in the scientific literature, it is associated with problems in terms of feasibility (for cytometry and RNA analysis only on-site analysis is possible, while for DNA analysis central testing is also possible), costs and reproducibility (ethnic variability!). To date all biomarkers have only limited value in terms of the above-mentioned aims. The present review compiles "PROs and CONs" in a subjective way in order to provoke a discussion on the meaningfulness of biomarkers, while at the same time supporting and encouraging further research in this field.

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Document 118

Sharp, Richard R; McGowan, Michelle L; Verma, Jonathan A; Landy, David C; McAdoo, Sallie; Carson, Sandra A; Simpson, Joe Leigh; McCullough, Laurence B
Moral attitudes and beliefs among couples pursuing PGD for sex selection.
Reproductive biomedicine online 2010 Dec; 21(7): 838-47
Abstract: This article reports the results from a study of couples participating in a research protocol in which IVF/preimplantation genetic diagnosis (PGD) was available for non-medical sex selection. The study sought to characterize the moral attitudes and beliefs of couples actively pursuing IVF/PGD solely for purposes related to sex selection. Eighteen couples participated in ethnographic interviews from November 2005 to April 2006. These interviews explored couples' motivations for pursuing sex selection, moral beliefs and attitudes regarding sex selection and sources of moral ambivalence about the use of IVF/PGD for sex selection. Couples reported a combination of motivations for pursuing sex selection, including a desire to limit family size, concerns about parental age and financial concerns about multiple pregnancies. Many couples compared their decision to choices about abortion, maintaining that individuals have a right to make such decisions privately. Couples frequently expressed anxiety about telling their other children and family members about their plans to use IVF/PGD for sex selection. Few couples cited concerns about the physical or emotional burdens of IVF/PGD. The study's findings suggest that couples pursuing IVF/PGD for sex selection view this as an ethically complex decision and express considerable uncertainty about the ethical acceptability of this practice.

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Document 119

King, William Douglas; Wyatt, Gail E; Liu, Honghu; Williams, John K; DiNardo, Anthony D; Mitsuyasu, Ronald T
Pilot assessment of HIV gene therapy-hematopoietic stem cell clinical trial acceptability among minority patients and their advisors.
Journal of the National Medical Association 2010 Dec; 102(12): 1123-8
Abstract: Clinical trials involving technologically involved novel treatments such as gene therapy delivered through hematopoietic stem cells as human immunodeficiency virus (HIV) treatment will need to recruit ethnically diverse patients to ensure the acceptance among broad groups of individuals and generalizability of research findings. Five focus groups of 47 HIV-positive men and women, religious and community leaders and health providers, mostly from African American and low-income communities, were conducted to examine knowledge about gene therapy and stem cell research and to assess the moral and ethical beliefs that might influence participation in clinical trials. Three themes emerged from these groups: (1) the need for clarification of terminology and the ethics of understanding gene therapy-stem cell research, (2) strategies to avoid mistrust of medical procedures and provider mistrust, and (3) the conflict between science and religious beliefs as it pertains to gene therapy-stem cell research.
Document 120

Wiseman, Mel; Dancyger, Caroline; Michie, Susan

**Communicating genetic risk information within families: a review.**

Familial cancer 2010 Dec; 9(4): 691-703

**Abstract:** This review of family communication of genetic risk information addresses questions of what the functions and influences on communication are; what, who and how family members are told about genetic risk information; what the impact for counsellee, relative and relationships are; whether there are differences by gender and condition; and what theories and methodologies are used. A systematic search strategy identified peer-reviewed journal articles published 1985-2009 using a mixture of methodologies. A Narrative Synthesis was used to extract and summarise data relevant to the research questions. This review identified 33 articles which found a consistent pattern of findings that communication about genetic risk within families is influenced by individual beliefs about the desirability of communicating genetic risk and by closeness of relationships within the family. None of the studies directly investigated the impact of communication on counsellees or their families, differences according to gender of counsellee or by condition nor alternative methods of communication with relatives. The findings mainly apply to late onset conditions such as Hereditary Breast and Ovarian Cancer. The most frequently used theory was Family Systems Theory and methods were generally qualitative. This review points to multifactorial influences on who is communicated with in families and what they are told about genetic risk information. Further research is required to investigate the impact of genetic risk information on family systems and differences between genders and conditions.

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Document 121

**Biobanking DNA.**

American journal of medical genetics. Part A 2010 Dec; 152A(12): fmviii-fmix

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Document 122

Laegsgaard, M M; Stamp, A S; Hall, E O C; Mors, O

**The perceived and predicted implications of psychiatric genetic knowledge among persons with multiple cases of depression in the family.**

Acta psychiatrica Scandinavica 2010 Dec; 122(6): 470-80

**Abstract:** Psychiatric genetic research raises hope regarding better treatment and prevention, but also regarding a possible de-stigmatizing effect of attributing mental illness to genetics. This study explores i) the impact on family relations of participating in a genetic study; ii) the impact of biogenetic attributions on perceptions of depression and stigma and iii) the perceived benefits and concerns regarding psychiatric genetic testing.

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Document 123

European Society of Human Genetics

**Statement of the ESHG on direct-to-consumer genetic testing for health-related purposes.**

European journal of human genetics : EJHG 2010 Dec; 18(12): 1271-3

**Abstract:** Many private companies offer direct-to-consumer (DTC) genetic testing services. Some tests may detect severe and highly penetrant monogenic disorders, while other tests are for genetic variants found associated with increased susceptibility for common and complex diseases in large-scale population studies. Through its Public and Professional Policy committee followed by member and expert consultation, the European Society of Human
Genetics has developed the following policy on advertising and provision of predictive genetic tests by such DTC companies: (1) clinical utility of a genetic test shall be an essential criterion for deciding to offer this test to a person or a group of persons; (2) laboratories providing genetic tests should comply with accepted quality standards, including those regarding laboratory personnel qualifications; (3) information about the purpose and appropriateness of testing should be given before the test is done; (4) genetic counselling appropriate to the type of test and disease should be offered; and for some tests psychosocial evaluation and follow-up should be available; (5) privacy and confidentiality of sensitive genetic information should be secured and the data safely guarded; (6) special measures should be taken to avoid inappropriate testing of minors and other legally incapacitated persons; (7) all claims regarding genetic tests should be transparent; advertisement should be unbiased and marketing of genetic tests should be fair; (8) in biomedical research, health care and marketing, respect should be given to relevant ethical principles, as well as international treaties and recommendations regarding genetic testing; and (9) nationally approved guidelines considering all the above-mentioned aspects should be made and followed.

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**Document 124**

O'Neill, Suzanne C; Valdimarsdottir, Heiddis B; Demarco, Tiffani A; Peshkin, Beth N; Graves, Kristi D; Brown, Karen; Hurley, Karen E; Isaacs, Claudine; Hecker, Sharon; Schwartz, Marc D

**BRCA1/2 test results impact risk management attitudes, intentions, and uptake.**

*Breast cancer research and treatment* 2010 Dec; 124(3): 755-64

**Abstract:** Women who receive positive or uninformative BRCA1/2 test results face a number of decisions about how to manage their cancer risk. The purpose of this study was to prospectively examine the effect of receiving a positive versus uninformative BRCA1/2 genetic test result on the perceived pros and cons of risk-reducing mastectomy (RRM) and risk-reducing oophorectomy (RRO) and breast cancer screening. We further examined how perceived pros and cons of surgery predict intention for and uptake of surgery. 308 women (146 positive, 162 uninformative) were included in RRM and breast cancer screening analyses. 276 women were included in RRO analyses. Participants completed questionnaires at pre-disclosure baseline and 1-, 6-, and 12-months post-disclosure. We used linear multiple regression to assess whether test result contributed to change in pros and cons and logistic regression to predict intentions and surgery uptake. Receipt of a positive BRCA1/2 test result predicted stronger pros for RRM and RRO (P < 0.001), but not perceived cons of RRM and RRO. Pros of surgery predicted RRM and RRO intentions in carriers and RRO intentions in uninformatives. Cons predicted RRM intentions in carriers. Pros and cons predicted carriers' RRO uptake in the year after testing (P < 0.001). Receipt of BRCA1/2 mutation test results impacts how carriers see the positive aspects of RRO and RRM and their surgical intentions. Both the positive and negative aspects predict uptake of surgery.

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**Document 125**

Ross, Lainie Friedman

**Mandatory versus voluntary consent for newborn screening?**

*Kennedy Institute of Ethics journal* 2010 Dec; 20(4): 299-328

**Abstract:** Virtually every infant in the United States undergoes a heel stick within the first week of life to test for a variety of metabolic, endocrine, and hematological conditions as part of state-run universal newborn screening (NBS) programs. The history of this mandatory public health program is examined, as well as whether the policy was morally justifiable. Three changes in NBS practice necessitate a re-evaluation of the mandatory nature of NBS. First is the adoption of NBS for hemoglobinopathies in the 1980s that led to the identification of many sickle cell carriers and carriers of other hemoglobin variants. In all other contexts, carrier testing requires consent, and there is no moral rationale why NBS ought to be exceptional. Second is the application of tandem mass spectrometry (MS/MS) to NBS in the 1990s that led to the identification of many metabolic conditions and variants, some of which were not treatable and others of which had unknown clinical relevance. To the extent that the conditions do not need emergent diagnosis and treatment, there is less justification for mandatory screening. Third, there is great interest in using residual blood spots for research, and the cornerstone of research ethics is the voluntary consent of the participant (or his or her proxy). These three changes support revising mandatory NBS with a tiered consent process to best balance respect for parental autonomy and the promotion of children's health.
Document 126
Kurtz, M; Black Golde, P; Berlinger, N
*Ethical considerations in CYP2D6 genotype testing for codeine-prescribed breastfeeding mothers.*
Clinical pharmacology and therapeutics 2010 Dec; 88(6): 760-2

**Abstract:** In this issue, Madadi et al. report on interviews with codeine-prescribed breastfeeding mothers concerning preferences and attitudes toward receiving their CYP2D6 genotype and overall study findings. We address three sets of ethics questions raised by this article. Should genetic information be disclosed to research participants in genetic research? What should clinicians take into account when considering this genetic test in managing infant opioid toxicity risk? What conditions support or hinder the integration of genetic information into patient care?

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Document 127
Mahowald, Mary B
*Protocell research and its implications.*
Perspectives in biology and medicine 2010 Winter; 53(1): 136-47

**Abstract:** If and when protocells exist, they will exhibit three requisites for life: regeneration, replication, and evolution. Based on a recent collection of articles, this essay examines two major questions: (1) should research on development of protocells continue, and (2) what are the implications of this research for our understanding of "life." On the first question, I agree with contributors that the research should continue if there are adequate and ongoing safeguards against its misuse. On the second, I believe that creation of protocells is highly likely to escalate, rather than settle, controversies about the meaning and value of life, especially human life.

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Document 128
Tuffs, Annette
*Experts demand major revisions of German gene diagnostics law.*
BMJ (Clinical research ed.) 2010 November 22; 341: c6685

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Document 129
Bredenoord, Annelien L; Braude, Peter
*Ethics of mitochondrial gene replacement: from bench to bedside.*
BMJ (Clinical research ed.) 2010 November 8; 341: c6021

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Document 130
Matsui, Kenji; Kita, Yoshikuni
*Why do people consent to participate in genetic epidemiological studies?*

**Abstract:** This investigation aimed to determine in a research setting why people in the general population consent to participate in genetic epidemiological studies.
Document 131

Johnsson, Linus; Helgesson, Gert; Rafnar, Thorunn; Halldorsdottir, Ingibjorg; Chia, Kee-Seng; Eriksson, Stefan; Hansson, Mats G

**Hypothetical and factual willingness to participate in biobank research.**
European journal of human genetics : EJHG 2010 Nov; 18(11): 1261-4

**Abstract:** In the debate on biobank regulation, arguments often draw upon findings in surveys on public attitudes. However, surveys on willingness to participate in research may not always predict actual participation rates. We compared hypothetical willingness as estimated in 11 surveys conducted in Sweden, Iceland, United Kingdom, Ireland, United States and Singapore to factual participation rates in 12 biobank studies. Studies were matched by country and approximate time frame. Of 22 pairwise comparisons, 12 suggest that factual willingness to participate in biobank research is greater than hypothetical, six indicate the converse relationship, and four are inconclusive. Factual donors, in particular when recruited in health care or otherwise face-to-face with the researcher, are possibly motivated by factors that are less influential in a hypothetical context, such as altruism, trust, and sense of duty. The value of surveys in assessing factual willingness may thus be limited.

Document 132

Povey, Sue; Al Aqeel, Aida I; Cambon-Thomsen, Anne; Dalgleish, Raymond; den Dunnen, Johan T; Firth, Helen V; Greenblatt, Marc S; Barash, Carol Isaacson; Parker, Michael; Patrinos, George P; Savige, Judith; Sobrido, Maria-Jesus; Winship, Ingrid; Cotton, Richard G H; Ethics Committee of the Human Genome Organization (HUGO)

**Practical guidelines addressing ethical issues pertaining to the curation of human locus-specific variation databases (LSDBs).**
Human mutation 2010 Nov; 31(11): 1179-84

**Abstract:** More than 1,000 Web-based locus-specific variation databases (LSDBs) are listed on the Website of the Human Genetic Variation Society (HGVS). These individual efforts, which often relate phenotype to genotype, are a valuable source of information for clinicians, patients, and their families, as well as for basic research. The initiators of the Human Variome Project recently recognized that having access to some of the immense resources of unpublished information already present in diagnostic laboratories would provide critical data to help manage genetic disorders. However, there are significant ethical issues involved in sharing these data worldwide. An international working group presents second-generation guidelines addressing ethical issues relating to the curation of human LSDBs that provide information via a Web-based interface. It is intended that these should help current and future curators and may also inform the future decisions of ethics committees and legislators. These guidelines have been reviewed by the Ethics Committee of the Human Genome Organization (HUGO).

Document 133

Andersson, Kristin; Bray, Freddie; Arbyn, Marc; Storm, Hans; Zanetti, Roberto; Hallmans, Göran; Coebergh, Jan W; Dillner, Joakim

**The interface of population-based cancer registries and biobanks in etiological and clinical research—current and future perspectives.**
Acta oncoligica (Stockholm, Sweden) 2010 Nov; 49(8): 1227-34

**Abstract:** The availability of quality assured, population-based cancer registries and biobanks with high quality samples makes it possible to conduct research on large samples sets with long follow-up within a reasonable time frame. Defined quality for both cancer registries and biobanks is essential for enabling high quality biobank-based research. Recent networking projects have brought these infrastructures together to promote the combined use of cancer registries and biobanks in cancer research.
Document 134
Allen, Monica J; Powers, Michelle L E; Gronowski, K Scott; Gronowski, Ann M
**Human tissue ownership and use in research: what laboratorians and researchers should know.**
Clinical chemistry 2010 Nov; 56(11): 1675-82
**Abstract:** The use of human blood and tissue is critical to biomedical research. A number of treaties, laws, and regulations help to guide the ethical collection of these specimens. However, there are no clearly defined regulations regarding the ownership of human tissue specimens and who can control their fate.

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Document 135
Tuffs, Annette
**German MPs are to vote on allowing preimplantation genetic diagnosis.**
BMJ (Clinical research ed.) 2010 October 25; 341: c6017

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Document 136
Lin, Chiou-Fen; Lu, Meei-Shiow; Chung, Chun-Chih; Yang, Che-Ming
**The establishment of an ethical guideline for genetic testing through citizen consensus via the Internet in Taiwan.**
Journal of medical Internet research 2010 October 18; 12(4): e47
**Abstract:** With the rapid advance of genetics, the application of genetic testing has become increasingly popular. Test results have had a tremendous impact on individuals who receive the test and his or her family. The ethical, legal, and social implications (ELSI) of genetic testing cannot be overlooked. The Internet is a potential tool for public engagement.

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Document 137
Hofman, Véronique; Bonnetaud, Christelle; Gaziello, Marie Clotilde; Ilie, Marius; Lassalle, Sandra; Butori, Catherine; Lerda, Nathalie; Selva, Eric; Gavric-Tanga, Virginie; Castillo, Laurent; Guevara, Nicolas; Santini, José; Pop, Daniel; Vénissac, Nicolas; Mouroux, Jérôme; Chabannon, Christian; Hofman, Paul
**[The Nice CHU biobank experience to collect patients' informed consent for research context (2004-2009)]. = L’expérience de la tumorothèque du CHU de Nice pour le recueil des consentements éclairés dans le cadre de la recherche (2004-2009).**
Annales de pathologie 2010 Oct; 30(5): 337-43
**Abstract:** Over the last 10 years, significant financial support from the French National Institute of Cancer (INCa), the Ministry of Health (DGOS), and the Health and Research National Institute (Inserm) helped biobanks—of which tumour banks represent a prominent example of hospital-based infrastructures—to improve their operations, and in some instances to adopt the rules of Biological Ressource Centers as defined by OECD. Nowadays, the use of biological samples of human origin is strictly subordinated to regulations that integrate bioethical principles. However, in spite of the establishment of these regulations, requirement to obtain an authorisation and/or to register the biological collections with the Ministry of Research, many uncertainties persist. While French regulations mandate that samples can be used for research as long as patients did not oppose to such use, many biobank curators face practical and theoretical issues when establishing a Material Transfer Agreement with scientists, due to the lack of harmonization between national regulations—particularly due to a different perception of privacy and free will in anglo-american and other countries—and different demands on the side of private industry or editorial boards of scientific journals. The goal of this article is (1) to describe the procedure followed to collect patients' informed consent at the Biobank of CHU de Nice and (2) to assess the number of obtained consents in comparison to the number of collected samples between 01/09/2004 and 31/12/2009, the number of consents obtained before or after collecting...
the samples, and the number of patients' refusal to collect their biological resources. This balance-sheet is settled for the three major collections (thoracic, thyroid and head and neck tissues) from the Biobank of CHU de Nice. Results show that 88% of consents were obtained during this period (82% in a prospective manner and 6% in a retrospective manner). Refusal was notified by writing in nine cases only. The percentage of consents varies slightly according to the collection involved and is stable from 2004 to 2009. Overall, our procedure is quite efficient at obtaining informed consents from a majority of patients for whom the tumour bank stores biological samples. This situation provides optimal conditions for the use of collected samples in the context of national and international research projects.

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**Document 138**
Hawkins, Alice K

**Biobanks: importance, implications and opportunities for genetic counselors.**

**Abstract:** Biobanks are collections of human biological tissue specimens and related health data. Biobank research hopes to provide novel insights into the genetic component of disease, ultimately leading to a more personalized approach to healthcare. However, biobanks have sparked debate due to the ethical, legal, and social implications surrounding utilization of population samples and data. These controversies include issues of consent, privacy and confidentiality, return of results and data-sharing. This paper provides an overview of the different types and scope of biobanks and an examination of the most pertinent ethical, legal and social considerations surrounding such research, as well as how some of these concerns are being addressed. The paper finishes with a discussion of the relevance of biobanks to the genetic counseling field and concludes that genetic counselors are in a position to make a unique, educated and practical contribution to the ongoing dialogue and direction of biobank research.

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**Document 139**
Clayton, Ellen Wright; Smith, Maureen; Fullerton, Stephanie M; Burke, Wylie;McCarty, Catherine A; Koenig, Barbara A; McGuire, Amy L; Beskow, Laura M; Dressler, Lynn; Lemke, Amy A; Ramos, Erin M; Rodriguez, Laura Lyman; Consent and Community Consultation Working Group of the eMERGE Consortium

**Confronting real time ethical, legal, and social issues in the Electronic Medical Records and Genomics (eMERGE) Consortium.**
Genetics in medicine : official journal of the American College of Medical Genetics 2010 Oct; 12(10): 616-20

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**Document 140**
Hong, Kyung-Won; Oh, Bermseok

**Overview of personalized medicine in the disease genomic era.**
BMB reports 2010 Oct; 43(10): 643-8

**Abstract:** Sir William Osler (1849-1919) recognized that "variability is the law of life, and as no two faces are the same, so no two bodies are alike, and no two individuals react alike and behave alike under the abnormal conditions we know as disease". Accordingly, the traditional methods of medicine are not always best for all patients. Over the last decade, the study of genomes and their derivatives (RNA, protein and metabolite) has rapidly advanced to the point that genomic research now serves as the basis for many medical decisions and public health initiatives. Genomic tools such as sequence variation, transcription and, more recently, personal genome sequencing enable the precise prediction and treatment of disease. At present, DNA-based risk assessment for common complex diseases, application of molecular signatures for cancer diagnosis and prognosis, genome-guided therapy, and dose selection of therapeutic drugs are the important issues in personalized medicine. In order to make personalized medicine effective, these genomic techniques must be standardized and integrated into health systems and clinical workflow. In addition, full application of personalized or genomic medicine requires dramatic changes in regulatory and reimbursement policies as well as legislative protection related to privacy. This review aims to provide a general
overview of these topics in the field of personalized medicine.

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**Document 141**

Deakin, Claire T; Alexander, Ian E; Kerridge, Ian

**The ethics of gene therapy: balancing the risks.**


**Abstract:** Gene therapy research is characterized by heightened uncertainty about the risks associated with the complex products involved, particularly the risk of genotoxicity. Recognizing that uncertainty concerning risks is inescapable in first-in-human clinical trials of gene therapy, decisions on how to balance the risks nevertheless must be made. Ethics can facilitate translational progress by, first, evaluating decision-making processes during risk assessment; and second, focusing on questions that require a degree of subjective judgement. Such assessments include determining the level of risk that is acceptable in trials, the category of patients that should be exposed to the risks, and the level of certainty with respect to risk that is required for both researchers and participants to make decisions. Analysis of these issues is affected by the burden of illness, existing treatment alternatives and the possible benefits of gene therapy. Patients' attitudes and experiences in this regard can reasonably inform the decision-making of researchers. Reflecting upon the approaches used to balance risks and possible benefits in gene therapy trials may improve decision-making processes across the spectrum of decisions that are made from the initial conception of a study up to decisions by research participants about consent. This manner of reflection facilitates the advancement of science, while protecting the welfare of research participants.

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**Document 142**

Hershberger, Patricia E; Pierce, Penny F

**Conceptualizing couples' decision making in PGD [pre-implantation genetic diagnosis]: emerging cognitive, emotional, and moral dimensions.**


**Abstract:** To illuminate and synthesize what is known about the underlying decision making processes surrounding couples' preimplantation genetic diagnosis (PGD) use or disuse and to formulate an initial conceptual framework that can guide future research and practice.

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**Document 143**

Ahman, Annika; Runestam, Karin; Sarkadi, Anna

**Did I really want to know this? Pregnant women's reaction to detection of a soft marker during ultrasound screening.**

Patient education and counseling 2010 Oct; 81(1): 87-93

**Abstract:** To investigate women's expectations of routine ultrasound and experiences when soft markers were discovered: what the disclosure meant, how it affected them, how they experienced the information given and why they did or did not choose amniocentesis.

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**Document 144**

McGuire, Amy L; Beskow, Laura M

**Informed consent in genomics and genetic research.**

Annual review of genomics and human genetics 2010 Sep 22; 11: 361-81

**Abstract:** There are several features of genetic and genomic research that challenge established norms of informed consent.
In this paper, we discuss these challenges, explore specific elements of informed consent for genetic and genomic research conducted in the United States, and consider alternative consent models that have been proposed. All of these models attempt to balance the obligation to respect and protect research participants with the larger social interest in advancing beneficial research as quickly as possible.
workshop, "Advancing Rare Disease Research: The Intersection of Patient Registries, Biospecimen Repositories, and Clinical Data." http://rarediseases.info.nih.gov/PATIENT_REGISTRIES_WORKSHOP/. The workshop was sponsored by the Office of Rare Diseases Research (ORDR). The focus was the building of an infrastructure for an internet-based global registry linking to biorepositories. Such a registry would serve the patients, investigators, and drug companies. To aid researchers the participants suggested the creation of a centralized database of biorepositories for rare biospecimens (RD-HUB) http://biospecimens.ordr.info.nih.gov/ that could be linked to the registry. Over two days of presentations and breakout sessions, several hundred attendees discussed government rules and regulations concerning privacy and patients' rights and the nature and scope of data to be entered into a central registry as well as concerns about how to validate patient and clinician-entered data to ensure data accuracy. Mechanisms for aggregating data from existing registries were also discussed. The attendees identified registry best practices, model coding systems, international systems for recruiting patients into clinical trials and novel ways of using the internet directly to invite participation in research. They also speculated about who would bear ultimate responsibility for the informatics in the registry and who would have access to the information. Hurdles associated with biospecimen collection and how to overcome them were detailed. The development of the recommendations was, in itself, an indication of the commitment of the rare disease community as never before.

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Document 149
Beskow, Laura M; Friedman, Joëlle Y; Hardy, N Chantelle; Lin, Li; Weinfurt, Kevin P
Simplifying informed consent for biorepositories: stakeholder perspectives.
Genetics in medicine : official journal of the American College of Medical Genetics 2010 Sep; 12(9): 567-72
Abstract: Complex and sometimes controversial information must be conveyed during the consent process for participation in biorepositories, and studies suggest that consent documents in general are growing in length and complexity. As a first step toward creating a simplified biorepository consent form, we gathered data from multiple stakeholders about what information was most important for prospective participants to know when making a decision about taking part in a biorepository.

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Document 150
Hens, Kristien; Nys, Herman; Cassiman, Jean-Jacques; Dierickx, Kris
The use of diagnostic collections of DNA for research: interviews at the eight Belgian centers for human genetics.
Abstract: The attitudes towards the reuse for research of biological samples that were gathered in a diagnostics context have changed over the last years. A few decades ago, people would not hesitate to use such samples without explicit consent. Then, in conjunction with a move towards a stress to personal autonomy in bioethics, many would argue that written consent for such secondary use is necessary. Not much is known about the actual practices with regard to this subject. We have interviewed spokes-persons of all eight Belgian centers for medical genetics, and have found that they would all adhere to the latter stream of thought. As such, they would not use diagnostic DNA for research purposes without written consent. Recently, however, international guidelines have moved towards the concept of presumed consent for diagnostic samples. There is agreement that patients and donors should be informed about possible research uses, and should be given the opportunity to opt out, but there is no need for explicitly written consent to be able to use these samples. Extracted DNA may fall under the same regime as other tissue that is gathered in a diagnostic or surgical context in university hospitals. Such policy satisfies both the requirement of respect for donor's autonomy as well as the requirement of using research resources sensibly and is backed by international guidelines and opinions.

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Document 151
Roberts, J Scott; Shalowitz, David I; Christensen, Kurt D; Everett, Jessica N; Kim, Scott Y H; Raskin, Leon; Gruber,
Returning individual research results: development of a cancer genetics education and risk communication protocol.

Abstract: The obligations of researchers to disclose clinically and/or personally significant individual research results are highly debated, but few empirical studies have addressed this topic. We describe the development of a protocol for returning research results to participants at one site of a multicenter study of the genetic epidemiology of melanoma. Protocol development involved numerous challenges: (1) deciding whether genotype results merited disclosure; (2) achieving an appropriate format for communicating results; (3) developing education materials; (4) deciding whether to retest samples for additional laboratory validation; (5) identifying and notifying selected participants; and (6) assessing the impact of disclosure. Our experience suggests potential obstacles depending on researcher resources and the design of the parent study, but offers a process by which researchers can responsibly return individual study results and evaluate the impact of disclosure.

Received December 7, 2009. Accepted April 19, 2010.

Document 152

Meacham, Meredith C; Starks, Helene; Burke, Wylie; Edwards, Kelly

Researcher perspectives on disclosure of incidental findings in genetic research.

Abstract: Genetic research can produce information that is beyond the aims of the research study yet may be of clinical or personal interest to study participants. We conducted semi-structured interviews with 44 researchers who were asked to describe how they would respond to a hypothetical vignette regarding the disclosure of findings with unanticipated clinical significance to research study participants. Interviews were transcribed and analyzed using content and thematic analyses. Researchers' decision-making processes about whether to disclose incidental findings were governed by potentially conflicting duties in three primary domains: information quality, adherence to rules, and participant welfare. There are several actions researchers can take to prepare for incidental findings, including: adding specific language in informed consent documents to state clearly how investigators will handle disclosure; exploring how prepared participants might be during the consent process to make decisions about how they would like to be approached in the event of incidental findings; developing procedures for appropriately communicating individual results and providing follow-up support based on participant preferences; and, in genetic research, having an awareness of the range of traits expressed by the genes under study.

Document 153

Glantz, Leonard H; Roche, Patricia; Annas, George J

Gift giving to biobanks.

Abstract: This paper considers the implications of genetic testing in the case of familial hypercholesterolaemia, drawing on twenty semi-structured interviews with general practitioners (family doctors in primary care), nurses and specialists in hospital clinics (secondary care) in the UK. Though these professionals appear aware of and interested in the genetic component of the condition, and DNA testing is underway in at least some centres, their accounts suggest that the genetic test is not having a major impact on clinical work. Instead we find that professionals report that they generally rely on other information when making a diagnosis, especially cholesterol levels understood as a key risk factor, while the results of DNA tests, if used, come late in a much longer series of clinical investigations.
judgements and interventions. In addition to elaborating professional views of genetic testing, the research provides a way of understanding other studies that describe lay people as not necessarily privileging genetic explanations of familial hypercholesterolaemia.

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Document 155

Watson, R William G; Kay, Elaine W; Smith, David

**Integrating biobanks: addressing the practical and ethical issues to deliver a valuable tool for cancer research.**

Nature reviews. Cancer 2010 Sep; 10(9): 646-51

**Abstract:** Cancer is caused by complex interactions between genes, environment and lifestyles. Biobanks of well-annotated human tissues are an important resource for studying the underlying mechanisms of cancer. Although such biobanks exist, their integration to form larger biobanks is now required to provide the diversity of samples that are needed to study the complexity and heterogeneity of cancer. Clear guidelines and policies are also required to address the challenges of integrating individual institutional or national biobanks and build public trust. This Science and Society article highlights some of the main practical and ethical issues that are undergoing discussion in the integration of tissue biobanks for cancer.

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Document 156

O'Dowd, Adrian

**Genetic testing services are to be regulated to protect UK patients.**

BMJ (Clinical research ed.) 2010 August 4 341(): c4215

Georgetown users check Georgetown Journal Finder for access to full text

Document 157

Noonan, Kevin E

**Waking up and smelling the coffee.**

Nature biotechnology 2010 Aug; 28(8): 778-9; discussion 779

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Document 158

Carbone, Julia; Gold, E Richard; Sampat, Bhaven; Chandrasekharan, Subhashini; Knowles, Lori; Angrist, Misha; Cook-Deegan, Robert

**DNA patents and diagnostics: not a pretty picture.**

Nature biotechnology 2010 Aug; 28(8): 784-91

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Document 159

Mackoff, Rishona L; Iverson, Ellen F; Kiekel, Preston; Dorey, Frederick; Upperman, Jeffrey S; Metzenberg, Aida B

**Attitudes of genetic counselors towards genetic susceptibility testing in children.**


**Abstract:** Genetic susceptibility research and testing is leading to an era of personalized medicine. Genetic
counselors act as liaisons between the medical genetics community and the public. Understanding the opinions of genetic counselors will be important in developing testing guidelines. Attitudes towards genetic susceptibility testing in children were assessed for 216 NSGC members. Genetic counselors were likely to support testing if the results would determine: disease progression or prognosis, likelihood of survival after a specific treatment, or risk for an adverse drug reaction. Genetic counselors were unlikely to support testing to determine susceptibility to later disease development or in the absence of available intervention. There was a strong positive correlation between attitudes associated with desire to test their own child, if at risk and their support for genetic testing in any child at risk. Respondents strongly favored parent/guardian and child's rights over doctor or insurance rights. They indicated assent should be obtained prior to testing, when appropriate, and that a copy of results should be kept in a permanent medical record. Respondents expressed concerns about insurance discrimination, testing in the absence of medical necessity, and taking away a child's autonomy.

Miller, Fiona Alice; Hayeems, Robin Zoe; Bytautas, Jessica Peace

**What is a meaningful result? Disclosing the results of genomic research in autism to research participants.**


**Abstract:** Developments in genomics research have been accompanied by a controversial ethical injunction: that researchers disclose individually relevant research results to research participants. With the explosion of genomic research on complex psychiatric conditions such as autism, researchers must increasingly contend with whether--and which results--to report. We conducted a qualitative study with researchers and participants involved in autism genomics research, including 4 focus groups and 23 interviews with parents of autistic children, and 23 interviews with researchers. Respondents considered genomic research results 'reportable' when results were perceived to explain cause, and answer the question 'why;' that is, respondents set a standard for reporting individually relevant genetic research results to individual participants that is specific to autism, reflecting the metaphysical value that genetic information is seen to offer in this context. In addition to this standard of meaning, respondents required that results be deemed 'true.' Here, respondents referenced standards of validity that were context nonspecific. Yet in practice, what qualified as 'true' depended on evidentiary standards within specific research disciplines as well as fundamental, and contested, theories about how autism is 'genetic.' For research ethics, these finding suggest that uniform and context-free obligations regarding result disclosure cannot readily be specified. For researchers, they suggest that result disclosure to individuals should be justified not only by perceived meaning but also by clarity regarding appropriate evidentiary standards, and attention to the status of epistemological debates regarding the nature and cause of disorders.

Howard, Heidi C; Knoppers, Bartha Maria; Borry, Pascal

**Blurring lines. The research activities of direct-to-consumer genetic testing companies raise questions about consumers as research subjects.**

EMBO reports 2010 Aug; 11(8): 579-82

Genomic research and wide data sharing: views of prospective participants.

Genetics in medicine : official journal of the American College of Medical Genetics 2010 Aug; 12(8): 486-95

**Abstract:** Sharing study data within the research community generates tension between two important goods: promoting scientific goals and protecting the privacy interests of study participants. This study was designed to explore the perceptions, beliefs, and attitudes of research participants and possible future participants regarding genome-wide association studies and repository-based research.
Document 163
Sirugo, Giorgio; Williams, Scott M; Royal, Charnaine D M; Newport, Melanie J; Hennig, Branwen J; Mariani-Costantini, Renato; Buonaguro, Franco M; Velez Edwards, Digna R; Ibrahim, Muntaser; Soodyall, Himla; Wonkam, Ambroise; Ramesar, Raj; Rotimi, Charles N
The American journal of tropical medicine and hygiene 2010 Aug; 83(2): 226-9
Abstract: The African Society of Human Genetics (AfSHG), founded in 2003 with its inaugural meeting in Accra, Ghana, has the stated missions of (1) disseminating information about human genetics research in Africa, (2) establishing a mentorship network providing educational resources, including the development of appropriate technology transfer, (3) providing advocacy for human genetic research in Africa, and (4) encouraging collaborative research. Despite its young age, the AfSHG has developed a strong cadre of active researchers, both within and outside of Africa, with more than 400 members (from 16 countries across Africa as well as 8 other countries), and has held six successful meetings, five in Africa and one in the United States.

Document 164
Roehr, Bob
US presidential ethics commission grapples with synthetic biology.
BMJ (Clinical research ed.) 2010 July 13; 341: c3732

Document 165
Tuffs, Annette
Court allows preimplantation genetic diagnosis in Germany.
BMJ (Clinical research ed.) 2010 July 12; 341: c3741

Document 166
Agovic, Amina
Battle brewing over the BRCA1/2 gene patents.
Revista de derecho y genoma humano = Law and the human genome review / Catedra de Derecho y Genoma Humano/Fundación BBV-Diputación Foral de Bizkaia 2010 Jul-Dec(33): 171-94
Abstract: The revolutionary discovery of DNA and the successful mapping of the human genome have allowed scientists worldwide to engage in unprecedented research on the cutting-edge biomedical technology such as genetic engineering (gene-splicing or recombinant DNA). However, as is often the case with modern biotechnologies, gene-related innovation is heavily dependent on strong patent protection, primarily due to the high costs of research and commercialisation in this area. The aim of this paper is to provide a description of the District Court Ruling in the case of Association for Molecular Pathology et al v United States Patent and Trademark Office et al (ACLU v Myriad). In doing so, the article provides information on the relevant background at issues, including a brief introduction to general patentability requirements in relation to genes and the controversy surrounding the patentability of genetic material. The analysis of the complaint filed in the ACLU v Myriad case and the details of the District Court Ruling follows. The paper concludes with an outlook of the future legal actions involving Myriad's BRCA1/2 and the assessment of the potential impact that the BRCA1/2 District Court Ruling and subsequent appeal(s) may have on the American patent law.
Document 167

After Havasupai litigation, Native Americans wary of genetic research.
American journal of medical genetics. Part A 2010 Jul; 152A(7): fmix

Document 168

Erez, A; Plunkett, K; Sutton, V R; McGuire, A L
The right to ignore genetic status of late onset genetic disease in the genomic era; Prenatal testing for Huntington disease as a paradigm.
American journal of medical genetics. Part A 2010 Jul; 152A(7): 1774-80

Abstract: During the last decade, the field of human genome research has gone through a phase of rapid discovery that has provided scientists and physicians with a wide variety of research tools that are applicable to important medical issues. We describe a true case of familial Huntington disease (HD) in which we modified personal details to protect patient's privacy, where the proband at risk preferred not to know his disease status but wanted to know the status in his unborn child. Once we found the father to be negative, the case raised an important ethical question regarding the management of this as well as future pregnancies. This article discusses the arguments for and against the right not to know of one's carrier status, as well as professional obligations in the context of withholding unwanted information that may have direct implications not only for the patient himself but also for other family members. HD has served as a model for many other adult onset genetic diseases in terms of carrier testing guidelines. Hence, we feel it is time to revisit the issue of prenatal testing for HD and consider updating the current recommendations regarding the patient's right to "genetic ignorance", or the right not to know genetic information.

Document 169

Tassé, Anne Marie; Budin-Ljøsne, Isabelle; Knoppers, Bartha Maria; Harris, Jennifer R
Retrospective access to data: the ENGAGE consent experience.

Abstract: The rapid emergence of large-scale genetic databases raises issues at the nexus of medical law and ethics, as well as the need, at both national and international levels, for an appropriate and effective framework for their governance. This is even more so for retrospective access to data for secondary uses, wherein the original consent did not foresee such use. The first part of this paper provides a brief historical overview of the ethical and legal frameworks governing consent issues in biobanking generally, before turning to the secondary use of retrospective data in epidemiological biobanks. Such use raises particularly complex issues when (1) the original consent provided is restricted; (2) the minor research subject reaches legal age; (3) the research subject dies; or (4) samples and data were obtained during medical care. Our analysis demonstrates the inconclusive, and even contradictory, nature of guidelines and confirms the current lack of compatible regulations. The second part of this paper uses the European Network for Genetic and Genomic Epidemiology (ENGAGE Consortium) as a case study to illustrate the challenges of research using previously collected data sets in Europe. Our study of 52 ENGAGE consent forms and information documents shows that a broad range of mechanisms were developed to enable secondary use of the data that are part of the ENGAGE Consortium.

Document 170

Arnason, Vilhjálmur
Bioethics in Iceland.
Document 171

Beskow, Laura M; Burke, Wylie

**Offering individual genetic research results: context matters.**

Science translational medicine 2010 Jun 30; 2(38): 38cm20

**Abstract:** The disclosure of individual genetic research results to study participants continues to be the subject of vigorous debate, centered primarily on the nature of the results. We suggest that research context, which is foreseeable when a study is designed, is a vital consideration that has not been sufficiently incorporated into the discussion. Adapting an ancillary care framework to explore what different contexts might call for with regard to offering individual genetic research results, our analysis suggests that, beyond exceptionally rare circumstances that give rise to a duty to rescue, a one-size-fits-all threshold cannot be developed for decisions about returning individual results. Instead, researchers and institutional review boards must consider the scope of entrustment involved in the research, as well as the intensity and duration of interactions with participants and the vulnerability and dependence of the study population.

Document 172

Novak, Marianne J U; Tabrizi, Sarah J

**Huntington's disease.**

BMJ (Clinical research ed.) 2010 June 30; 340: c3109

Document 173

Martin, Douglas K; Greenwood, Heather L; Nisker, Jeff

**Public perceptions of ethical issues regarding adult predictive genetic testing.**


**Abstract:** The purpose of this study was to explore the views of members of the general public regarding ethical issues in adult predictive genetic testing. The literature pertaining to ethical issues regarding to adult predictive genetic testing is largely restricted to the views of 'experts' who have emphasized informed consent, patent issues, and insurance discrimination. Occasionally the views of patients who have undergone genetic counselling and testing have been elicited, adding psychosocial and family issues. However, the general public has not had the opportunity to contribute. In order to explore theatre as a health policy research tool, 1,200 audience members attended the play 'Sarah's Daughters' in seven Canadian cities, following which audience discussions were audiotaped. This study performed a secondary qualitative analysis of the data to identify the ethical issues of adult predictive genetic testing important to members of the general public. The identified issues were: (1) need for public education; (2) choice to undergo genetic counselling and testing; (3) access to genetic counselling and testing; and (4) obligations regarding the handling of genetic information. Audience members emphasized public education and access to information regarding potential choices, which was different from the emphasis on informed consent and other ethical issues prominent in the literature. Members of the general public emphasized ethical issues that were different than those identified by experts and patients. It is essential that members of the public be included in complex and controversial public policy decisions.

Document 174

Legato, Marianne J
Sailing the sea of synthetic biology: Dr. Venter and the Sorcerer II.
Gender medicine 2010 Jun; 7(3): 276-7

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**Document 175**

Ersig, Anne L; Ayres, Lioness; Hadley, Donald W; Koehly, Laura M

**Explanations of risk in families without identified mutations for hereditary nonpolyposis colorectal cancer.**
Journal of nursing scholarship : an official publication of Sigma Theta Tau International Honor Society of Nursing / Sigma Theta Tau 2010 Jun; 42(2): 139-46

**Abstract:** Genetic testing for hereditary forms of cancer does not always identify a causative mutation. Little is known about personal or family response to these indeterminate results when a hereditary form of cancer is suspected. This study explored thoughts about and responses to risk for hereditary nonpolyposis colorectal cancer (HNPCC) when a family member has received indeterminate genetic test results.

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**Document 176**

Streiffer, Robert

**Chimeras, moral status, and public policy: implications of the abortion debate for public policy on human/nonhuman chimera research.**
The Journal of law, medicine & ethics : a journal of the American Society of Law, Medicine & Ethics 2010 Summer; 38(2): 238-50

**Abstract:** Researchers are increasingly interested in creating chimeras by transplanting human embryonic stem cells (hESCs) into animals early in development. One concern is that such research could confer upon an animal the moral status of a normal human adult but then impermissibly fail to accord it the protections it merits in virtue of its enhanced moral status. Understanding the public policy implications of this ethical conclusion, though, is complicated by the fact that claims about moral status cannot play an unfettered role in public policy. Arguments like those employed in the abortion debate for the conclusion that abortion should be legally permissible even if abortion is not morally permissible also support, to a more limited degree, a liberal policy on hESC research involving the creation of chimeras.

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**Document 177**

Schoenl, William; Peck, Danielle

**Advertising eugenics: Charles M. Goethe's campaign to improve the race.**
Endeavour 2010 Jun; 34(2): 75-80

**Abstract:** Over the last several decades historians have shown that the eugenics movement appealed to an extraordinarily wide constituency. Far from being the brainchild of the members of any one particular political ideology, eugenics made sense to a diverse range of Americans and was promoted by professionals ranging from geneticists and physicians to politicians and economists.(1) Seduced by promises of permanent fixes to national problems, and attracted to the idea of a scientifically legitimate form of social activism, eugenics quickly grew in popularity during the first decades of the twentieth century. Charles M. Goethe, the land developer, entrepreneur, conservationist and skilled advertiser who founded the Eugenics Society of Northern California, exemplifies the broad appeal of the eugenics movement. Goethe played an active role within the American eugenics movement at its peak in the 1920s. The last president of the Eugenics Research Association,(2) he also campaigned hard against Mexican immigration to the US and he continued open support for the Nazi regime's eugenic practices into the later 1930s.(3) This article examines Goethe's eugenic vision and, drawing on his correspondence with the leading geneticist Charles Davenport, explores the relationship between academic and non-academic advocates of eugenics in America.

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Document 178
Goulart, Maria Carolina Vaz; Iano, Flávia Godoy; Silva, Paulo Maurício; Sales-Peres, Silvia Helena de Carvalho; Sales-Peres, Arsênio
Ciência & saúde coletiva 2010 Jun; 15 Suppl 1: 1709-13
Abstract: The molecular biology has provided the basic tool for geneticists deepening in the molecular mechanisms that influence different diseases. It should be noted the scientific and moral responsibility of the researchers, because the scientists should imagine the moral consequences of the commercial application of genetic tests, since this fact involves not only the individual and their families, but the entire population. Besides being also necessary to make a reflection on how this information from the human genome will be used, for good or bad. The objective of this review was to bring the light of knowledge, data on characteristics of the ethical application of molecular biology, linking it with the rights of human beings. After studying literature, it might be observed that the Human Genome Project has generated several possibilities, such as the identification of genes associated with diseases with synergistic properties, but sometimes modifying behavior to genetically intervene in humans, bringing benefits or social harm. The big challenge is to decide what humanity wants on this giant leap.

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Document 179
Beskow, Laura M; Linney, Kristen N; Radtke, Rodney A; Heinzen, Erin L; Goldstein, David B
Ethical challenges in genotype-driven research recruitment.
Genome research 2010 Jun; 20(6): 705-9

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Document 180
Maglo, Koffi N
Genomics and the conundrum of race: some epistemic and ethical considerations.
Perspectives in biology and medicine 2010 Summer; 53(3): 357-72
Abstract: This article addresses the question of whether race is a biological category and whether it is permissible to use it in biomedicine. I suggest that instrumentalism, a view that race is a problem-solving tool rather than a concept with an objective referent in nature, may be more consistent with the available scientific evidence. I argue that, to be morally permissible, the instrumentalist use of race in research and medicine requires stringent guidelines. I then provide four normative rules to guide race research in the biomedical sciences. The paper gathers evidence from the biomedical sciences. The paper gathers evidence from philosophy of science, genomics, legal history, and normative ethics in order to ground the biomedical use of race in a converging ethical and epistemic framework.

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Document 181
Knoppers, Bartha Maria
Consent to 'personal' genomics and privacy. Direct-to-consumer genetic tests and population genome research challenge traditional notions of privacy and consent.
EMBO reports 2010 Jun; 11(6): 416-9

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Document 182
Lev, Ori; Miller, Franklin G; Emanuel, Ezekiel J

The ethics of research on enhancement interventions.

Kennedy Institute of Ethics journal 2010 Jun ; 20(2): 101-13

Abstract: Biomedical enhancement interventions to make people stronger, smarter, and happier are currently being developed. Research to assess these enhancements should be conducted before their introduction into clinical practice. But, many worry that enhancement research is unethical. Some contend that the practice of biomedical enhancements is unethical; accordingly, research that enables such practice would be unethical. Others suggest that research on enhancement interventions does not promote health, exposing research participants to risks with no potential compensating health benefits either to themselves or to society. Categorically condemning research on biomedical enhancements as unethical is unwarranted, however, since at least some research on biomedical enhancements is likely to produce significant health benefits. Indeed, under certain circumstances enhancement research would be urgent, as it would address major public health concerns. Therefore, a blanket prohibition on enhancement research is unjustified. Instead, like any other clinical research, each proposed enhancement study should be reviewed individually to assess whether it fulfills the ethical requirements that make a clinical study permissible.

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Wade, Christopher H.; Wilfond, Benjamin S.; McBride, Colleen M.

Effects of genetic risk information on children's psychosocial wellbeing: a systematic review of the literature.

Genetics in Medicine 2010 June; 12(6): 317-326

Abstract: PURPOSE: As advances in research have made a growing number of genetic tests available, clinicians will increasingly be faced with making decisions about when offering genetic testing services to children is appropriate. A key factor in such decisions involves determining whether knowledge of genetic health risks might have an impact on children's psychosocial wellbeing. METHODS: We conducted a systematic review of the literature using five online databases to identify studies that assessed the impact of communicating nondiagnostic carrier or presymptomatic genetic test results to children. RESULTS: A total of 17 articles met the inclusion criteria for this review. These studies used a wide range of methodologies to explore carrier and predictive testing. Although there was little quantitative evidence that receiving genetic test results led to a significant impact on children's psychosocial wellbeing, it was found that methodological inconsistencies, small samples, and reliance on assessments most appropriate for psychopathology make any firm conclusions about the impact of genetic testing on children premature. CONCLUSION: Currently, there is insufficient evidence to inform a nuanced understanding of how children respond to genetic testing. This suggests a strong need for further research that uses rigorous approaches to address children's emotional states, self-perception, and social wellbeing.

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Katsnelson, Alla

Synthetic genome resets biotech goals.

Nature 2010 May 27; 465(7297): 406

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Hens, K; Snoeck, J; Nys, H; Cassiman, J-J; Dierickx, K

An exploratory survey of professionals on the use of stored tissue samples from minors for genetic research.

Genetics and molecular research : GMR 2010 May 25; 9(2): 973-80

Abstract: The ethical aspects of the use of stored tissue samples collected from minors are of topical interest. However, the views of professionals working in the field of genetics have not been investigated in depth anywhere. We conducted a survey among 194 such professionals in Belgium. This list was composed of the members of the High Council for Anthropogenetics, supplemented with all professionals working in the field of genetics that we found
on the websites of the eight Belgian centers of human genetics and of the associated university registries. We achieved a response rate of 35.5%. The vast majority (92%) think that research on stored tissue samples is useful. Most respondents stated that parental consent is valid (82.5%), and 76.5% thought that children should also be given the right to assent when they are able to comprehend the implications of the storage of biological samples and of genetic research. Slightly more than half put the age at which young people can understand storage or research rather high: 16-18 years (51 and 53.1%, respectively). Although there is some consensus in the literature that donors should be allowed to give broad consent for future research on their biological samples, only 47.6% in our survey thought that parents should be allowed to consent to any future research on their children's samples. The aim of our study was to give some basis for future ethical reflections and policies on the subject of stored tissue samples from minors for genetic research. We concluded that a large majority of Belgian researchers and clinicians in the field of genetic research think research on stored tissue samples from minors is useful. They also think that parental consent for such research is valid, but that children should be allowed to assent as they grow older.
risk profiles play in facilitating pharmacogenomics research. We first take a look at how personal genomics services, exemplified by the company 23andMe, communicate information on drug response to customers. We then discuss the most important benefits and issues we see arising with the idea of 'crowdsourcing' pharmacogenomics research via commercial genome-scan providers. We conclude with a brief vision for the future.

Goebel, Jürgen W; Pickardt, Thomas; Bedau, Maren; Fuchs, Michael; Lenk, Christian; Paster, Inga; Spranger, Tarde M; Stockter, Ulrich; Bauer, Ulrike; Cooper, David N; Krawczak, Michael

Legal and ethical consequences of international biobanking from a national perspective: the German BMB-EUCoop project.

Abstract: The international transfer of human biomaterial and data has become a prerequisite for collaborative biomedical research to be successful. However, although a national legal framework for 'biobanking' has already been formulated in many countries, little is known about how an international exchange of data and samples might affect the legal position of national biobanks and their donors. The German Telematics Platform and the Competence Network 'Congenital Heart Defects' jointly instigated a project (BMB-EUCoop) to (i) identify and assess the legal risks ensuing for biobanks and their donors in the context of Europe-wide research collaborations, (ii) devise practical recommendations to minimize or avoid these risks, and (iii) provide generic informational text, contracts and agreements to facilitate their practical implementation. Four different countries were included in the study; namely, the UK, Netherlands, Austria and Switzerland. The results of the study indicate that the degree of similarity between legal systems in different countries varies according to the respective field of jurisdiction. Although personality and property rights have long been enshrined in virtually identical pieces of law, the applicable medical professional regulations were found to be somewhat heterogeneous. Furthermore, clear-cut differences were often found to be lacking between regulations that reflect either 'soft law' or the nationally binding 'hard law' that has emerged from it. In view of the potential ambiguities, the experts uniformly concluded that the rights and interests of national (in this case, German) biobanks and their donors would be best protected by explicitly addressing any uncertainties in formal contractual agreements.

Fox, Dov

Retracing liberalism and remaking nature: designer children, research embryos, and featherless chickens.
Bioethics 2010 May; 24(4): 170-8

Abstract: Liberal theory seeks to achieve toleration, civil peace, and mutual respect in pluralistic societies by making public policy without reference to arguments arising from within formative ideals about what gives value to human life. Does it make sense to set aside these conceptions of the good when it comes to controversies about stem cell research and the genetic engineering of people or animals? Whether it is reasonable to bracket our worldviews in such cases depends on how we answer the moral questions that the use of these biotechnologies presuppose. I argue that the moral language of liberal justice - of rights and duties, interests and opportunities, freedom and consent, equality and fairness - cannot speak to these underlying concerns about what the human embryo is, why the natural lottery matters to us, and whether 'animal nature' is worth preserving. I conclude that liberal theory is incapable of furnishing a coherent or desirable account to govern the way we use our emerging powers of biotechnology.

Levy, Daniel; Splansky, Greta Lee; Strand, Nicole K; Atwood, Larry D; Benjamin, Emelia J; Blease, Susan; Cupples, L Adrienne; D'Agostino, Ralph B Sr.; Fox, Caroline S; Kelly-Hayes, Margaret; Koski, Greg; Larson, Martin G; Mutalik, Karen M; Oberacker, Elizabeth; O'Donnell, Christopher J; Sutherland, Patrice; Valentino, Maureen;
**Consent for genetic research in the Framingham Heart Study.**

American journal of medical genetics. Part A 2010 May ; 152A(5): 1250-6

**Abstract:** Extensive efforts have been aimed at understanding the genetic underpinnings of complex diseases that affect humans. Numerous genome-wide association studies have assessed the association of genes with human disease, including the Framingham Heart Study (FHS), which genotyped 550,000 SNPs in 9,000 participants. The success of such efforts requires high rates of consent by participants, which is dependent on ethical oversight, communications, and trust between research participants and investigators. To study this we calculated percentages of participants who consented to collection of DNA and to various uses of their genetic information in two FHS cohorts between 2002 and 2009. The data included rates of consent for providing a DNA sample, creating an immortalized cell line, conducting research on various genetic conditions including those that might be considered sensitive, and for notifying participants of clinically significant genetic findings were above 95%. Only with regard to granting permission to share DNA or genetic findings with for-profit companies was the consent rate below 95%. We concluded that the FHS has maintained high rates of retention and consent for genetic research that has provided the scientific freedom to establish collaborations and address a broad range of research questions. We speculate that our high rates of consent have been achieved by establishing frequent and open communications with participants that highlight extensive oversight procedures. Our approach to maintaining high consent rates via ethical oversight of genetic research and communication with study participants is summarized in this report and should be of help to other studies engaged in similar types of research. Published 2010 Wiley-Liss, Inc.

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**National Biobanks: Clinical Labor, Risk Production, and the Creation of Biovalue.**

Science, Technology, and Human Values 2010 May; 35(3): 330-355

**Abstract:** The development of genomics has dramatically expanded the scope of genetic research, and collections of genetic biosamples have proliferated in countries with active genomics research programs. In this essay, we consider a particular kind of collection, national biobanks. National biobanks are often presented by advocates as an economic "resource" that will be used by both basic researchers and academic biologists, as well as by pharmaceutical diagnostic and clinical genomics companies. Although national biobanks have been the subject of intense interest in recent social science literature, most prior work on this topic focuses either on bioethical issues related to biobanks, such as the question of informed consent, or on the possibilities for scientific citizenship that they make possible. We emphasize, by contrast, the economic aspect of biobanks, focusing specifically on the way in which national biobanks create biovalue. Our emphasis on the economic aspect of biobanks allows us to recognize the importance of what we call clinical labor—that is, the regularized, embodied work that members of the national population are expected to perform in their role as biobank participants—in the creation of biovalue through biobanks. Moreover, it allows us to understand how the technical way in which national biobanks link clinical labor to databases alters both medical and popular understandings of risk for common diseases and conditions.

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**Informed decision making about predictive DNA tests: arguments for more public visibility of personal deliberations about the good life.**

Medicine, Health Care, and Philosophy 2010 May; 13(2): 127-138

**Abstract:** Since its advent, predictive DNA testing has been perceived as a technology that may have considerable impact on the quality of people's life. The decision whether or not to use this technology is up to the individual client. However, to enable well considered decision making both the negative as well as the positive freedom of the individual should be supported. In this paper, we argue that current professional and public discourse on predictive DNA-testing is lacking when it comes to supporting positive freedom, because it is usually framed in terms of risk and risk management. We show how this 'risk discourse' steers thinking on the good life in a particular way. We go on to argue that empirical research into the actual deliberation and decision making processes of individuals and families may be used to enrich the environment of personal deliberation in three ways: (1) it points at a richer set of values that deliberators can take into account, (2) it acknowledges the shared nature of genes, and (3) it shows how
one might frame decisions in a non-binary way. We argue that the public sharing and discussing of stories about personal deliberations offers valuable input for others who face similar choices: it fosters their positive freedom to shape their view of the good life in relation to DNA-diagnostics. We conclude by offering some suggestions as to how to realize such public sharing of personal stories.

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Document 194

McGuire, Amy L.; Lupski, James R.

**Personal genome research: what should the participant be told?**

Trends in Genetics 2010 May; 26(5): 199-201

**Abstract:** Should the results of whole genome sequencing research be disclosed to participants, in particular when the results have uncertain or indeterminate phenotypic consequences? This controversial question is considered in light of one author's (J.L.) experience as a geneticist who recently had his own genome sequenced.

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Document 195

**Testing time for gene patents.** A surprising US court decision highlights the need to modernize gene-patenting practices if patients are to benefit from advances in genetic research. [editorial]

Nature 2010 April 15; 463(7291): 957

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Document 196

Abbott, Alison

**The human race: what was it like to participate in the fastest, fiercest research race in biology?**

Nature 2010 April 1; 464(7289): 668-669

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Document 197

**The human genome at ten.** Nearly a decade on from the completion of the draft sequence of the human genome, researchers should work with the same intensity and focus to apply the results to health. [editorial]

Nature 2010 April 1; 464(7289): 649-650

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Document 198

van der Vorm, A; van der Laan, A L; Borm, G; Vernooij-Dassen, M; Olde Rikkert, M; van Leeuwen, E; Dekkers, W
Experts' opinions on ethical issues of genetic research into Alzheimer's disease: results of a Delphi study in the Netherlands.

Clinical genetics 2010 Apr; 77(4): 382-8

**Abstract:** Most publications on the ethical aspects of genetic research into Alzheimer's Disease (AD) concentrate on the differences between the opinions of professionals and non-professionals. Differences in rating of morally relevant issues between groups of professionals have not yet been described. A modified Delphi study in two rounds was held to identify differences between groups of experts (i.e. clinicians, representatives of patient organisations, ethicists and persons with a commercial background). The strongest correlation was found between the opinions of ethicists and representatives of patient organisations (0.67) and between clinicians and ethicists (0.62). Moderate correlation (0.55) was found between the opinions of clinicians and representatives of patient organisations. Persons with a commercial background showed a weak correlation with clinicians (0.41), ethicists (0.35) and representatives of patient organisations (0.30). These differences in rating of morally relevant issues between various professional groups are relevant for clinical practice and dementia care, particularly the different rating of prenatal diagnosis found between clinicians and representatives of patient organisations. Interdisciplinary consultations between various professional groups -including at least researchers, clinicians and ethicists -are recommended to guarantee that all considerations will be incorporated into the debate on ethical issues of genetic research into AD.

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**Document 199**

Cook-Deegan, Robert; Heaney, Christopher

**Gene patents and licensing: case studies prepared for the Secretary's Advisory Committee on Genetics, Health, and Society.**

Genetics in medicine : official journal of the American College of Medical Genetics 2010 Apr; 12(4 Suppl): S1-2

**Abstract:** Researchers at the Center for Public Genomics at Duke University analyzed how patenting and licensing affect clinical access to genetic testing in the United States. The research was requested by the Secretary's Advisory Committee on Genetics, Health, and Society. Conditions studied were breast and ovarian cancers, colon cancers, Alzheimer disease, cystic fibrosis, hearing loss, hereditary hemochromatosis, long QT syndrome, spinocerebellar ataxia, Tay-Sachs disease, and Canavan disease.

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**Document 200**

Cook-Deegan, Robert; DeRienzo, Christopher; Carbone, Julia; Chandrasekharan, Subhashini; Heaney, Christopher; Conover, Christopher

**Impact of gene patents and licensing practices on access to genetic testing for inherited susceptibility to cancer: comparing breast and ovarian cancers with colon cancers.**

Genetics in medicine : official journal of the American College of Medical Genetics 2010 Apr; 12(4 Suppl): S15-38

**Abstract:** Genetic testing for inherited susceptibility to breast and ovarian cancer can be compared with similar testing for colorectal cancer as a "natural experiment." Inherited susceptibility accounts for a similar fraction of both cancers and genetic testing results guide decisions about options for prophylactic surgery in both sets of conditions. One major difference is that in the United States, Myriad Genetics is the sole provider of genetic testing, because it has sole control of relevant patents for BRCA1 and BRCA2 genes, whereas genetic testing for familial colorectal cancer is available from multiple laboratories. Colorectal cancer-associated genes are also patented, but they have been nonexclusively licensed. Prices for BRCA1 and 2 testing do not reflect an obvious price premium attributable to exclusive patent rights compared with colorectal cancer testing, and indeed, Myriad's per unit costs are somewhat lower for BRCA1/2 testing than testing for colorectal cancer susceptibility. Myriad has not enforced patents against basic research and negotiated a Memorandum of Understanding with the National Cancer Institute in 1999 for institutional BRCA testing in clinical research. The main impact of patenting and licensing in BRCA compared with colorectal cancer is the business model of genetic testing, with a sole provider for BRCA and multiple laboratories for colorectal cancer genetic testing. Myriad's sole-provider model has not worked in jurisdictions outside the United States, largely because of differences in breadth of patent protection, responses of government health services, and difficulty in patent enforcement.

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Document 201
Chandrasekharan, Subhashini; Pitlick, Emily; Heaney, Christopher; Cook-Deegan, Robert
Impact of gene patents and licensing practices on access to genetic testing for hereditary hemochromatosis.
Genetics in medicine : official journal of the American College of Medical Genetics 2010 Apr; 12(4 Suppl): S155-70
Abstract: Hereditary hemochromatosis is an iron metabolism disorder that leads to excess iron buildup, especially in the heart, liver, and pancreas. Mutations in the HFE gene are the single most common cause of hereditary hemochromatosis, which can be treated effectively if diagnosed early. Patents cover the HFE gene, related proteins, screening methods, and testing kits. Most initial testing for hereditary hemochromatosis is biochemical, but HFE deoxyribonucleic acid testing or genotyping is used to confirm a diagnosis of inherited hemochromatosis. Concerns over patents covering HFE testing emerged in 2002, when scholars argued that exclusive licensing and the patent-enabled sole provider model then in place led to high prices and limited access. Critics of the sole provider model noted that the test was available at multiple laboratories before the enforcement of patents. By 2007, however, Bio-Rad Limited, acquired the key intellectual property and sublicensed it widely. In part because of broad, nonexclusive licensing, there are now multiple providers and testing technologies, and research continues. This case study illustrates how both changes in intellectual property ownership and evolving clinical utility of HFE genetic testing in the last decade have effected the licensing of patents and availability of genetic testing.

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Document 202
Chandrasekharan, Subhashini; Fiffer, Melissa
Impact of gene patents and licensing practices on access to genetic testing for hearing loss.
Genetics in medicine : official journal of the American College of Medical Genetics 2010 Apr; 12(4 Suppl): S171-93
Abstract: Genetic testing for heritable hearing loss involves a mix of patented and unpatented genes, mutations and testing methods. More than half of all hearing loss is linked to inherited mutations, and five genes are most commonly tested for in the United States. There are no patents on three of these genes, but Athena Diagnostics holds exclusive licenses to test for a common mutation in the GJB2 gene associated with about 50% of all cases as well as mutations in the MTRNR1 gene. This fragmented intellectual property landscape made hearing loss a useful case study to assess whether patent rights in genetic testing can proliferate or overlap, and whether it is possible to gather the rights necessary to perform testing. Testing for hearing loss is widely available, primarily from academic medical centers. Based on literature reviews and interviews with researchers, research on the genetics of hearing loss has generally not been impeded by patents. There is no consistent evidence of a premium in testing prices attributable to patent status. Athena Diagnostics has, however, used its intellectual property to discourage other providers from offering some tests. There is no definitive answer about the suitability of current patenting and licensing of commonly tested genes because of continuing legal uncertainty about the extent of enforcement of patent rights. Clinicians have also expressed concerns that multiplex tests will be difficult to develop because of overlapping intellectual property and conflict with Athena's sole provider business model.

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Document 203
Chandrasekharan, Subhashini; Heaney, Christopher; James, Tamara; Conover, Chris; Cook-Deegan, Robert
Impact of gene patents and licensing practices on access to genetic testing for cystic fibrosis.
Genetics in medicine : official journal of the American College of Medical Genetics 2010 Apr; 12(4 Suppl): S194-211
Abstract: Cystic fibrosis is one of the most commonly tested autosomal recessive disorders in the United States. Clinical cystic fibrosis is associated with mutations in the CFTR gene, of which the most common mutation among Caucasians, DeltaF508, was identified in 1989. The University of Michigan, Johns Hopkins University, and the Hospital for Sick Children, where much of the initial research occurred, hold key patents on cystic fibrosis genetic sequences, mutations, and methods for detecting them. Several patents, including the one that covers detection of the DeltaF508 mutation, are jointly held by the University of Michigan and the Hospital for Sick Children in Toronto, with Michigan administering patent licensing in the United States. The University of Michigan broadly licenses the DeltaF508 patent for genetic testing with >60 providers of genetic testing to date. Genetic testing is now used in newborn screening, diagnosis, and for carrier screening. Interviews with key researchers and intellectual property managers, a survey of laboratories' prices for cystic fibrosis genetic testing, a review of literature on cystic fibrosis...
tests' cost-effectiveness, and a review of the developing market for cystic fibrosis testing provide no evidence that patents have significantly hindered access to genetic tests for cystic fibrosis or prevented financially cost-effective screening. Current licensing practices for cystic fibrosis genetic testing seem to facilitate both academic research and commercial testing. More than 1000 different CFTR mutations have been identified, and research continues to determine their clinical significance. Patents have been nonexclusively licensed for diagnostic use and have been variably licensed for gene transfer and other therapeutic applications. The Cystic Fibrosis Foundation has been engaged in licensing decisions, making cystic fibrosis a model of collaborative and cooperative patenting and licensing practice.

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Document 204

Gold, E Richard; Carbone, Julia

**Myriad Genetics: In the eye of the policy storm.**

*Genetics in medicine : official journal of the American College of Medical Genetics* 2010 Apr; 12(4 Suppl): S39-70

**Abstract:** From the late 1980s, a storm surrounding the wisdom, ethics, and economics of human gene patents has been brewing. The various winds of concern in this storm touched on the impact of gene patents on basic and clinical research, on health care delivery, and on the ability of public health care systems to provide equal access when faced with costly patented genetic diagnostic tests. Myriad Genetics, Inc., along with its subsidiary, Myriad Genetic Laboratories, Inc., a small Utah-based biotechnology company, found itself unwittingly in the eye of this storm after a series of decisions it made regarding the commercialization of a hereditary breast cancer diagnostic test. This case study examine the background to Myriad's decisions, the context in which these decisions were made and the policy, research and business response to them.

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Document 205

Skeehan, Katie; Heaney, Christopher; Cook-Deegan, Robert

**Impact of gene patents and licensing practices on access to genetic testing for Alzheimer disease.**

*Genetics in medicine : official journal of the American College of Medical Genetics* 2010 Apr; 12(4 Suppl): S71-82

**Abstract:** Genetic testing for Alzheimer disease includes genotyping for apolipoprotein E, for late-onset Alzheimer disease, and three rare autosomal dominant, early-onset forms of Alzheimer disease associated with different genes (APP, PSEN1, and PSEN2). According to researchers, patents have not impeded research in the field, nor were patents an important consideration in the quest for the genetic risk factors. Athena Diagnostics holds exclusive licenses from Duke University for three "method" patents covering apolipoprotein E genetic testing. Athena offers tests for apolipoprotein E and genes associated with early-onset, autosomal-dominant Alzheimer disease. One of those presenilin genes is patented and exclusively licensed to Athena; the other presenilin gene was patented but the patent was allowed to lapse; and one (amyloid precursor protein) is patented as a research tool. Direct-to-consumer testing is available for some Alzheimer disease-related genes, apparently without a license. Athena Diagnostics consolidated its position in the market for Alzheimer disease genetic testing by collecting exclusive rights to patents arising from university research. Duke University also used its licenses to Athena to enforce adherence to clinical guidelines, including elimination of the service from Smart Genetics, which was offering direct-to-consumer risk assessment based on apolipoprotein E genotyping.

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Document 206

Appelbaum, Paul S

**Law & psychiatry: Genetic discrimination in mental disorders: the impact of the genetic information nondiscrimination act.**


**Abstract:** Genetics is one of the most active areas of research on mental disorders. As genetic tests related to psychiatric disorders and their treatments proliferate in research and clinical settings, the possibility becomes more
troubling that such information will be used for purposes other than those for which it was collected. Because of this, the federal Genetic Information Nondiscrimination Act of 2008 is of substantial importance to persons with mental disorders, persons at risk for the conditions, and family members of both groups. This column discusses the process of passing the legislation, along with the implications of the act.

Andermann, Anne; Blancquaert, Ingeborg; Déry, Véronique

**Genetic screening: a conceptual framework for programmes and policy-making.**
Journal of health services research & policy 2010 Apr; 15(2): 90-7

**Abstract:** OBJECTIVE: Policy-makers are faced with increasing pressures from a range of different stakeholders to introduce or expand genetic screening programmes. A shared understanding is therefore needed of the many factors influencing these complex policy decisions. Our aim was to develop a theoretical framework that highlights the multiple components and influences involved in genetic screening and the policy-making process. METHODS: As part of a larger research programme, existing policy frameworks relating to genetic screening were identified through a review of the literature. Major themes were identified and synthesized into an overarching framework, which was further refined through discussions with key informants. RESULTS: The framework consists of three parts. The first part conceptualizes genetic screening as an integrated public health programme. The second part describes the policy-making process at each stage in the life cycle of the programme. The third part depicts the broader context within which policy-making occurs. CONCLUSION: This framework can support policy-makers by fostering a common understanding and facilitating dialogue with stakeholders. The framework has also been used as the conceptual foundation for the development of a more elaborate decision-guide.

Freeman, B D; Kennedy, C R; Frankel, H L; Clarridge, B; Bolcic-Jankovic, D; Iverson, E; Shehane, E; Celious, A; Zehnbauer, B A; Buchman, T G

**Ethical considerations in the collection of genetic data from critically ill patients: what do published studies reveal about potential directions for empirical ethics research?**
The pharmacogenomics journal 2010 Apr; 10(2): 77-85

**Abstract:** Critical illness trials involving genetic data collection are increasingly commonplace and pose challenges not encountered in less acute settings, related in part to the precipitous, severe and incapacitating nature of the diseases involved. We performed a systematic literature review to understand the nature of such studies conducted to date, and to consider, from an ethical perspective, potential barriers to future investigations. We identified 79 trials enrolling 24,499 subjects. Median (interquartile range) number of participants per study was 263 (116.75-430.75). Of these individuals, 16,269 (66.4%) were Caucasian, 1327 (5.4%) were African American, 1707 (7.0%) were Asian Pacific Islanders and 139 (0.6%) were Latino. For 5020 participants (20.5%), ethnicity was not reported. Forty-eight studies (60.8%) recruited subjects from single centers and all studies examined a relatively small number of genetic markers. Technological advances have rendered it feasible to conduct clinical studies using high-density genome-wide scanning. It will be necessary for future critical illness trials using these approaches to be of greater scope and complexity than those so far reported. Empirical research into issues related to greater ethnic inclusivity, accuracy of substituted judgment and specimen stewardship may be essential for enabling the conduct of such trials.

Narayanan, Nithya

**Patenting of human genetic material v. bioethics: revisiting the case of John Moore v. Regents of the University of California.**
Indian Journal of Medical Ethics 2010 April-June; 7(2): 82-89

**Abstract:** Moore v. Regents of the University of California was one of the first cases internationally that dealt with
the patenting of human genetic material. The case is closely related to the development of medicine and of biotechnology applied to medicine. These developments require the utilisation of human body parts, both for experiments and for transplant, and present certain major medico-legal problems. However, the case did not produce conclusive decisions on the various key legal issues that it raised involved in biomedical research and the patenting of human genetic material. This article re-examines the case from an Indian and an international perspective. After a brief introduction in Part I, Part II of the article describes existing laws in various countries with respect to the patenting of human genetic material. Part III discusses legal regimes applicable in the context of biological materials. Part IV elaborates on the importance of the doctrine of informed consent in the context of biomedical research on human subjects. Part V discusses the significance of bioethics in research and the patenting of biotechnology, according to international law. Part VI concludes the article with an assertion of the urgent need for legislation in this area.

http://www.issuesinmedicalethics.org/ (link may be outdated)
**Document 213**

Blackford, Russell

*Genetically engineered people.*

*Politics and the life sciences : the journal of the Association for Politics and the Life Sciences* 2010 Mar; 29(1): 82-4

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**Document 214**

Bronstein, Jamie

*Objecting to the Genetic Virtue Program.*


Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 215**

Sprinkle, R H

*Moral suasion, installed.*


Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 216**

Valentine, Alex J

*Comment on 'Big science, little science'.*

*EMBO reports* 2010 Mar; 11(3): 152

Georgetown users check [Georgetown Journal Finder](#) for access to full text

**Document 217**

Pàmpols Ros, Teresa; Terracini, Benedetto; de Abajo Iglesias, Francisco J; Feito Grande, Lydia; Martín-Aribas, M Concepción; Fernández Soria, José María; Redondo Martín Del Olmo, Tomás; Campos Castelló, Jaime; Herrera Carranza, Joaquín; Júdez Gutiérrez, Javier; Abascal Alonso, Moisés; Morales Piga, Antonio; Comité de Etica, Instituto de Investigación de Enfermedades Raras

*[The ethical aspects of population screening programme of rare diseases]. = Recomendaciones sobre los aspectos éticos de los programas de cribado de población para enfermedades raras.*

*Revista española de salud pública* 2010 Mar-Apr; 84(2): 121-36

**Abstract:** The Committee on Ethics of the Instituto de Investigación de Enfermedades Raras (CEIIER) of the Spanish National Institute of Health Carlos III, presents this article dealing with ethical guidelines regarding the implementation of screening population programmes with special emphasis on genetic screening. After a critical review it has been addressed 24 recommendations concerning 14 topics: evaluation of the opportunity of the programme, including ethical analysis besides scientific evidences and cost/benefits issues; the need to differentiate between research and public health intervention and to built a specific and comprehensive programme; the creation of an interdisciplinary working group which control its implementation and prepare a protocol including justification, development, therapeutic or preventive actions and follow-up activities; the review of the programme by an independent Ethical committee; the guarantee of the voluntary, universal and equitable population access, which requires sufficient information on the programme and their specific relevant facts, as incidental detection of heterozygous state in minors in newborn screening and the relevance of non directive genetic counselling specially in prenatal screening offered to pregnant women; considerations regarding future uses of samples for research
purposes; total quality and periodic programme evaluation; guarantee of personal data confidentiality and the conflict of interest statement of the members of all the Committees involved in the programme.

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**Document 218**

Valentine, Alex J  
**Comment on 'Big science, little science'.**  
*EMBO reports* 2010 Mar; 11(3): 152

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**Document 219**

Kaphingst, Kimberly A; McBride, Colleen M  
**Patient responses to genetic information: studies of patients with hereditary cancer syndromes identify issues for use of genetic testing in nephrology practice.**  
*Seminars in nephrology* 2010 Mar; 30(2): 203-14

**Abstract:** Advances in the genetic basis of kidney disease may mean that genetic testing is increasingly important in reducing disease morbidity and mortality among patients. However, there is little research examining patient responses to genetic information for Mendelian and common kidney diseases. Existing research on kidney and other hereditary cancer syndromes can inform three major issues relevant to the nephrology context as follows: (1) how patients understand their risk of disease after genetic counseling and testing, (2) their emotional responses to the information, and (3) their uptake of recommended risk-reducing strategies. Prior research suggests that genetic counseling and testing may improve patient understanding of genetics, but patients still might not fully understand the meaning of their results for disease risk. Genetic counseling and testing does not appear to result in long-term negative emotional effects among patients who carry mutations or those who do not. Finally, although genetic counseling and testing may improve adherence to recommended screening strategies, adherence varies substantially across different risk-reduction options. Previous research also suggests that computer-based interventions might be a useful adjunct to genetic counseling approaches. Examining whether and how these prior findings relate to the context of hereditary kidney disease is an important area for future research.

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**Document 220**

Hwa, Hsiao-Lin; Huang, Lian-Hua; Hsieh, Fon-Jou; Chow, Song-Nan  
**Informed consent for antenatal serum screening for Down syndrome.**  
*Taiwanese journal of obstetrics & gynecology* 2010 Mar; 49(1): 50-6

**Abstract:** OBJECTIVE: Respect for patients’ autonomy is a principle issue in medical ethics. Patients' understanding of antenatal serum screening for Down syndrome upon informed consent has barely been assessed. Our objective was to evaluate pregnant women's perceived level of understanding of this serum screening. MATERIALS AND METHODS: Pregnant women between the 15(th) and 21(st) gestational week were randomized into control and experimental groups, and were asked to complete a questionnaire before and after genetic counselling provided by researchers. The primary endpoints were the perceived level of understanding of serum screening for Down syndrome and the autonomy of the decision making for this serum screening. The secondary endpoints were the anxiety and depression levels of these women. RESULTS: Participants in the experimental group (n = 96) had a significantly higher perceived level of understanding of antenatal serum screening for Down syndrome than participants in the control group (n = 97). There were significantly more respondents in the experimental group making the decision themselves to undergo serum screening than women in the control group. Anxiety and depression levels were not significantly different between the women in the two groups. CONCLUSION: Pregnant women should be offered more information to allow them to make an informed decision before they undergo antenatal serum screening for Down syndrome. Comprehensive genetic counseling improved pregnant women's autonomy in deciding whether to participate in serum screening. Health service providers should make effort to fulfill the ethical requirements of informed consent.
Document 221
Longstaff, Holly; Burgess, Michael M

Recruiting for representation in public deliberation on the ethics of biobanks.
Public understanding of science (Bristol, England) 2010 Mar ; 19(2): 212-24

Abstract: This paper addresses the dilemmas of participant sampling and recruitment for deliberative science policy projects. Results are drawn from a deliberative public event that was held in April and May, 2007. The research objective of The BC Biobank Deliberation was to assess deliberative democracy as an approach to legitimate policy advice from a subset of British Columbians concerning the secondary use of human tissues for prospective genomic and genetic research. The overall goal was to have participants identify key values that should guide a biobank in British Columbia. This paper assesses our team's group decision-making processes concerning participant sampling for the 2007 event. Results presented here should allow the reader to critically examine our team's choices and could also be used to assist advocates of deliberative democracy and others who may wish to propose similar events in the future.

Document 222
Peshkin, Beth N; Demarco, Tiffani A; Tercyak, Kenneth P

On the development of a decision support intervention for mothers undergoing BRCA1/2 cancer genetic testing regarding communicating test results to their children.
Familial cancer 2010 Mar ; 9(1): 89-97

Abstract: Parent communication of BRCA1/2 test results to minor-age children is an important, yet understudied, clinical issue that is commonly raised in the management of familial cancer risk. Genetic counseling professionals and others who work with parents undergoing this form of testing often confront questions about the risks/benefits and timing of such disclosures, as well as the psychosocial impact of disclosure and nondisclosure on children's health and development. This paper briefly reviews literature on the prevalence and outcome of parent-child communication surrounding maternal BRCA1/2 test results. It also describes a formative research process that was used to develop a decision support intervention for mothers participating in genetic counseling and testing for BRCA1/2 mutations to address this issue, and highlights the conceptual underpinnings that guided and informed the intervention's development. The intervention consists of a print-based decision aid to facilitate parent education and counseling regarding if, when, and potentially how to disclose hereditary cancer risk information to children. We conclude with a summary of the role of social, behavioral, and decision science research to support the efforts of providers of familial cancer care regarding this important decision, and to improve the outcomes of cancer genetic testing for tested parents and their nontested children.

Document 223
Duncan, Rony E; Gillam, Lynn; Savulescu, Julian; Williamson, Robert; Rogers, John G; Delatycki, Martin B

The challenge of developmentally appropriate care: predictive genetic testing in young people for familial adenomatous polyposis.

Abstract: Predictive genetic tests for familial adenomatous polyposis (FAP) are routinely offered to young people during early adolescence. While this is not controversial, due to the medical benefit conferred by the test, it is nonetheless challenging as a consequence of the stage of life of the young people, and the simultaneous involvement of multiple family members. Despite these challenges, it is possible to ensure that the test is offered in such a way that it actively acknowledges and facilitates young people's developing autonomy and psychosocial well-being. In this paper we present findings from ten in-depth interviews with young people who have undergone predictive genetic testing for FAP (four male, six female; five gene-positive, five gene-negative; aged 10-17 years at the time of their predictive test; aged 12-25 years at the time of their research interview). We present five themes
that emerged from the interviews which highlight key ethical challenges associated with such testing. These are: (1) the significance of the test; (2) young people's lack of involvement in the decision to be tested; (3) young people's limited understanding; (4) provision of the blood test at the first visit; and (5) group testing of family members. We draw on these themes to make eight recommendations for future practice. Together, these recommendations highlight the importance of providing developmentally appropriate care to young people undergoing predictive genetic testing for FAP.

Document 224
Dye, Danielle E.; Youngs, Leanne; McNamara, Beverley; Goldblatt, Jack; O'Leary, Peter
The disclosure of genetic information: a human research ethics perspective

Document 225
Mascalzoni, Deborah; Janssens, A. Cecile J.W.; Stewart, Alison; Pramstaller, Peter; Gyllensten, Ulf; Rudan, Igor; van Duijn, Comelia M.; Wilson, James F.; Campbell, Harry; Quillan, Ruth M.C.
Comparison of participant information and informed consent forms of five European studies in genetic isolated populations.
European Journal of Human Genetics 2010 March; 18(3): 296-302
Abstract: Family-based research in genetically isolated populations is an effective approach for identifying loci influencing variation in disease traits. In common with all studies in humans, those in genetically isolated populations need ethical approval; however, existing ethical frameworks may be inadequate to protect participant privacy and confidentiality and to address participants' information needs in such populations. Using the ethical-legal guidelines of the Council for International Organizations of Medical Sciences (CIOMS) as a template, we compared the participant information leaflets and consent forms of studies in five European genetically isolated populations to identify additional information that should be incorporated into information leaflets and consent forms to guarantee satisfactorily informed consent. We highlight the additional information that participants require on the research purpose and the reasons why their population was chosen; on the potential risks and benefits of participation; on the opportunities for benefit sharing; on privacy; on the withdrawal of consent and on the disclosure of genetic data. This research raises some important issues that should be addressed properly and identifies relevant types of information that should be incorporated into information leaflets for this type of study.

Document 226
Wolf, Leslie E.; Bouley, Timothy A.; McCulloch, Charles E.
Genetic research with stored biological materials: ethics and practice.
IRB: Ethics and Human Research 2010 March-April; 32(2): 7-18

Document 227
Lemke, Amy A.; Trinidad, Susan B.; Edwards, Karen L.; Starks, Helene; Wiesner, Georgia L.
Attitudes toward genetic research review: results from a national survey of professionals involved in human subjects protection.
Abstract: The recent expansion of human genetics research has raised complex ethical and regulatory issues. However, few published reports describe the views of professionals involved in human subjects protection (HSP) regarding the risks and benefits of genetic research. This anonymous, web-based study elicited the opinions of 208 HSP professionals about review of genetic research. The majority of respondents felt that different guidance is needed for various aspects of genetic protocol review compared with other types of human subjects research. Importantly, opinions were divided on specific genetic research issues, such as what constitutes human subjects research, when to re-consent, and the likelihood and risks of research participant identification. Findings from this study illustrate the need for a collaborative approach to ethics oversight in the review and conduct of genetic research.

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Document 228

Tucker, Jonathan B.

Double-edged DNA: preventing the misuse of gene synthesis

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Document 229

An absurd law. Turkey's government is about to pass legislation that could cripple the country's biological research [editorial]
Nature 2010 February 25; 463(7284): 1000

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http://www.nature.com/nature/journal/v463/n7284/ (link may be outdated)

Document 230

Sui, Suli; Sleeboom-Faulkner, Margaret

Choosing offspring: prenatal genetic testing for thalassaemia and the production of a 'saviour sibling' in China.
Culture, health & sexuality 2010 Feb; 12(2): 167-75

Abstract: This paper focuses on the pre-natal genetic testing and reproductive decision-making around thalassaemia in China. Findings are based on fieldwork conducted in hospitals and research institutions, interviews with families with thalassaemia-affected children, interviews with geneticists and genetic researchers and a literature review conducted between September and November 2007. The paper aims to provide insight into the ways in which those who carry thalassaemia decide to have a test for the condition and the choices available to prospective parents. The paper also analyses factors affecting reproductive choices and the decision to produce a 'saviour sibling', including financial implications, state family planning policy, images and information conveyed through the media and propaganda, advice and counselling from doctors, psychological pressure from the community and social discrimination. The paper concludes with a discussion on the issues involved in the creation of saviour siblings, some of which are particular to China.

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Document 231

Kato, Masae

Quality of offspring? Socio-cultural factors, pre-natal testing and reproductive decision-making in Japan.
Culture, health & sexuality 2010 Feb; 12(2): 177-89
Abstract: Japan is one of the few countries to have enacted legislation on eugenics. Consequently, there has been active public debate about the practice of selective abortion for over 35 years. Furthermore, discrimination against disabilities is deep-rooted in Japanese society and the quality of offspring is a common concern. Given this background, the obvious conclusion might be that couples in Japan would have no hesitation in using reproductive technologies to ensure the best possible chance of giving birth to higher quality offspring. Yet, research indicates that when it comes to decision-making in the course of a pregnancy, not all individuals choose testing or termination, even when prenatal diagnosis indicates the presence of congenital conditions. Other factors play a role in reproductive decision-making, including age at time of pregnancy and reproductive history including infertility treatment. Against this background, this paper analyses accounts of five pregnancies - two of which resulted in termination and three which went to full term despite receiving test results showing possible birth defects - with the aim of identifying factors influencing whether or not to terminate a pregnancy.

Document 232
Melas, Philippe A.; Sjöholm, Louise K.; Forsner, Tord; Edhborg, Maigun; Juth, Niklas; Forsell, Yvonne; Lavebratt, Catharina
Examining the public refusal to consent to DNA biobanking: empirical data from a Swedish population-based study.
Journal of Medical Ethics 2010 February; 36(2): 93-8
Abstract: OBJECTIVES: To investigate empirically the motivations for not consenting to DNA biobanking in a Swedish population-based study and to discuss the implications. DESIGN: Structured questionnaires and semistructured interviews. SETTING: A longitudinal epidemiological project (PART) ongoing since 1998 in Stockholm, Sweden. The DNA-collection wave took place during 2006-7. PARTICIPANTS: 903 individuals completed the questionnaire (participation rate 36%) and 23 were interviewed. All individuals had participated in both non-genetic waves of the project, but refused to contribute saliva samples during the DNA-collection wave. MAIN OUTCOME MEASURES: Motivations behind refusing to consent to DNA biobanking, with subsequent focus on participants' explanations regarding this unwillingness. RESULTS: Public refusal to consent to DNA biobanking, as revealed by the questionnaire, was mainly explained by a lack of personal relevance of DNA contribution and feelings of discomfort related to the DNA being used for purposes other than the respective study. Interviews of individuals representing the second motivation, revealed a significant mistrust of DNA biobank studies. The underlying beliefs and attitudes were associated with concerns about integrity, privacy, suspiciousness and insecurity. However, most interviewees were supportive of genetic research per se and interpreted their mistrust in the light of distressing environmental influences. CONCLUSION: The results suggest a need for guidelines on benefit sharing, as well as trustworthy and stable measures to maintain privacy, as a means for increasing personal relevance and trust among potential participants in genetic research. Measures taken from biobanks seem insufficient in maintaining and increasing trust, suggesting that broader societal measures should be taken.

Document 233
Bowen, Deborah J.; Harris, J.; Jorgensen, C.M.; Myers, M.F.; Kuniyuki, A.
Socioeconomic influences on the effects of a genetic testing direct-to-consumer marketing campaign.
Public Health Genomics 2010 February; 13(3): 131-142

Document 234
Forsberg, Joanna Stjernschantz; Eriksson, Stefan; Hansson, Mats G.
Changing defaults in biobank research could save lives too.
European Journal of Epidemiology 2010 February; 25(2): 65-68
Abstract: In an effort to increase the amount of organs available for transplantation, many countries have implemented presumed consent for organ donation. Presuming a wish to contribute to medical advances through
biobank research on previously taken tissue samples could similarly improve health and wellbeing. In this article we analyze common arguments for and against presumed consent for organ donation and assess their relevance in the context of biobank research. In spite of obvious differences between biobank research and organ transplantation the cases for implementing presumption of a positive attitude appear quite analogous. It has repeatedly been shown that a majority of the general population supports these projects and selecting informed consent as the default position decreases the amount of organs and samples available and thus reduces the prospect of promoting health. We conclude that instead of presuming that individuals do not wish to contribute to the advancement of healthcare through biobank research on previously taken samples, ethics committees should presume that they do.

**Document 235**

Melas, Philippe A.; Sjöholm, Louise K.; Forsner, Tord; Edhborg, Maigun; Juth, Niklas; Forsell, Yvonne; Lavebratt, Catharina

*Examining the public refusal to consent to DNA biobanking: empirical data from a Swedish population-based study.*

Journal of Medical Ethics 2010 February; 36(2): 93-98

**Abstract:** OBJECTIVES: To investigate empirically the motivations for not consenting to DNA biobanking in a Swedish population-based study and to discuss the implications. DESIGN: Structured questionnaires and semistructured interviews. SETTING: A longitudinal epidemiological project (PART) ongoing since 1998 in Stockholm, Sweden. The DNA-collection wave took place during 2006-7. PARTICIPANTS: 903 individuals completed the questionnaire (participation rate 36%) and 23 were interviewed. All individuals had participated in both non-genetic waves of the project, but refused to contribute saliva samples during the DNA-collection wave. MAIN OUTCOME MEASURES: Motivations behind refusing to consent to DNA biobanking, with subsequent focus on participants' explanations regarding this unwillingness. RESULTS: Public refusal to consent to DNA biobanking, as revealed by the questionnaire, was mainly explained by a lack of personal relevance of DNA contribution and feelings of discomfort related to the DNA being used for purposes other than the respective study. Interviews of individuals representing the second motivation, revealed a significant mistrust of DNA biobank studies. The underlying beliefs and attitudes were associated with concerns about integrity, privacy, suspiciousness and insecurity. However, most interviewees were supportive of genetic research per se and interpreted their mistrust in the light of distressing environmental influences. CONCLUSION: The results suggest a need for guidelines on benefit sharing, as well as trustworthy and stable measures to maintain privacy, as a means for increasing personal relevance and trust among potential participants in genetic research. Measures taken from biobanks seem insufficient in maintaining and increasing trust, suggesting that broader societal measures should be taken.

**Document 236**

Bussey-Jones, Jada; Garrett, Joanne; Henderson, Gail; Moloney, Mairead; Blumenthal, Connie; Corbie-Smith, Gail

*The role of race and trust in tissue/blood donation for genetic research*  
Genetics in Medicine 2010 February; 12(2): 116-121

Supported by: NHGRI-funded publication; Grants P50 HG004488 and R01 HG002830-02

**Document 237**

Kinney, Anita Yeomans; Gammon, Amanda; Coxworth, James; Simonsen, Sara E.; Arce-Laretta, Maritza

*Exploring attitudes, beliefs, and communication preferences of Latino community members regarding BRCA1/2 mutation testing and preventive strategies*  
Genetics in Medicine 2010 February; 12(2): 105-115
Document 238

Greger, M.

**Trait selection and welfare of genetically engineered animals in agriculture.**

**Abstract:** The release of the Final Guidance from the US Food and Drug Administration on the commercialization of genetically engineered animals has sparked renewed discussion over the ethical, consumer, and regulatory implications of transgenesis in animal agriculture. Animal welfare critiques have focused on unexpected phenotypic effects in animals used in transgenic research, rather than on the health and welfare implications of the intended productivity enhancement. Unless breeding goals are redefined to reflect social concerns, the occurrence and magnitude of undesirable side effects may increase and consumer confidence in the nascent technology may be undermined.

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Document 239

Caulfield, T.; Ries, N.M.; Ray, P.N.; Shuman, C.; Wilson, B.

**Direct-to-consumer genetic testing: good, bad or benign?**
Clinical Genetics 2010 February; 77(2): 101-105

**Abstract:** A wide variety of genetic tests are now being marketed and sold in direct-to-consumer (DTC) commercial transactions. However, risk information revealed through many DTC testing services, especially those based on emerging genome wide-association studies, has limited predictive value for consumers. Some commentators contend that tests are being marketed prematurely, while others support rapid translation of genetic research findings to the marketplace. The potential harms and benefits of DTC access to genetic testing are not yet well understood, but some large-scale studies have recently been launched to examine how consumers understand and use genetic risk information. Greater consumer access to genetic tests creates a need for continuing education for health care professionals so they can respond to patients' inquiries about the benefits, risks and limitations of DTC services. Governmental bodies in many jurisdictions are considering options for regulating practices of DTC genetic testing companies, particularly to govern quality of commercial genetic tests and ensure fair and truthful advertising. Intersectoral initiatives involving government regulators, professional bodies and industry are important to facilitate development of standards to govern this rapidly developing area of personalized genomic commerce.

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Document 240

Miller, Henry I

**The UN's water torture.**

**Abstract:** The United Nations is a bastion of corruption, profligacy and incompetence that is a particular threat to the inhabitants of poor nations. Its policies, programs and agencies have made a growth industry of the unscientific regulation of important technologies—of which gene-splicing [also known as recombinant DNA technology or genetic modification (GM)] is only one. The UN's actions regularly defy scientific consensus and common sense, instead pandering to extremists. The result is vastly inflated research and development costs, less innovation, and diminished exploitation of superior techniques and products that could offer monumental humanitarian and economic benefits.

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Document 241

Shedlosky-Shoemaker, Randi; Ngo, Tho L; Ferketich, Amy K; Porter, Kyle; Leventhal, Howard; Kelly, Kimberly M
Exploring perceptions of genetic testing: an examination of perceived accuracy over time.
Patient education and counseling 2010 Jan; 78(1): 34-9

Abstract: Despite the potential impact of perceptions of genetic testing, little research has examined these perceptions. The current study examined factors associated with perceived accuracy of genetic testing to detect BRCA1/2 mutations and change in perceived accuracy.

Hallowell, N.; Cooke, S.; Crawford, G.; Lucassen, A.; Parker, M.; Snowdon, C.
An investigation of patients' motivations for their participation in genetics-related research.
Journal of Medical Ethics 2010 January; 36(1): 37-45

Abstract: DESIGN: Qualitative interview study. PARTICIPANTS: Fifty-nine patients with a family history of cancer who attend a regional cancer genetics clinic in the UK were interviewed about their current and previous research experiences. Findings: Interviewees gave a range of explanations for research participation. These were categorised as (a) social—research participation benefits the wider society by progressing science and improving treatment for everyone; (b) familial—research participation may improve healthcare and benefit current or future generations of the participant's family; and (c) personal—research participation provides therapeutic or non-therapeutic benefits for oneself. CONCLUSIONS: We discuss the distinction drawn between motives for research participation focused upon self (personal) and others (familial/social), and observe that personal, social and familial motives can be seen as interdependent. For example, research participation that is undertaken to benefit others, particularly relatives, may also offer a number of personal benefits for self, such as enabling participants to feel that they have discharged their social or familial obligations. We argue for the need to move away from simple, static, individualised notions of research participation to a more complex, dynamic and inherently social account.

Sáenz de Tejada López, M; Valle Mansilla, J I; Ruiz-Canela, M
Deficiencias en las Hojas de Información de Estudios Genómicos. = Deficiencies in consent forms for genomic research.
Cuadernos de Bioética 2010 January-April; 21(71): 95-108

Bordet, Sylvie; Bennett, Jami; Knoppers, Bartha Maria; McNagny, Kelly M.
The changing landscape of human-animal chimera research: A Canadian regulatory perspective.
Stem Cell Research 2010 January; 4(1): 10-16

Hohlfeld, Reinhard
Multiple Sclerosis 2010 January; 16(1): 3-14

Abstract: This article is based on the ECTRIMS lecture given at the 25( th) ECTRIMS meeting which was held in Dusseldorf, Germany, from 9 to 12 September 2009. Five challenges have been identified: (1) safeguarding the principles of medical ethics; (2) optimizing the risk/benefit ratio; (3) bridging the gap between multiple sclerosis and experimental autoimmune encephalitis; (4) promoting neuroprotection and repair; and (5) tailoring multiple sclerosis therapy to the individual patient. Each of these challenges will be discussed and placed in the context of current
research into the pathogenesis and treatment of multiple sclerosis.

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Document 246

Williams, Pamela Holtzclaw; Schepp, Karen; McGrath, Barbara; Mitchell, Pamela

The stewardship model: current viability for genetic biobank practice development.


Abstract: The "stewardship model" of ethics relationships is a conceptual framework initially proposed by Jeffers in Advances in Nursing Science, 24(2), 2001. It conceptualized ethical responsibilities in the practice of systematic collection and storage of biospecimens in biobanks for future healthcare genetic research. Since the article's publication 8 years ago, genetic biobanks have grown in number around the world and discernible biobank relational conceptualizations were published. Nursing leadership adopted competency standards for all genetic nursing practices. The involvement of nurses has increased and is projected for further significant increase as biobank practices emerge from research into clinical care settings. This assessment of current viability of this previously established stewardship model offers fresh insights to existing and future nursing research and practice. The purpose of this article was to analyze the original stewardship model's components, the relational parties, and characteristics; by contrasting those with proposed conceptualizations and existing biobank practices developed subsequent to its publication. The model's current viability and theoretical development status are assessed for its ability to support a future nursing evidence base for best practices. Proposals for the model's expansion are suggested.

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Document 247

Ehrich, Kathryn; Williams, Clare

A 'healthy baby': The double imperative of preimplantation genetic diagnosis.

Health 2010 January; 14(1): 41-56

Abstract: This article reports from a study exploring the social processes, meanings and institutions that frame and produce 'ethical problems' and clinical dilemmas for practitioners, scientists and others working in the specialty of preimplantation genetic diagnosis (PGD). A major topic in the data was that, in contrast to IVF, the aim of PGD is to transfer to the woman's womb only those embryos likely to be unaffected by serious genetic disorders; that is, to produce 'healthy babies'. Staff described the complex processes through which embryos in each treatment cycle must meet a double imperative: they must be judged viable by embryologists and 'unaffected' by geneticists. In this article, we focus on some of the ethical, social and occupational issues for staff ensuing from PGD's double imperative.

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Document 248

Resnik, David B.

Genomic research data: open vs. restricted access.


http://www.thehastingscenter.org/Publications/IRB/Archive.aspx (link may be outdated)

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Document 249

Jackson, Ronald; Ramshaw, Ian

The mousepox experience. An interview with Ronald Jackson and Ian Ramshaw on dual-use research.
Interview by Michael J. Selgelid and Lorna Weir.
EMBO Reports 2010 January; 11(1): 18-24

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Document 250

Trent, Ron J.; et al.
National Health and Medical Research Council (Australia)
MEDICAL GENETIC TESTING: INFORMATION FOR HEALTH PROFESSIONALS

http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e99.pdf (link may be outdated)

Document 251

Andrews, Lori B.; Mehlman, Maxwell J.; and Rothstein, Mark A.
GENETICS: ETHICS, LAW, AND POLICY

Document 252

Olson, Steve and Berger, Adam C., rapporteurs
Institute of Medicine (United States). Board on Health Sciences Policy. Roundtable on Translating Genomic-Based Research for Health
CHALLENGES AND OPPORTUNITIES IN USING RESIDUAL NEWBORN SCREENING SAMPLES FOR TRANSLATIONAL RESEARCH: WORKSHOP SUMMARY
Call number: RJ255.6 .D55 C43 2010

http://www.nap.edu (link may be outdated)

Document 253

National Health and Medical Research Council (Australia)
BIOBANKS INFORMATION PAPER

http://www.nhmrc.gov.au/%5Ffiles%5Fnhmrc/file/your%5Fhealth/egenetics/practioners/biobanks%5Finformation%5Fpaper.pdf (link may be outdated)

Document 254

Naji, Anas Hasan Muhammad
Al-Basmah al-wirathiyah wa mada mashru’iyatiha fi ithbat wa nafy al-nasab, dirasah muqâranah fi daw’ al-qanun al-wad’i wa al-shariah al-Islamiyah = DNA fingerprinting and its authority in establishing or negating paternity, a comparative study in light of positive law and Islamic sharia
Document 255
Merino, Noël, ed.
HUMAN GENETICS
Call number: QH431 .H8356 2010

Document 256
Ong, Aihwa and Chen, Nancy N., eds.
ASIAN BIOTECH: ETHICS AND COMMUNITIES OF FATE
Call number: HD9999 .B443 A7815 2010

Document 257
Forgó, Nikolaus; Kollek, Regine; Arning, Marian; Kruegel, Tina; and Petersen, Imme
ETHICAL AND LEGAL REQUIREMENTS OF TRANSNATIONAL GENETIC RESEARCH
Call number: K3611 .I5 E87 2010

Document 258
Elger, Bernice
ETHICAL ISSUES OF HUMAN GENETIC DATABASES: A CHALLENGE TO CLASSICAL HEALTH RESEARCH ETHICS
Call number: RB155 .E455 2010

Document 259
Judd, Sandra J., ed.
GENETIC DISORDERS SOURCEBOOK: BASIC CONSUMER HEALTH INFORMATION ABOUT HEREDITARY DISORDERS, INCLUDING DISORDERS RESULTING FROM ABNORMALITIES IN SPECIFIC GENES, SUCH AS HEMOPHILIA, SICKLE CELL DISEASE, AND CYSTIC FIBROSIS, CHROMOSOMAL DISORDERS, SUCH AS DOWN SYNDROME, FRAGILE X SYNDROME, AND KLINEFELTER SYNDROME, AND COMPLEX DISORDERS WITH ENVIRONMENTAL AND GENETIC COMPONENTS, SUCH AS ALZHEIMER DISEASE, CANCER, HEART DISEASE, AND OBESITY, ALONG WITH INFORMATION ABOUT THE HUMAN GENOME PROJECT, GENETIC TESTING AND PRIVACY CONCERNS, THE SPECIAL NEEDS OF CHILDREN WITH GENETIC DISORDERS, CURRENT RESEARCH INITIATIVES, A GLOSSARY OF TERMS, AND A DIRECTORY OF RESOURCES FOR FURTHER HELP AND INFORMATION
Call number: RB155.5 .G455 2010

Document 260
Khanna, Aparna; Reddy, Samba Siva; Jan, Majahar; Totey, Swapnil; Rao, T Vasudev; Rao, Shailesh A V; Naik, Arun L; Totey, Satish; Venkataramana, Neelam K
Establishment of a brain tumor tissue repository in India: maintaining quality standards.
Journal of stem cells 2010; 5(2): 89-101
**Abstract:** Tumor tissue repositories (TTRs) play a pivotal role in both basic and translational research by acting as a conduit to facilitate innovative research, thereby providing solutions to treat the incurable disease—'Cancer'. One of the fundamental requirements to achieve this goal would be the acquisition of high quality tumor tissue specimens that are stored in such a manner that its integrity is preserved. Further, a quality system should be in place that assures the compliance of procedures that are the key to a smooth functioning of all the inter-related departments that play a key role in the entire operations. To address this, we have initiated an effort to build a tumor tissue repository of brain tumor tissues in the Southern part of the Indian sub-continent. One of the cardinal features of brain tumors is the heterogeneity, both phenotypically and genotypically. Moreover, significant gaps exist in current understanding of the molecular pathways involved in the genesis, progression, and biological and clinical behavior of brain tumors. We hope that our initiative will provide researchers accessibility to a reserve of high quality tissues in this part of the globe. We have created and validated a complete histology service including tissue processing, embedding, sectioning and H&E staining for fixed tissues, in addition to creating and staining frozen sections. To our knowledge, such a structured initiative to store brain tumor samples is the first of its kind in the India.

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Document 261

Kretlow, Ariane; Butzke, Daniel; Goetz, Mario E; Grune, Barbara; Halder, Marlies; Henkler, Frank; Liebsch, Manfred; Nobiling, Rainer; Oelgeschlaeger, Michael; Reifenberg, Kurt; Schaefer, Bernd; Seiler, Andrea; Luch, Andreas

**Implementation and enforcement of the 3Rs principle in the field of transgenic animals used for scientific purposes. Report and recommendations of the BfR expert workshop, May 18-20, 2009, Berlin, Germany.**

ALTEX 2010; 27(2): 117-34

**Abstract:** In 2007, 2.7 million vertebrates were used for animal experiments and other scientific purposes in Germany alone. Since 1998 there has been an increase in the number of animals used for research purposes, which is partly attributable to the growing use of transgenic animals. These animals are, for instance, used as in vivo models to mimic human diseases like diabetes, cancer or Alzheimer's disease. Here, transgenic model organisms serve as valuable tools, being instrumental in facilitating the analysis of the molecular mechanisms underlying human diseases, and might contribute to the development of novel therapeutic approaches. Due to variable and, sometimes low, efficiency (depending on the species used), however, the generation of such animals often requires a large number of embryo donors and recipients. The experts evaluated methods that could possibly be utilised to reduce, refine or even replace experiments with transgenic vertebrates in the mid-term future. Among the promising alternative model organisms available at the moment are the fruit fly Drosophila melanogaster and the roundworm Caenorhabditis elegans. Specific cell culture experiments or three-dimensional (3D) tissue models also offer valuable opportunities to replace experiments with transgenic animals or reduce the number of laboratory animals required by assisting in decision-making processes. Furthermore, at the workshop an in vitro technique was presented which permits the production of complete human antibodies without using genetically modified ("humanised") animals. Up to now, genetically modified mice are widely used for this purpose. Improved breeding protocols, enhanced efficiency of mutagenesis as well as training of laboratory personnel and animal keepers can also help to reduce the numbers of laboratory animals. Well-trained staff in particular can help to minimise the pain, suffering and discomfort of animals and, at the same time, improve the quality of data obtained from animal experiments. This, in turn, can lead to a reduction in the numbers of animals needed for each experiment. The experts also came to the conclusion that the numbers of laboratory animals can be reduced by open access to a central database that provides detailed documentation of completed experiments involving transgenic animals. This documentation should not be restricted to experiments with substantial scientific results that warrant publication, but should also include those with "negative" outcome, which are usually not published. Capturing all kinds of results within such a database provides added value to the respective scientists and the scientific community as a whole; it could also help to stimulate collaborations and to ensure funding for future research. An important aspect to be considered in the generation of this kind of database is the quality and standardisation of the information provided on existing in vitro models and the respective opportunities for their use. The experts felt that the greatest potential for reducing the numbers of laboratory animals in the near future realistically might not be offered by the complete replacement of transgenic animal models but by opportunities to examine specific questions to a greater degree using in vitro models, such as cell and tissue cultures including organotypic models. The use of these models would considerably reduce the number of in vivo experiments using transgenic animals. However, the overall number of experimental animals may still be increasing or remain unaffected, e.g. when transgenic animals continue to serve as the source of primary cells and organs/tissues for in vitro experiments.

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Quality control of phenotypic forms data in the Type 1 Diabetes Genetics Consortium.

Abstract: When collecting phenotypic data in clinics across the globe, the Type 1 Diabetes Genetics Consortium (T1DGC) used several techniques that ensured consistency, completeness, and accuracy of the data.

Biobanking, consent, and commercialization in international genetics research: the Type 1 Diabetes Genetics Consortium.

Abstract: and

A framework for the prioritization of investment in the provision of genetic tests.

Abstract: The UK Genetic Testing Network (UKGTN) established a process for the evaluation of genetic tests for entry onto the National Health Service (NHS) Directory of Molecular Genetic Testing. The Network requested the development and piloting of a prioritization framework that could be used for the commissioning of genetic tests by the NHS.

Relative responsibilities: is there an obligation to discuss genomics research participation with family members?

Abstract: One of the many ethical challenges presented by research in genomics is that, although informed consent to research has traditionally been a matter for the individual participant, genomics research carries potential implications for genetic relatives. There are specific issues that arise when research is focused around populations.
or around family groups; this paper deals with the place of relatives of participants in genomics research more
generally. Recently, in response to this challenge, recommendations have attempted to tread a middle ground by
retaining traditional models of informed consent whilst suggesting that potential research recruits should be
encouraged to discuss participation with their families. It is argued here that this may produce an unfair account of
the responsibilities of research participants, that it may ignore the very many difficulties of communication within
families about genetics and health, and that it may create unrealistic hurdles to the ethical conduct of research.
Research conducted in the context of clinical genetics and on health communication more widely is drawn upon to
illustrate these points. A clear recommendation is made that providing materials that may assist research
participants to communicate with family members may be beneficial and may raise ethical standards, but that it may
be unwise to burden participants with the suggestion that they owe specific obligations to genetic relatives to
discuss research participation with them.

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**Document 267**

Wolff, K; Brun, W; Kvale, G; Ehrencrona, H; Soller, M; Nordin, K  
**How to handle genetic information: a comparison of attitudes among patients and the general population.**  
Public health genomics 2010; 13(7-8): 396-405  
**Abstract:** So far there are no studies comparing the attitudes of patients with hereditary conditions to the attitudes of
the general public on how to handle genetic risk information which mutation carriers refuse to disclose to relevant
family members. The purpose of the present study was to investigate whether such patients and members of
the general public want to be informed about the existence of hereditary conditions within their family, and under which
conditions they want healthcare providers to breach confidentiality.

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**Document 268**

Arar, N; Seo, J; Lee, S; Abboud, H E; Copeland, L A; Noel, P; Parchman, M  
**Preferences regarding genetic research results: comparing veterans and nonveterans responses.**  
Public health genomics 2010; 13(7-8): 431-9  
**Abstract:** Communicating genetic research results to participants presents ethical challenges. Our objectives were
to examine participants' preferences in receiving future genetic research results and to compare preferences reported
by veteran and nonveterans participants.

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**Document 269**

How intellectual property rights affect innovation.  

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**Document 270**

Lochmüller, Hanns; Schneiderat, Peter  
**Biobanking in rare disorders.**  
Advances in experimental medicine and biology 2010; 686: 105-13  
**Abstract:** Biobanks are collections of biomaterials with associated data. Biobanking is an essential tool to provide
access to high quality human biomaterial for fundamental and translational research. Research for rare disorders
benefits from the provision of human biomaterials through biobanks, and each human sample from a person with a
rare disorder has a high value as it may hold the key to answer an important research question. Transnational
cooperation in biobanking is an important catalyst to share limited resources and achieve optimal outcomes as in
other areas of rare disorder research. Networks of biobanks aim to assure common practices and quality standards, and facilitate access to rare disorder biomaterials for the scientific community.

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### Document 271

**Nor, Siti Nurani Mohamed**

**Human genetic technologies and Islamic bioethics**


Call number: QH438.7 .G4116 2010

### Document 272

**Hoeyer, K**

**Donors perceptions of consent to and feedback from biobank research: time to acknowledge diversity?**

Public health genomics 2010; 13(6): 345-52

**Abstract:** Many studies have explored public perspectives on when and how to provide informed consent to biobank research and when to get feedback on research results. Little has been done to explore overarching trends in these studies.

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### Document 273

**Meslin, Eric M; Cho, Mildred K**

**Research ethics in the era of personalized medicine: updating science's contract with society.**

Public health genomics 2010; 13(6): 378-84

**Abstract:** With the completed sequence of the human genome has come the prospect of substantially improving the quality of life for millions through personalized medicine approaches. Still, any advances in this direction require research involving human subjects. For decades science and ethics have enjoyed an allegiance reflected in a common set of ethical principles and procedures guiding the conduct of research with human subjects. Some of these principles emphasize avoiding harm over maximizing benefit. In this paper we revisit the priority given to these ethical principles - particularly the principles that support a cautious approach to science - and propose a reframing of the 'social contract' between science and society that emphasizes reciprocity and meeting public needs.

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### Document 274

**Offit, Kenneth; Thom, Peter**

**Ethicolegal aspects of cancer genetics.**

Cancer treatment and research 2010; 155: 1-14

**Abstract:** In the wake of efficacious preventive interventions based on hereditary cancer risk assessment, a number of ethical and legal challenges have emerged. These include issues such as appropriate testing of children and embryos, the "duty to warn" relatives about familial risk, reproductive genetic testing, the risk of genetic discrimination, and equitable access to testing. These and other issues will be discussed within the framework of a bioethical model, with reference to recent case law.

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### Document 275
Whitehouse, Peter J; George, Daniel
Protecting life and lives: putting gene research in context.

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Hardy, John; Gwinn, Katrina
Protected to death.

Abstract: Despite progress in human gene discovery, we believe that regulations regarding subject protections have not fully kept pace. We believe that weaknesses in the current regulatory system include variations in the understanding of genetic principles and in the application of regulations. We discuss what our thoughts regarding steps needed to create an environment where information is gathered from all parties involved, including via research into many of the remaining questions, in order to ensure that research participant protection is adequate, appropriate and is an evolving process which will allow it to keep pace with the rapid advances in human genetics.

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O'Doherty, Kieran C; Hawkins, A
Structuring public engagement for effective input in policy development on human tissue biobanking.
Public health genomics 2010; 13(4): 197–206

Abstract: We begin with the premise that human tissue biobanking is associated with ethical ambiguities and regulatory uncertainty, and that public engagement is at least one important element in addressing such challenges. One is then confronted with how to achieve public engagement that is both meaningful and effective. In particular, how can public engagement on the topic of biobanking be implemented so that (a) it is perceived broadly as legitimate and (b) the results of the engagement are relevant and useful to the institutional and regulatory context? In this paper we build on previous work that has addressed the former point and focus primarily on the latter. We argue that one way to increase the likelihood of results of public engagement being taken up in policy is through framing the issues that are deliberated by members of the public based in part on the practical policy questions for which input is sought. In this approach, we move discussion on the social and ethical implications of biobanking from abstract principles, to their consideration in the context of local biobanking practices. This is illustrated using a practical example involving a public engagement conducted to inform institutional policy for biobanking in British Columbia, Canada.

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Meslin, Eric M
The value of using top-down and bottom-up approaches for building trust and transparency in biobanking.
Public health genomics 2010; 13(4): 207–14

Abstract: With the domestic and international proliferation of biobanks and their associated connections to health information databases, scholarly attention has been turning from the ethical issues arising from the construction of biobanks to the ethical issues that emerge in their operation and management. Calls for greater transparency in governance structures, coupled with stern reminders of the value of maintaining public trust, are seen as critical components in the success of these resources. Two different approaches have been adopted for addressing these types of ethical issues: the first is a 'top-down' approach which focuses on developing policy, procedures, regulations and guidelines to aid decision-makers. The second is a 'bottom-up' approach, which begins with those who are most affected by the issues and attempts to inductively develop consensus recommendations and policy. While both approaches have merit, I argue that more work needs to be done on 'bottom-up' strategies if trust and transparency are to be more than mere slogans. Using 2 case examples from Indiana, the paper summarizes data from a set of surveys we recently conducted that address issues arising from biobanks that provide some insight into issues
associated with trust and transparency.


Document 279
Knoppers, Bartha Maria; Leroux, T; Doucet, H; Godard, B; Laberge, C; Stanton-Jean, M; Fortin, S; Cousineau, J; Monardes, C; Girard, N; Levesque, L; Durand, C; Farmer, Y; Dion-Labrie, M; Bouthillier, M-E; Avard, D

Framing genomics, public health research and policy: points to consider.
Public health genomics 2010; 13(4): 224-34

Abstract: Genetic information can be used to target interventions that improve health and prevent disease. Indeed, the results of population genomics research could be useful for public health and national pandemic plans. Yet, firm scientific evidence originating from such research and the indicators of the role of health determinants, gene-gene and gene-environment interaction remain to be assessed and validated before being integrated into pandemic plans or public health programmes. It is not clear what is the role of the State in research on the elucidation of the determinants of gene-gene and gene-environment interactions and how, when, and if such data can be accessed and used for such planning. Over a period of 3 years, we sought to address these questions by gathering data and literature relevant to research in public health genomics, preparing issues papers and, finally, consulting with stakeholders on a provisional 'points to consider' document at various times. Examining in turn the issues of privacy, State powers, stakeholder perceptions, and public participation, we propose in this article, for each of these themes, a series of recommendations aiming to provide guidance on the role of the State in the use of genomic information for public health research, prevention and planning.


Document 280
Lippi, Giuseppe; Longo, Umile Giuseppe; Maffulli, Nicola

Genetics and sports.
British medical bulletin 2010; 93: 27-47

Abstract: INTRODUCTION: The limit of each individual to perform a given type of exercise depends on the nature of the task, and is influenced by a variety of factors, including psychology, environment and genetic make up. Genetics provide useful insights, as sport performances can be ultimately defined as a polygenic trait. SOURCES OF DATA: We searched PubMed using the terms 'sports' and 'genetics' over the period 1990 to present. AREAS OF AGREEMENT: The physical performance phenotypes for which a genetic basis can be suspected include endurance capacity, muscle performance, physiological attitude to train and ability of tendons and ligaments to withstand injury. Genetic testing in sport would permit to identify individuals with optimal physiology and morphology, and also those with a greater capacity to respond/adapt to training and a lesser chance of suffering from injuries. AREAS OF CONTROVERSY: Ethical and practical caveats should be clearly emphasized. The translation of an advantageous genotype into a champion's phenotype is still influenced by environmental, psychological and sociological factors. EMERGING AREAS FOR DEVELOPING RESEARCH: The current scientific evidence on the relationship between genetics and sports look promising. There is a need for additional studies to determine whether genome-wide genotyping arrays would be really useful and cost-effective. Since exercise training regulates the expression of genes encoding various enzymes in muscle and other tissues, genetic research in sports will help clarify several aspects of human biology and physiology, such as RNA and protein level regulation under specific circumstances.


Document 281
Mayor, Susan

Commission agrees framework to regulate genetic tests sold direct to consumers.
BMJ (Clinical research ed.) 2010 340(): c2752

Georgetown users check Georgetown Journal Finder for access to full text
Kim, Pauline T.

**Regulating the use of genetic information: perspectives from the U.S. experience**


Georgetown users check [Georgetown Journal Finder](http://ssrn.com/abstract=1625490) for access to full text

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O'Leary, Peter; Zimmern, R.L.

**Genomics and public health: translating research into public benefit. [editorial]**


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Knoppers, Bartha Maria; Leroux, T.; Doucet, H.; Godard, B.; Laberge, C.; Stanton-Jean, M.; Fortin, S.; Cousineau, J.; Monardes, C.; Girard, N.; Levesque, L.; Durand, C.; Farmer, Y.; Dion-Labrie, M.; Bouthillier, M.-E.; Avard, D.

**Framing genomics, public health research and policy: points to consider.**

Public Health Genomics 2010; 13(4): 224-234

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Devettere, Raymond J.

**Medical genetics**


Call number: R724 .D48 2010

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Hodgkinson, Kathy; Pullman, Daryl

**Duty to warn and genetic disease.**


**Abstract:** In this clinical column, we discuss the ambiguous distinction between genetic research and clinical genetics, particularly for Mendelian diseases with high recurrence risk, high morbidity and/or mortality and the possible amelioration of such diseases by screening or treatment. We use arrhythmogenic right ventricular cardiomyopathy as an example of a lethal Mendelian disorder, which prompted the discussion contained in this column. Working with such diseases may mean that genetic researchers have some responsibility for both immediate research subjects and their extended families, as they obtain molecular genetic information. For some diseases, therefore, a willingness to accept genetic research results should be an inclusion criterion, and it may be considered unethical for research ethics boards to approve genetic studies unless measures to ensure clinical follow-
up have been established. We recommend managing the tensions between genetic research and clinical practice by using disease-based genetic registers, organized within a clinical genetic service.

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**Document 287**

Dolgin, Elie

**The genome finishers.**

*Nature* 2009 December 17; 462(7275): 843-845

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http://www.nature.com/nature/journal/v462/n7275/ (link may be outdated)

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**Document 288**

Bedau, Mark A; Parke, Emily C; Tangen, Uwe; Hantsche-Tangen, Brigitte

**Social and ethical checkpoints for bottom-up synthetic biology, or protocells.**

*Systems and synthetic biology* 2009 Dec; 3(1-4): 65-75

**Abstract:** An alternative to creating novel organisms through the traditional "top-down" approach to synthetic biology involves creating them from the "bottom up" by assembling them from non-living components; the products of this approach are called "protocells." In this paper we describe how bottom-up and top-down synthetic biology differ, review the current state of protocell research and development, and examine the unique ethical, social, and regulatory issues raised by bottom-up synthetic biology. Protocells have not yet been developed, but many expect this to happen within the next five to ten years. Accordingly, we identify six key checkpoints in protocell development at which particular attention should be given to specific ethical, social and regulatory issues concerning bottom-up synthetic biology, and make ten recommendations for responsible protocell science that are tied to the achievement of these checkpoints.

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**Document 289**

Kaneshiro, Julie

**OHRP's guidance on GINA: Genetic Information Nondiscrimination Act has research exceptions**

*Protecting Human Subjects* 2009 Winter; (19): 7

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http://humansubjects.energy.gov/doe-resources/newsletter/ (link may be outdated)

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**Document 290**

Murphy, Juli; Scott, Joan; Kaufman, David; Geller, Gail; LeRoy, Lisa; Hudson, Kathy

**Public perspectives on informed consent for biobanking.**

*American Journal of Public Health* 2009 December; 99(12): 2128-2134

**Abstract:** The National Institutes of Health and other federal health agencies are considering establishing a national biobank to study the roles of genes and environment in health. We assessed the public's attitudes toward the proposed biobank, including preferences for providing informed consent. Sixteen focus groups were conducted, and themes arising from the focus groups were tested in a large, representative survey (n=4659) of the general population. Our research demonstrates that when considering participating in a genomic biobank, individuals want ongoing choices and control over access to their samples and information.
Jegede, Ayodele S.

**Culture and genetic screening in Africa**

Developing World Bioethics 2009 December; 9(3): 128-137

*Abstract:* Africa is a continent in transition amidst a revival of cultural practices. Over previous years the continent was robbed of the benefits of medical advances by unfounded cultural practices surrounding its cultural heritage. In a fast moving field like genetic screening, discussions of social and policy aspects frequently need to take place at an early stage to avoid the dilemma encountered by Western medicine. This paper, examines the potential challenges to genetic screening in Africa. It discusses how cultural practices may affect genetic screening. It views genomics science as a culture which is trying to diffuse into another one. It argues that understanding the existing culture will help the diffusion process. The paper emphasizes the importance of genetic screening for Africa, by assessing the current level of burden of diseases in the continent and shows its role in reducing disease prevalence. The paper identifies and discusses the cultural challenges that are likely to confront genetic screening on the continent, such as the worldview, rituals and taboos, polygyny, culture of son preference and so on. It also discusses cultural practices that may promote the science such as inheritance practices, spouse selection practices and naming patterns. Factors driving the cultural challenges are identified and discussed, such as socialization process, patriarchy, gender, belief system and so on. Finally, the paper discusses the way forward and highlights the ethical considerations of doing genetic screening on the continent. However, the paper also recognizes that African culture is not monolithic and therefore makes a case for exceptions.

Kaiser, Jocelyn

**Biotechnology. Bankruptcy won't stop deCODE, says its founder, Stefánsson.**

Science 2009 November 27; 326(5957): 1172

Edelman, Emily; Eng, Charis

**A practical guide to interpretation and clinical application of personal genomic screening**

BMJ: British Medical Journal 2009 November 14; 339(7730): 1136-1140

Ardaillou, Raymond

**[Transgenic mice: a major advance in biomedical research] = Les souris transgéniques: un progrès dans la recherche biomédicale.**

Abstract: Transgenic mice bear stable, artificially induced genetic modifications that are transmitted to their offspring. They are prepared from cultured embryonic stem cells isolated from blastocysts. The stem cells are then transfected with a vector comprising a selection cassette and the sequence to be introduced, modified or suppressed, lying between two sequences identical to those flanking the target gene. The target gene is thereby "knocked out" and replaced by the selection cassette, through homogeneous recombination. Cells in which recombination has successfully taken place are sorted by detecting the selection cassette, and are injected into an embryo. This results in so-called mosaic mice which, after crossing, will give birth to mice that are either heterozygous or homozygous for the knocked out gene. A variety of genomic modifications can be obtained with this approach, including gene knock-out, insertion of multiple gene copies, introduction of a reporter gene under the control of the promoter of the gene of interest, and "conditional" mutations that are expressed in a given tissue or for a specific period of time. Transgenic mice can be used to examine the phenotype resulting from a null mutation or from the introduction of multiple gene copies, as well as factors controlling the synthesis of a specific protein, the phenotypic consequences of point mutations, and the genes involved in embryo development. Institutes have been created specifically to phenotype transgenic mice, frequently using non invasive techniques. The results thus obtained are collected in databases, thus allowing scientists to determine the minimal number of animals necessary for a given experiment.

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Document 295

Raz, Aviad E; Schicktanz, Silke

Diversity and uniformity in genetic responsibility: moral attitudes of patients, relatives and lay people in Germany and Israel.

Medicine, health care, and philosophy 2009 Nov; 12(4): 433-42

Abstract: The professional and institutional responsibility for handling genetic knowledge is well discussed; less attention has been paid to how lay people and particularly people who are affected by genetic diseases perceive and frame such responsibilities. In this exploratory study we qualitatively examine the attitudes of lay people, patients and relatives of patients in Germany and Israel towards genetic testing. These attitudes are further examined in the national context of Germany and Israel, which represent opposite regulatory approaches and bioethical debates concerning genetic testing. Three major themes of responsibility emerged from the inter-group and cross-cultural comparison: self-responsibility, responsibility for kin, and responsibility of society towards its members. National contrast was apparent in the moral reasoning of lay respondents concerning, for example, the right not to know versus the duty to know (self-responsibility) and the moral conflict concerning informing kin versus the moral duty to inform (responsibility for kin). Attitudes of respondents affected by genetic diseases were, however, rather similar in both countries. We conclude by discussing how moral discourses of responsibility are embedded within cultural (national, religious) as well as phenomenological (being affected) narratives, and the role of public engagement in bioethical discourse.

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Document 296

Raz, Aviad E.; Schicktanz, Silke

Diversity and uniformity in genetic responsibility: moral attitudes of patients, relatives and lay people in Germany and Israel.

Medicine, Health Care, and Philosophy 2009 November; 12(4): 433-442

Abstract: The professional and institutional responsibility for handling genetic knowledge is well discussed; less attention has been paid to how lay people and particularly people who are affected by genetic diseases perceive and frame such responsibilities. In this exploratory study we qualitatively examine the attitudes of lay people, patients and relatives of patients in Germany and Israel towards genetic testing. These attitudes are further examined in the national context of Germany and Israel, which represent opposite regulatory approaches and bioethical debates concerning genetic testing. Three major themes of responsibility emerged from the inter-group and cross-cultural comparison: self-responsibility, responsibility for kin, and responsibility of society towards its members. National contrast was apparent in the moral reasoning of lay respondents concerning, for example, the right not to know versus the duty to know (self-responsibility) and the moral conflict concerning informing kin versus the moral duty to inform (responsibility for kin). Attitudes of respondents affected by genetic diseases were, however, rather similar in both countries. We conclude by discussing how moral discourses of responsibility are embedded within cultural (national, religious) as well as phenomenological (being affected) narratives, and the role of public engagement in bioethical discourse.
(national, religious) as well as phenomenological (being affected) narratives, and the role of public engagement in bioethical discourse.

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http://www.springerlink.com/content/102960/ (link may be outdated)

Document 297
Genetics without borders [editorial]
Nature 2009 October 8; 461(7265): 697

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http://www.nature.com/nature/ (link may be outdated)

Document 298
Ng, Pauline C.; Murray, Sarah S.; Levy, Samuel; Venter, J. Craig
An agenda for personalized medicine
Nature 2009 October 8; 461(7265): 724-726

Georgetown users check Georgetown Journal Finder for access to full text

http://www.nature.com/nature/ (link may be outdated)

Document 299
Lahn, Bruce T.; Ebenstein, Lanny
Let's celebrate human genetic diversity
Nature 2009 October 8; 461(7265): 726-728

Georgetown users check Georgetown Journal Finder for access to full text

http://www.nature.com/nature/ (link may be outdated)

Document 300
Bathe, Oliver F.; McGuire, Amy L.
The ethical use of existing samples for genome research
Genetics in Medicine 2009 October; 11(10): 712-715

Georgetown users check Georgetown Journal Finder for access to full text

http://www.nature.com/nature/ (link may be outdated)

Document 301
Eberl, Jason T.; Ballard, Rebecca A.
Metaphysical and ethical perspectives on creating animal-human chimeras
Journal of Medicine and Philosophy 2009 October; 34(5): 470-486

Abstract: This paper addresses several questions related to the nature, production, and use of animal-human (a-h) chimeras. At the heart of the issue is whether certain types of a-h chimeras should be brought into existence, and, if they are, how we should treat such creatures. In our current research environment, we recognize a dichotomy between research involving nonhuman animal subjects and research involving human subjects, and the classification
of a research protocol into one of these categories will trigger different ethical standards as to the moral permissibility of the research in question. Are a-h chimeras entitled to the more restrictive and protective ethical standards applied to human research subjects? We elucidate an Aristotelian-Thomistic metaphysical framework in which to argue how such chimeras ought to be defined ontologically. We then examine when the creation of, and experimentation upon, certain types of a-h chimeras may be morally permissible.
**Abstract:** The person from whom body materials were collected, first becomes their owner in analogy to section 953 German Civil Code. This applies also if the body materials were taken within the framework of a treatment contract and remain there after the treatment/diagnosis have ended. Only if an explicit consent of the patient was given to the effect that the body materials are to be owned by the clinic/doctor, only then is it possible to transfer ownership. A conclusive transfer of ownership does not occur. A complete anonymisation makes the body materials ownerless since an assignment to a person is not possible any longer. In this case, the former carrier of the body materials has no further chance to make claim to any rights. In that case, science and biotechnological industry are free to utilize the body materials. The former carrier of the body materials may make claims to benefit sharing only if instead of an anonymisation only a pseudonymisation takes place. However, it is common practice that the payment for damages according to existing rights to benefit sharing after unlawful use is quite small. Only a trustee model could achieve that property rights be observed, that personal or personality rights are protected in the best possible manner and that proper benefit sharing be done.

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**Document 307**

Commin, Virginie

**Legal issues surrounding French research-focused biobanks.**

Journal international de bioéthique = International journal of bioethics 2009 Sep; 20(3): 69-86, 149

**Abstract:** The French law does not name them expressly under this word; nevertheless the legislator provided them recently with a relatively interconnected legal framework. On one hand, the technical specific rules related to the activities of biobanks (on which conditions a biobank can be established, on which conditions samples can be given thereto). On the other hand, there is an application to biobanks of the big principles of "French-style" bioethics: 'non property' principle, informed consent and data confidentiality principles. We shall show that in so doing, the French legislator grasped and answered the main part of the questions raised and so paved the way for a sustained activity of biobanks in France. In spite of this dense legal framework, the law has not anticipated at present all the questions arising from the practice of biobanks, notably the rights of the donors such as an on-going control on the use of biological material and associated data they gave for research purposes, as well as researchers' right to access biobanks and current issues related to ownership. We shall thus discover the French legal framework for biobanks used for research purposes. Then we shall try to clear issues remaining unresolved.

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**Document 308**

Simon, Jürgen; Robienski, Jürgen

**Framework for setting up and operating biobanks.**


**Abstract:** With regard to the use of bio materials, there is a great need for clarification of the legal ramifications. And since procuring and storing bio materials is becoming an increasingly important point for answering molecular-genetic questions within medical research, finding an answer soon for the related legal and organisational questions is extremely important. This article examines the modern uses of bio materials, suitable types of legal entity for biobanks as well as questions related to ownership of samples.

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**Document 309**

Simon, Jürgen; Robienski, Jürgen

**Property, personality rights and data protection with regard to biobanks -- a layered system.**


**Abstract:** The person from whom body materials were collected, first becomes their owner in analogy to section 953 German Civil Code. This applies also if the body materials were taken within the framework of a treatment contract and remain there after the treatment/diagnosis have ended. Only if an explicit consent of the patient was given to the effect that the body materials are to be owned by the clinic/doctor, only then is it possible to transfer ownership. A
conclusive transfer of ownership does not occur. A complete anonymisation makes the body materials ownerless since an assignment to a person is not possible any longer. In that case, the former carrier of the body materials has no further chance to make claim to any rights. In that case, science and biotechnological industry are free to utilize the body materials. The former carrier of the body materials may make claims to benefit sharing only if instead of an anonymisation only a pseudonymisation takes place. However, it is common practice that the payment for damages according to existing rights to benefit sharing after unlawful use is quite small. Only a trustee model could achieve that property rights be observed, that personal or personality rights are protected in the best possible manner and that proper benefit sharing be done.

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Document 310

Commin, Virginie

**Legal issues surrounding French research-focused biobanks.**


**Abstract:**
The French law does not name them expressly under this word; nevertheless the legislator provided them recently with a relatively interconnected legal framework. On one hand, the technical specific rules related to the activities of biobanks (on which conditions a biobank can be established, on which conditions samples can be given thereto). On the other hand, there is an application to biobanks of the big principles of "French-style" bioethics: 'non property' principle, informed consent and data confidentiality principles. We shall show that in so doing, the French legislator grasped and answered the main part of the questions raised and so paved the way for a sustained activity of biobanks in France. In spite of this dense legal framework, the law has not anticipated at present all the questions arising from the practice of biobanks, notably the rights of the donors such as an on-going control on the use of biological material and associated data they gave for research purposes, as well as researchers' right to access biobanks and current issues related to ownership. We shall thus discover the French legal framework for biobanks used for research purposes. Then we shall try to clear issues remaining unresolved.

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Document 311

Petrini, Carlo

**A bibliography concerning informed consent and biobanking: documents from national and international bodies.**


**Abstract:**
The article contains a list of national and international documents addressing the ethical aspects of biobanking, which were drafted by national bioethics committees; national ad hoc commissions; and national and international agencies, organizations, and societies. The greater part of the documents specifically focuses on questions involving the ethics of informed consent for biobanking. The documents are grouped according to the nature of the promulgating body, and are listed alphabetically within each group according to the promulgating body. Special attention is devoted to documents issued by the European Union and the Council of Europe.

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Document 312

Marturano, Antonio

**When speed truly matters, openness is the answer.**

Bioethics 2009 September; 23(7): 385-393

**Abstract:**
In this paper I analyse the ethical implications of the two main competing methodologies in genomic research. I do not aim to provide another contribution from the mainstream legal and public policy perspective; rather I offer a novel approach in which I analyse and describe the patent-and-publish regime (the proprietary regime) led by biologist J. Craig Venter and the 'open-source' methodologies led by biotechnology Nobel laureate John Sulston. The 'open-source methodologies' arose in biotechnology as an alternative to the patent-and-publish regime in the wake of the explosion in computer technology. Indeed, the tremendous increase in computer technology has generated a
corresponding increase in the pace of genomics research. I conclude this paper by arguing that while the patent-and-publish method is a transactional method based on the exchange of extrinsic goods (patents in exchange for research funds), the free and open-source methodology (FLOSS) is a transformational method based on a visionary ideal of science, which leads to prioritizing intrinsic goods in scientific research over extrinsic goods.

Document 313
Gurwitz, David; Fortier, Isabel; Lunshof, Jeantine E.; Knoppers, Bartha Maria
Children and population biobanks.
Science 2009 August 14; 325(5942): 818-819

Document 314
Foster, Morris W.; Mulvihill, John J.; Sharp, Richard R.
Evaluating the utility of personal genomic information
Genetics in Medicine 2009 August; 11(8): 570-574

Document 315
Khoury, Muin J.; McBride, Colleen M.; Schully, Sheri D.; Ioannidis, John P.A.; Feero, W. Gregory; Janssens, A. Cecile J.W.; Gwinn, Marta; Simons-Morton, Denise G.; Berhardt, Jay M.; Cargill, Michele; Chanock, Stephen J.; Church, George M.; Coates, Ralph J.; Collins, Francis S.; Croyle, Robert T.; Davis, Barry R.; Downing, Gregory J.; Duross, Amy; Friedman, Susan; Gail, Mitchell H.; Ginsburg, Geoffrey S.; Green, Robert C.; Greene, Mark H.; Greenland, Philip; Gulcher, Jeffrey R.; Hsu, Andro, et al.
The scientific foundation for personal genomics: recommendations from a National Institutes of Health-Centers for Disease Control and Prevention multidisciplinary workshop
Genetics in Medicine 2009 August; 11(8): 559-567

Document 316
Grosse, Scott D.; McBride, Colleen M.; Evans, James P.; Khoury, Muin J.
Personal utility and genomic information: look before you leap
Genetics in Medicine 2009 August; 11(8): 575-576

Document 317
Verhoeff, R.P.; Moors, E.H.M.; Osseweijer, P.
Interactive communication in pharmacogenomics innovations: user-producer interaction from an innovation and science communication perspective

**Abstract:** Pharmacogenomics is a quickly evolving field of research that increasingly impacts individuals and society. As some innovations in biotechnology have experienced strong public opposition during the 1990s, interaction between producers and users of these innovations may help in increasing their success in social and economic terms. However, conditions for effective interaction have so far remained under-explored. This paper explores user-producer interactions in pharmacogenomics from an innovation and science communication perspective in the Netherlands. To find possible ways of engaging stakeholders in an early stage of technology development, ie, when science policy is in the making, we present communication activities derived from the field of policy analysis. To articulate motives for two-way public participation in genomics innovation processes, we describe two levels at which pharmacogenomics developments will have an input: 1) at the meso-level of medical practice with already established medical technologies, values and routines, suppliers and health professionals (general practitioners, pharmacists), and 2) at the macro-level of society at large, with established institutions, infrastructures, and broadly shared values and beliefs among citizens in general. Thereby we offer a starting point for optimising decision-making processes in the field of pharmacogenomics innovations, including important aims to be reached, stakeholders to be involved, and some criteria for designing interactive communication activities.

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**http://www.gspjournal.com** (link may be outdated)

Document 318

Schermer, Maartje

**Genomics, obesity and enhancement: moral issues regarding aesthetics and health**


**Abstract:** Human enhancement is the term used for applications of biomedical knowledge that aim to improve human form or functioning beyond what is necessary to restore or sustain good health. Genomics is one of the research-areas that promises to offer such possibilities in the near future, and body weight – especially over-weight and obesity - is one of the human characteristics at which these will be directed. This paper offers an overview of some of the moral issues that the subject of enhancement raises when related to obesity and genomics. After a brief discussion of the different perspectives on obesity and on the meaning of the term enhancement, a framework is presented in which the moral issues at stake are organised according to perspective on obesity (health or aesthetics) and moral outlook (distributive justice vs private morality). An inventory is made of the different ethical discussions that possible future genomics-based options for the prevention or treatment of obesity and overweight may evoke. These include justice, obligations with regard to life-style, the limits of medical practice and the value of food and food-cultures. Finally, some speculations are made with regard to future possibilities for genetic modification and "self-evolution".

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**http://www.gspjournal.com** (link may be outdated)

Document 319

Robins, Rosemary

**Inventing oncomice: making natural animal, research tool and invention cohere**


**Abstract:** This paper examines how the oncomouse became a patentable invention. The oncomouse began life in the laboratory, where it was genetically modified for use as a research tool to assist with the study of human cancer. Its design, a product of genetic modification, made the oncomouse potentially patentable subject matter. The United States was the first jurisdiction to award the patent and several others followed. However, the question of animal patenting was most contentious in Europe and Canada. In this paper I examine debates about animal patenting within the legal and moral spaces created by United States, European and Canadian patent law, focusing on differences that emerged in each case. I argue that oncomouse as a patentable invention was made possible and acceptable as different ways of being mouse as natural animal, research tool and invention were made to cohere: that is as they were made to overlap and depend upon one another. In the paper I use the term "cohere" to describe the logic of animal patenting that emerged with, and was essential to, the outcome in each jurisdiction. I describe an ontological politics of connecting and separating different ways of being mouse, as the oncomouse's genetic
modification, risks, benefits, and suffering were juxtaposed with patent law, precedent, laboratory protocols, and understandings of human agency and control. As connections and separations were made, a relation, “natural animal-research tool-invention”, was established, and logic of animal patenting emerged: but differently each case.

http://www.gspjournal.com (link may be outdated)
Aarden, Erik; Van Hoyweghen, Ine; Vos, Rein; Horstman, Klasien

Providing preimplantation genetic diagnosis in the United Kingdom, The Netherlands and Germany: a comparative in-depth analysis of health-care access.

Human Reproduction 2009 July; 24(7): 1542-1547

http://humrep.oxfordjournals.org/ (link may be outdated)
Document 326
Drabiak-Syed, Katherine

**State codification of federal regulatory ambiguities in biobanking and genetic research.**

[Georgetown Journal Finder](#) for access to full text

Document 327
United Kingdom. Academy of Medical Sciences

**Genome-wide association studies: understanding the genetics of common disease. Symposium report.**

[http://www.acmedsci.ac.uk/index.php?pid=114](http://www.acmedsci.ac.uk/index.php?pid=114) (link may be outdated)

Document 328
Toccaceli, Virgilia; Fagnani, Corrado; Nisticò, Lorenza; D'Ippolito, Cristina; Giannantonio, Lorenzo; Brescianini, Sonia; Stazi, Maria Antonietta

**Research understanding, attitude and awareness towards biobanking: a survey among Italian twin participants to a genetic epidemiological study.**
BMC Medical Ethics [electronic] 2009 June 16; 10: 4

**Abstract:** BACKGROUND: The Italian Twin Registry (ITR) has been carrying out several genetic-epidemiological studies. Collection and storage of biological material from study participants has recently increased in the light of biobanking development. Within this scenario, we aimed at investigating understanding, awareness and attitude towards blood/DNA donation of research participants. About these quite unknown dimensions more knowledge is needed from ethical and social perspectives. METHODS: Cross-sectional mail survey to explore three dimensions: (i) understanding of aims and method of a specific study, (ii) attitude (three ideas for donation: "moral duty", "pragmatism", "spontaneity") and (iii) awareness (i.e. the recall of having been asked to donate) towards blood/DNA donation for research, among all the Italian twins who had participated in Euroclot (n = 181), a large international genetic-epidemiological study. Multivariate models were applied to investigate the association of sex, age, education and modality of Euroclot recruitment (twins enrolled in the ITR and volunteers) with the targeted dimensions. Pairwise twin concordance for the "pragmatic" attitude was estimated in monozygotic and dizygotic pairs. RESULTS: Response rate was 56% (99 subjects); 75.8% understood the Euroclot method, only 33.3% correctly answered about the study aim. A significantly better understanding of aim and method was detected in "volunteers". Graduated subjects were more likely to understand study aim. In the overall sample, the "pragmatic" attitude to blood donation reached 76.8%, and biobanking awareness 89.9%. The latter was significantly higher among women. Monozygotic twins were more concordant than dizygotic twins for the "pragmatic" attitude towards blood/DNA donation for research. CONCLUSION: Level of understanding of aims and methods of a specific research project seems to vary in relation to modalities of approaching research; most of the twins are well aware of having been asked to donate blood for biobanking activities, and seem to be motivated by a "pragmatic" attitude to blood/DNA donation. Genetic influences on this attitude were suggested. The framing of interests and concerns of healthy participants to genetic-epidemiological studies should be further pursued, since research, particularly for "common diseases", is
increasingly relying on population surveys and biobanking.

Document 329
Bombard, Yvonne; Veenstra, Gerry; Friedman, Jan M.; Creighton, Susan; Currie, Lauren; Paulsen, Jane S.; Bottorff, Joan L.; Hayden, Michael R.
The Canadian Respond-HD Collaborative Research Group
Perceptions of genetic discrimination among people at risk for Huntington's disease: a cross sectional survey
BMJ: British Medical Journal 2009 June 13; 338(7708): 1431

Document 330
Tomasson, Michael
Legal, ethical, and conceptual bottlenecks to the development of useful genomic tests.
Annals of health law / Loyola University Chicago, School of Law, Institute for Health Law 2009 Summer; 18(2): 231-60, 8 p. preceding i

Abstract: This article discusses advances in genomic research in the context of the debate surrounding gene patent rights and the limited rights of patient-participants in translational research. In addition, the author explores statutory and regulatory hurdles to advances in disease diagnosis, such as the Bayh-Dole Act, Medicare Legislation, and the Health Insurance Portability and Accountability Act. The author questions the effectiveness of increasingly commercialized academic research and the limited success of the private sector in genomic research. The author concludes that future genomic research will require significantly increased patient participation, which may necessitate a reshaping of the pharmaceutical approach to medicine and the limited stake that patients have in the breakthroughs developed through their participation in the process.

Document 331
Murphy, Eleanor; Thompson, Azure
An exploration of attitudes among black Americans towards psychiatric genetic research.
Psychiatry 2009 Summer; 72(2): 177-194

Document 332
Knoppers, Bartha Maria Knoppers
Return of "Accurate" and "Actionable" Results: Yes!
Document 333
Wasson, Katherine
Direct-to-Consumer Genomics and Research Ethics: Should a More Robust Informed Consent Process Be Included?
American Journal of Bioethics 2009 June-July; 9(6-7): 56-58
Georgetown users check Georgetown Journal Finder for access to full text
http://dx.doi.org/10.1080/15265160902893965 (link may be outdated)

Document 334
Hall, Wayne; Gartner, Coral
Direct-to-Consumer Genome-Wide Scans: Astrologicogenomics or Simple Scams?
American Journal of Bioethics 2009 June-July; 9(6-7): 54-56
Georgetown users check Georgetown Journal Finder for access to full text
http://dx.doi.org/10.1080/15265160902894021 (link may be outdated)

Document 335
Malm, Heidi
Genetic Privacy: Might There Be a Moral Duty to Share One's Genetic Information?
American Journal of Bioethics 2009 June-July; 9(6-7): 52-54
Georgetown users check Georgetown Journal Finder for access to full text
http://dx.doi.org/10.1080/15265160902923440 (link may be outdated)

Document 336
Reid, Lynette
Networking Genetics, Populations, and Race
American Journal of Bioethics 2009 June-July; 9(6-7): 50-52
Georgetown users check Georgetown Journal Finder for access to full text
http://dx.doi.org/10.1080/15265160902893957 (link may be outdated)

Document 337
Caulfield, Timothy
Direct-To-Consumer Genetics and Health Policy: A Worst-Case Scenario?
American Journal of Bioethics 2009 June-July; 9(6-7): 48-50
Georgetown users check Georgetown Journal Finder for access to full text
http://dx.doi.org/10.1080/15265160902918770 (link may be outdated)
**Document 343**
Bonham, Vence L.; Citrin, Toby; Modell, Stephen M.; Franklin, Tené Hamilton; Bleicher, Esther W.B.; Fleck, Leonard M.

**Community-based dialogue: engaging communities of color in the United States' genetics policy conversation.**
Journal of Health Politics, Policy and Law 2009 June; 34(3): 325-359

**Abstract:** Engaging communities of color in the genetics public policy conversation is important for the translation of genetics research into strategies aimed at improving the health of all. Implementing model public participation and consultation processes can be informed by the Communities of Color Genetics Policy Project, which engaged individuals from African American and Latino communities of diverse socioeconomic levels in the process of "rational democratic deliberation" on ethical and policy issues stretching from genome research to privacy and discrimination concerns to public education. The results of the study included the development of a participatory framework based on a combination of the theory of democratic deliberation and the community-based public health model which we describe as "community-based dialogue."

**Document 344**

**Time to connect [editorial]**
Nature 2009 May 28; 459(7246): 483

**Document 345**
Scheller, Richard; Miller, Greg

**Defying skeptics, Richard Scheller thinks Genentech will thrive. Interview by Greg Miller.**
Science 2009 May 1; 324(5927): 583

**Document 346**
Kaye, Jane; Heeney, Catherine; Hawkins, Naomi; de Vries, Jantina; Boddington, Paula

**Data sharing in genomics–re-shaping scientific practice.**
Nature Reviews. Genetics 2009 May; 10(5): 331-335

**Document 347**
Griffith, Gethin L.; Morrison, Val; Williams, J. Mark G.; Edwards, Rhiannon Tudor
Can we assume that research participants are utility maximisers?

Knoppers, Bartha Maria
Genomics and policymaking: from static models to complex systems?
Human Genetics 2009 May ; 125(4): 375-379

Vermeulen, Eric; Schmidt, Marjanka K.; Aaronson, Neil K.; Kuenen, Marianne; van Leeuwen, Flora E.
Obtaining 'fresh' consent for genetic research with biological samples archived 10 years ago.
European Journal of Cancer 2009 May; 45(7): 1168-1174

Yarborough, Mark; Sharp, Richard R.
Public trust and research a decade later: what have we learned since Jesse Gelsinger's death?
Molecular Genetics and Metabolism 2009 May; 97(1): 4-5

Christiansen, Karin
The silencing of Kierkegaard in Habermas' critique of genetic enhancement
Medicine, Health Care, and Philosophy 2009 May; 12(2): 147-156

Abstract: The main purpose of this paper is to draw attention to an important part of Habermas' critique of genetic enhancement, which has been largely ignored in the discussion; namely his use of Kierkegaard's reflections on the existential conditions for becoming one-self from Either/or and the Sickness unto Death. It will be argued that, although Habermas presents some valuable and highly significant perspectives on the effect of genetic enhancement on the individual's self-understanding and ability to experience him- or herself as a free and equal individual, he does not succeed in working out a consistent argument. The claim is that he fails to explain how the existential analysis is related to his reflections on the sociological and psychological impacts of genetic enhancement in the realm of communicative action. It is this lack of theoretical clarity, which seems to render Habermas vulnerable to some of the critique which has been raised against his theory from a number of different scientific disciplines and areas of research. Hence, the first part of the paper provides some examples of the nature and variety of this critique, the second part presents Habermas' own critique of genetic enhancement in the context of a dispute between so-called 'liberal' and 'conservative' arguments, and finally, the third part discusses the limits and possibilities of his position in a future debate about genetic enhancement.
Document 352
Kaufman, David; Murphy, Juli; Erby, Lori; Hudson, Kathy; Scott, Joan
Veterans' attitudes regarding a database for genomic research
Genetics in Medicine 2009 May; 11(5): 329-337
Georgetown users check Georgetown Journal Finder for access to full text

Document 353
An afternoon at UK Biobank. [editorial]
Lancet 2009 April 4; 373(9670): 1146
Georgetown users check Georgetown Journal Finder for access to full text

Document 354
Dal-Re, R.; Luque, I; Torres, R.; Lahuerta, J.
Drug development: assessment of pharmacogenetic studies by Spanish research ethics committees.
Pharmacogenomics Journal 2009 April; 9(2): 86-89
Georgetown users check Georgetown Journal Finder for access to full text

Document 355
Rothstein, Mark A.; Cai, Yu; Marchant, Gary E.
Ethical implications of epigenetics research.
Nature Reviews Genetics 2009 April; 10(4): 224
Georgetown users check Georgetown Journal Finder for access to full text

Document 356
Bonham, Vence L.; Sellers, Sherrill L.; Gallagher, Thomas H.; Frank, Danielle; Odunlami, Adebola O.; Price, Eboni G.; Cooper, Lisa A.
Physicians' attitudes toward race, genetics, and clinical medicine
Genetics in Medicine 2009 April; 11(4): 279-286
Georgetown users check Georgetown Journal Finder for access to full text

Document 357
Arribas-Ayllon, Michael; Sarangi, Srikant; Clarke, Angus
Professional ambivalence: accounts of ethical practice in childhood genetic testing
Journal of Genetic Counseling 2009 April; 18(2): 173-184
Document 358

Farrelly, Colin

Preimplantation genetic diagnosis, reproductive freedom, and deliberative democracy.
Journal of Medicine and Philosophy 2009 April; 34(2): 135-154

Abstract: In this paper I argue that the account of deliberative democracy advanced by Amy Gutmann and Dennis Thompson (1996, 2004) is a useful normative theory that can help enhance our deliberations about public policy in morally pluralistic societies. More specifically, I illustrate how the prescriptions of deliberative democracy can be applied to the issue of regulating non-medical uses of pre-implantation genetic diagnosis (PGD), such as gender selection. Deliberative democracy does not aim to win a philosophical debate among rival first-order theories, such as libertarianism, egalitarianism or feminism. Rather, it advances a second-order analysis that strives to help us determine what would constitute a reasonable balance between the conflicting fundamental values that arise in the context of regulating PGD. I outline a theoretical model (called the Reasonable Genetic Intervention Model) that brings these issues to the fore. Such a model incorporates the concern for both procedural and substantive principles; and it does so in a way that takes provisionality seriously.

Document 359

Ruiz-Canela, M.; Valle-Mansilla, J.I.; Sulmasy, D.P.

Researchers' preferences and attitudes on ethical aspects of genomics research: a comparative study between the USA and Spain
Journal of Medical Ethics 2009 April; 35(4): 251-257

Abstract: INTRODUCTION: The use of human samples in genomic research has increased ethical debate about informed consent (IC) requirements and the information that subjects should receive regarding the results of the research. However, there are no quantitative data regarding researchers' attitudes about these issues. METHODS: We present the results of a survey of 104 US and 100 Spanish researchers who had published genomic epidemiology studies in 61 journals during 2006. RESULTS: Researchers preferred a broader IC than the IC they had actually obtained in their published papers. US authors were more likely than their Spanish colleagues to support obtaining a broad IC, covering either any future research project or any projects related to a group of diseases (67.6% vs 43%; adjusted OR = 4.84, 95% CI, 2.32 to 10.12). A slight majority of researchers (55.8%) supported informing participants about individual genomic results only if the reliability and clinical validity of the information had been established. Men were more likely than women to believe that patients should be informed of research results even if these conditions were not met (adjusted OR = 2.89, 95% CI = 1.46 to 5.72). CONCLUSIONS: This study provides evidence of a wide range of views among scientists regarding some controversial ethical issues related to genomic research, suggesting the need for more study, debate and education. In the interim, journals might consider including the investigators' policies regarding these ethical issues in the papers they publish in the field of genomic epidemiology.

Document 360

Affleck, Paul

Is it ethical to deny genetic research participants individualised results?
Journal of Medical Ethics 2009 April; 35(4): 209-213
Abstract: This article examines a key ethical concern that has arisen in the work of the international research consortium GenoMEL (http://www.genomel.org) and that has relevance to all genetic research in humans. The question is whether it is ethical to deny research participants the opportunity to receive individualised genetic results obtained from the biological samples they provide. Where those results are of clinical importance, a "respect for persons" requirement would make the offering of those results imperative. However, where those results are of uncertain clinical value, the picture is less clear. This paper argues that researchers may not be ethically obliged to offer such results to their participants, because of competing ethical demands.

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http://jme.bmj.com (link may be outdated)

Document 361
Property rights. The granting of patents on human genes has so far not been the disaster it was predicted to be [editorial]
Nature 2009 March 26; 458(7237): 386

Georgetown users check Georgetown Journal Finder for access to full text

http://www.nature.com/nature (link may be outdated)

Document 362
Gaisser, Sibylle; Hopkins, Michael M.; Liddell, Kathleen; Zika, Eleni; Ibarreta, Dolores
The phantom menace of gene patents [commentary]
Nature 2009 March 26; 458(7237): 407-408

Georgetown users check Georgetown Journal Finder for access to full text

http://www.nature.com/nature (link may be outdated)

Document 363
Knight, Andrew J
Perceptions, knowledge and ethical concerns with GM foods and the GM process.
Public understanding of science (Bristol, England) 2009 Mar ; 18(2): 177-88
Abstract: Compared to their European counterparts, the American public has been characterized as relatively unknowledgeable and indifferent about genetically modified foods. To evaluate these claims, six focus groups were held in three Arkansas cities to: (1) determine the extent of knowledge the public possesses about genetically modified foods; (2) detail perceived benefits and risks associated with agricultural biotechnology applications; and (3) explore lay perceptions about the genetic modification process itself. Participants demonstrated partial knowledge, and tended to overestimate the number of genetically modified foods. However, participants tended to be familiar with debates surrounding benefits, risks and moral issues associated with agricultural biotechnology applications. Findings also showed that while participants were not overly concerned about combining genes between plants, they were concerned about inserting animal genes into plants. If these results are any indication, moral and ethical issues will dominate any discussion of foods derived from a mixture of animal and plant genes.

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Document 364
Ramsay, Lauren; Howe, David T.; Wellesley, Diana
Parental attitude to participating in long-term follow-up studies of their children's health after in utero diagnosis of abnormalities.
Georgetown users check [Georgetown Journal Finder](#) for access to full text.

### Document 365
Shyntum, Yvonne; Kalkreuter, Edward

**Stem cell patents--reexamination/litigation--the last 5 years.**


Georgetown users check [Georgetown Journal Finder](#) for access to full text.

### Document 366
Ertl, Hildegund

**The RAC: double, double, toil, and trouble? [editorial]**

Molecular Therapy 2009 March; 17(3): 397-399

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

http://www.nature.com/mt/ (link may be outdated)

### Document 367
Jones, David Albert

**What does the British public think about human-animal hybrid embryos?**

Journal of Medical Ethics 2009 March; 35(3): 168-170

**Abstract:** In the recent UK debate on the Human Fertilisation and Embryology Bill, there have been conflicting claims about the extent of public support for, or opposition to, human-animal hybrids. Self-selecting polls tend to show opposition to hybrids. Representative-sample polling shows spontaneous opposition but can elicit conditional approval of research, combined with underlying unease. Public opinion is very finely divided, with people generally opposed to this research unless it is likely to lead to medical advances.

Georgetown users check [Georgetown Journal Finder](#) for access to full text.

http://jme.bmj.com (link may be outdated)

### Document 368
Bussey-Jones, Jada; Henderson, Gail; Garrett, Joanne; Moloney, Mairead; Blumenthal, Connie; Corbie-Smith, Giselle

**Asking the right questions: views on genetic variation research among black and white research participants.**

Journal of General Internal Medicine 2009 March; 24(3): 299-304

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### Document 369
Pierce, Brandon L.; Carlson, Christopher S.; Kuszler, Patricia C.; Stanford, Janet L.; Austin, Melissa A.

**The impact of patents on the development of genome-based clinical diagnostics: an analysis of case studies.**

Genetics in Medicine 2009 March; 11(3): 202-209

Georgetown users check [Georgetown Journal Finder](#) for access to full text.
The HFEA public consultation process on hybrids and chimeras: informed, effective, and meaningful?

Baylis, Françoise

Abstract: In September 2007, the Human Fertilisation and Embryology Authority (HFEA) in the United Kingdom concluded that "there is no fundamental reason to prevent cytoplasmic hybrid research ... this area of research can, with caution and careful scrutiny, be permitted." Later, in January 2008, HFEA issued two research licenses to create humanesque cytoplasmic hybrid embryos from which stem cells could be derived. This article critically examines the public consultation process that preceded these decisions, concluding that the process was flawed and demonstrating how the HFEA documents summarizing the findings of the public consultation process misrepresent the public's contributions to this policymaking initiative.

Georgetown users check Georgetown Journal Finder for access to full text

Ancestry in translational genomic medicine: handle with care.

Gurwitz, David; Lunshof, Jeantine E.

Commercialization, patenting and genomics: researcher perspectives.

Murdoch, C.J.; Caulfield, Timothy

Christianity, health, and genetics

Smith, David H.

Religious and spiritual issues in medical genetics.

Fanning, Joseph B.; Clayton, Ellen Wright
Comité Consultatif de Bioéthique (Belgique) = Belgian Advisory Committee on Bioethics

Avis no. 45 du 19 janvier 2009 relatif aux banques de matériels corporels humains destinés à la recherche. Demande d'avis en date du 20 juin 2005, D'un centre de génétique humaine, relative à l'exploitation des banques d'ADN [Opinion no. 45 of 19 January 2009 on human tissue banks for research]

Bioethica Belgica 2009 February; (32): 1-23

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http://www.health.belgium.be/eportal/Healthcare/Consultativebodies/Commitees/Bioethics/Opinions/index.htm (link may be outdated)

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Laegsgaard, Mett Marri; Kristensen, Ann Suhl; Mors, Ole

Potential consumers' attitudes toward psychiatric genetic research and testing and factors influencing their intentions to test.

Genetic Testing and Molecular Biomarkers 2009 February; 13(1): 57-65

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Komduur, Rixt H.; Korthals, Michiel; te Molder, Hedwig

The good life: living for health and a life without risks? On a prominent script of nutrigenomics.


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Ozdemir, Vural; Suarez-Kurtz, Guilherme; Stenne, Raphaëlle; Somogyi, Andrew A; Someya, Toshiyuki; Kayaalp, S. O?uz; Kolker, Eugene

Risk assessment and communication tools for genotype associations with multifactorial phenotypes: the concept of "edge effect" and cultivating an ethical bridge between omics innovations and society.

Oomics 2009 February; 13(1): 43-61

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Ormond, K.E.; Cirino, A.L.; Helenowski, I.B.; Chisholm, R.L.; Wolf, W.A.

Assessing the understanding of biobank participants.


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http://www3.interscience.wiley.com/cgi-bin/fulltext/121657689/PDFSTART (link may be outdated)

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Secko, David M.; Preto, Nina; Niemeyer, Simon; Burgess, Michael M.
Informed consent in biobank research: a deliberative approach to the debate
Social Science and Medicine 2009 February; 68(4): 781-789

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Nicolás, Pilar
Ethical and juridical issues of genetic testing: a review of the international regulation.
Critical Reviews in Oncology/Hematology 2009 February; 69(2): 98-107

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Verhoeff, Roald; Boerwinkel, Dirk Jan; Waarlo, Arend Jan
Genomics in school. Science & society series on convergence research
EMBO Reports 2009 February; 10(2): 120-124

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Gitschier, Jane
Inferential genotyping of Y chromosomes in Latter­Day Saints founders and comparison to Utah samples in the HapMap project.
American Journal of Human Genetics 2009 February; 84(2): 251-258

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Avard, Denise; Silverstein, T.; Sillon, G.; Joly, Y.
Researchers' perceptions of the ethical implications of pharmacogenomics research with children.
Public Health Genomics 2009 February; 12(3): 191-201

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http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2790793/ (link may be outdated)

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Ilkilic, Ilhan; Paul, Norbert W.
Ethical aspects of genome diversity research: genome research into cultural diversity or cultural diversity in genome research?
Medicine, Health Care, and Philosophy 2009 February; 12(1): 25-34

Abstract: The goal of the Human Genome Diversity Project (HGDP) was to reconstruct the history of human evolution and the historical and geographical distribution of populations with the help of scientific research. Through this kind of research, the entire spectrum of genetic diversity to be found in the human species was to be explored with the hope of generating a better understanding of the history of humankind. An important part of this genome diversity research consists in taking blood and tissue samples from indigenous populations. For various reasons, it has not been possible to execute this project in the planned scope and form to date. Nevertheless, genomic diversity
research addresses complex issues which prove to be highly relevant from the perspective of research ethics, transcultural medical ethics, and cultural philosophy. In the article at hand, we discuss these ethical issues as illustrated by the HGDP. This investigation focuses on the confrontation of culturally diverse images of humans and their cosmologies within the framework of genome diversity research and the ethical questions it raises. We argue that in addition to complex questions pertaining to research ethics such as informed consent and autonomy of probands, genome diversity research also has a cultural-philosophical, meta-ethical, and phenomenological dimension which must be taken into account in ethical discourses. Acknowledging this fact, we attempt to show the limits of current guidelines used in international genome diversity studies, following this up by a formulation of theses designed to facilitate an appropriate inquiry and ethical evaluation of intercultural dimensions of genome research.

http://www.springerlink.com/content/102960/ (link may be outdated)

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Hofmann, Bjørn

Broadening consent -- and diluting ethics?
Journal of Medical Ethics 2009 February; 35(2): 125-129

Abstract: Biobank research is potentially fruitful. It is argued that broad consent is acceptable for future research on biological material because a) the benefit is high, b) it pays respect to people's autonomy, c) it is consistent with current practices and d) because the risk is low. Furthermore, broad consent should be allowed if information is handled safely, people can withdraw and expanded research should be approved by an ethics review board. However, these arguments are flawed and the criteria for broad consent are either too restrictive to allow any research or fail to address important challenges with biobank research. Broad consent for biobank research can hide substantial ethical challenges and threaten trust in research. This does not mean that biobank research should be abandoned or that people cannot authorise future research on donated biological material.

http://jme.bmj.com (link may be outdated)

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Hallowell, Nina; Cooke, S.; Crawford, G.; Parker, M.; Lucassen, A.

Healthcare professionals' and researchers' understanding of cancer genetics activities: a qualitative interview study.
Journal of Medical Ethics 2009 February; 35(2): 113-119

Abstract: AIMS: To describe individuals' perceptions of the activities that take place within the cancer genetics clinic, the relationships between these activities and how these relationships are sustained. DESIGN: Qualitative interview study. PARTICIPANTS: Forty individuals involved in carrying out cancer genetics research in either a clinical (n = 28) or research-only (n = 12) capacity in the UK. Findings: Interviewees perceive research and clinical practice in the subspecialty of cancer genetics as interdependent. The boundary between research and clinical practice is described as vague or blurred, and this ambiguity is regarded as being sustained by a range of methodological, ethical and economic factors. The implications of these findings for the "therapeutic misconception" are explored. It is argued that while research participation is seen as having therapeutic benefit for individual patients, the interviewees are not labouring under any misconceptions about the relationship between research and clinical care. It is suggested that concepts such as the "therapeutic misconception" may have less relevance in highly technological specialities that are characterised by a developing evidence base.

http://jme.bmj.com (link may be outdated)

Document 388
**Race and ancestry in biomedical research: exploring the challenges.**

Genome Medicine 2009 January 21; 1(1): 8

**Abstract:** The use of race in biomedical research has, for decades, been a source of social controversy. However, recent events, such as the adoption of racially targeted pharmaceuticals, have raised the profile of the race issue. In addition, we are entering an era in which genomic research is increasingly focused on the nature and extent of human genetic variation, often examined by population, which leads to heightened potential for misunderstandings or misuse of terms concerning genetic variation and race. Here, we draw together the perspectives of participants in a recent interdisciplinary workshop on ancestry and health in medicine in order to explore the use of race in research issue from the vantage point of a variety of disciplines. We review the nature of the race controversy in the context of biomedical research and highlight several challenges to policy action, including restrictions resulting from commercial or regulatory considerations, the difficulty in presenting precise terminology in the media, and drifting or ambiguous definitions of key terms.

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**Two cheers for GINA?**

Genome Medicine 2009 January 20; 1(1): 6

**Abstract:** The Genetic Information Nondiscrimination Act of 2008 (GINA) was recently enacted in the United States. Its supporters have applauded the passage of GINA, and they hope that it will alleviate public fear about genetic discrimination and facilitate genetic testing and participation in genetic research. Critics worry that GINA does not provide adequate protection because it fails to address discrimination on the basis of non-genetic health-related information, and it only regulates the use of genetic information in health insurance and employment. Despite these limitations, GINA represents a major step forward in US policy. Additional research is needed to assess the impact of GINA on industry practice and public opinion. In the mean time, education about GINA and its limitations can help individuals make more informed decisions about genetic testing and participation in genetic research.

Georgetown users check [Georgetown Journal Finder](http://genomemedicine.com/content/1/1/6) for access to full text

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**Racing forward: the Genomics and Personalized Medicine Act.**

Science 2009 January 16; 323(5912): 342

Supported by: NHGRI-funded publication; Grants K01 HL72465 and P50 HG003389

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**Ethics and biobanks.**

British Journal of Cancer 2009 January 13; 100(1): 8-12
Advancing civil rights, the next generation: the Genetic Information Nondiscrimination Act of 2008 and beyond.

Abstract: On the leading edge of civil rights law and bioethics/healthcare law, this Article provides the first law review analysis of the recently passed Genetic Information Nondiscrimination Act (GINA) of 2008, which extends important protection against discrimination in health insurance and employment. GINA also bolsters genetic research by freeing research subjects from the threat of genetic discrimination. This Article demonstrates how GINA further protects this society against the rising dangers of genetic discrimination beyond previously existing federal and state law.

The blurred distinction between treatable and untreatable conditions in newborn screening.

Abstract: Newborn screening is increasingly possible for conditions that do not have medical treatments that must be provided early in order to be effective. This raises a fundamental question of what information should be disclosed to parents. Historically the potential for treatment has been essential before conditions are included in newborn screening. Here I argue that the distinction between treatable and untreatable conditions is not a clear one and may be less useful in the future. I give examples of treatments that could be used even with "untreatable" conditions, envision a possible future of newborn screening, and suggest research and policy questions that need to be answered quickly so that screening can expand in a rational fashion.

Public attitudes to the storage of blood left over from routine general practice tests and its use in research.

Patient-tailored medicine, part two: personalized medicine and the legal landscape.
Educational and social-ethical issues in the pursuit of molecular medicine
Molecular Medicine 2009 January-February; 15(1-2): 60-63
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Samuel, Gabrielle N.; Selgelid, Michael J.; Kerridge, Ian
Managing the unimaginable. regulatory responses to the challenges posed by synthetic biology and synthetic genomics.
EMBO Reports 2009 January; 10(1): 7-11
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http://www.nature.com/embor/journal/v10/n1/ (link may be outdated)

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Schneider, Carl E.
Thou good and faithful servant.
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Document 399
Seavilleklein, Victoria
Challenging the rhetoric of choice in prenatal screening
Bioethics 2009 January; 23(1): 68-77
Abstract: Prenatal screening, consisting of maternal serum screening and nuchal translucency screening, is on the verge of expansion, both by being offered to more pregnant women and by screening for more conditions. The Society of Obstetricians and Gynaecologists of Canada and the American College of Obstetricians and Gynecologists have each recently recommended that screening be extended to all pregnant women regardless of age, disease history, or risk status. This screening is commonly justified by appeal to the value of autonomy, or women's choice. In this paper, I critically examine the value of autonomy in the context of prenatal screening to determine whether it justifies the routine offer of screening and the expansion of screening services. I argue that in the vast majority of cases the option of prenatal screening does not promote or protect women's autonomy. Both a narrow conception of choice as informed consent and a broad conception of choice as relational reveal difficulties in achieving adequate standards of free informed choice. While there are reasons to worry that women's autonomy is not being protected or promoted within the limited scope of current practice, we should hesitate before normalizing it as part of standard prenatal care for all.

Document 400
Bühl, Achim
AUF DEM WEG ZUR BIOMÄCHTIGEN GESELLSCHAFT? CHANCEN UND RISIKEN DER GENTECHNIK
Call number: QH438.7_A94 2009
**Document 401**

Bonnicksen, Andrea L.

**CHIMERAS, HYBRIDS, AND INTERSPECIES RESEARCH: POLITICS AND POLICYMAKING**


Call number: [QH445.7 .B66 2009](#)

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**Document 402**

Koepsell, David

**WHO OWNS YOU? THE CORPORATE GOLD-RUSH TO PATENT YOUR GENES**


Call number: [K1519 .B54 K64 2009](#)

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**Document 403**

Haugen, David M. and Musser, Susan, eds.

**GENETIC ENGINEERING**


Call number: [QH442 .G446 2009](#)

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**Document 404**

Caulfield, Timothy; Weijer, Charles

**Minimal risk and large-scale biobank and cohort research**


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**Document 405**

Conley, Dalton

**The promise and challenges of incorporating genetic data into longitudinal social science surveys and research.**

Biodemography and social biology 2009; 55(2): 238-51

**Abstract:** In this paper, I argue that social science and genomics can be integrated; however, the way this marriage is currently occurring rests on spurious methods and assumptions and, as a result, will yield few lasting insights. However, recent advances in both econometrics and in developmental genomics provide scientists with a novel opportunity to understand how genes and environment interact to produce social outcomes. Key to any causal inference about the interplay between genes and social environment is that either genotype be exogenously manipulated (i.e. through sibling fixed effects) while environmental conditions are held constant, and/or that environmental variation is exogenous in nature, i.e. experimental or arising from a natural experiment of sorts. Further, initial allele selection should be motivated by findings from genetic experiments in model animal studies linked to orthologous human genes. Likewise, genetic associations found in human population studies should then be tested through knock-out and over-expression studies in model organisms.

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**Document 406**

Greely, Henry T

**Collecting biomeasures in the Panel Study of Income Dynamics: ethical and legal concerns.**
**Abstract:** As social surveys like the Panel Study of Income Dynamics (PSID) consider adding biomeasures to their data collections, they will face complicated ethical, legal, and practical issues. Both fairly and not, research participants are likely to be more concerned about their biomeasures than about their social data. This heightened concern will force investigators to pay more attention to difficult issues such as the research participant's control over subsequent uses of the samples or data, the participant's right to withdraw from the project, protection of the research participant's privacy, return to the participant of important risk information gained through the research, some special issues involving children and families, and the process of informed consent. Investigators can navigate these issues successfully, but the effort will demand time, careful thought, and attention.

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**Document 407**

de Vrieze, Jop; Bouwman, Laura; Komduur, Rixt; Pin, Renske; Ronteltap, Amber; Vandeberg, Rens; van Dam, Frans; Penders, Bart

**Nutrition tailored to the individual? Not just yet - realigning nutrigenomic science with contemporary society.**

Journal of nutrigenetics and nutrigenomics 2009 2(4-5): 184-8

**Abstract:** About a decade ago, scientists and science journalists presented nutrigenomics as a grand promise that each of us would soon know which foods fit in our personal healthy diet. Meanwhile, expectations have been adjusted to fit a changed reality. Simultaneously, societal issues surrounding personalized nutrition continue to rise, including whether consumers need it, food industry can produce it, all relevant stakeholders are willing and able to work together, and if it is a desirable way to go for nutrition. The commentary below reports the main results of 6 research projects that focused on nutrigenomics and its role in society.

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Vandeberg, Rens L.J.; Boon, Wouter P.C.

**Anticipating emerging genomics technologies: the role of patents and publication for research and policy strategies**


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[http://www.gspjournal.com](http://www.gspjournal.com) (link may be outdated)

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**Document 409**

fat

al-Mâddah al-wirâthiyah: al-jínúm, qaāyyâ fiqhiyah (the hereditary material, genome: Islamic jurisprudential issues)


**Abstract:** This book contains several chapters that deal with shari Call number:

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**Document 410**

Herzfeld, Noreen L.

**Healing or enhancing?**


Call number: [BL265 .T4 H38 2009](#)
Document 411
Kerridge, Ian; Lowe, Michael; Stewart, Cameron
**Genetics and biotechnology**
Call number: [KU1520 .K47 2009](#)

Document 412
Williams-Jones, Bryn; Ozdemir, Vural
**Pharmacogenomic promises: reflections on semantics, genohype, and global justice**
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Geransar, Rose
**Banking on trust: issues of informed consent in pharmacogenetic research**
Call number: [T14.5 .E46 2009](#)

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Stingl, Lavinia; Völkel, Manfred; Lindl, Toni
**20 Years of hypertension research using genetically modified animals: no clinically promising approaches in sight.**
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Laurencot, Carolyn M.; Ruppel, Sheryl
**Regulatory aspects for translating gene therapy research into the clinic**
Methods in Molecular Biology 2009; 542: 397-421
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Kimmelman, Jonathan
**Ethics of cancer gene transfer clinical research**
Methods in Molecular Biology 2009; 542: 423-445
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Eskandarani, Hamza Ali
**Pre-implantation genetic diagnosis in the Gulf Cooperative Council countries: utilization and ethical attitudes**
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Borry, Pascal
Coming of age of personalized medicine: challenges ahead [meeting report]
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Mooney, Carla
Genetic testing and engineering
Call number: R724 .M664 2009

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Sutrop, Margit; Simm, Kadri
Public and private interests in the genomic era: a pluralist approach
Call number: BJ1581.2 .E85 2009 v. 4

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Rommetveit, Kjetil
Bioethics, biopower and the post-genomic challenge
Call number: BJ1581.2 .E85 2009 v. 4

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Karlsen, Jan Reinert; Strand, Roger
The ethical topography of research biobanking
Call number: BJ1581.2 .E85 2009 v. 4

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Skrikerud, Anne Marie; Grov, Jon
Puzzle-solving for fun and profit: the abusive potential of non-genetic health data in epidemiological biobanks
Call number: BJ1581.2 .E85 2009 v. 4
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Methodological considerations about the ethical and social implications of protocells
Call number: TP248.23 .E862 2009

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Hauskeller, Christine
Toward a critical evaluation of protocell research
Call number: TP248.23 .E862 2009

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Hessel, Andrew
Protocells, precaution, and open-source biology
Call number: TP248.23 .E862 2009

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Scully, Jackie Leach
Receiving and interpreting information: a joint enterprise
In: Rehmann-Sutter, Christoph; Müller, Hansjakob, eds. Disclosure Dilemmas: Ethics of Genetic Prognosis after the 'Right to Know/Not to Know' Debate. Farnham, England; Burlington, VT: Ashgate Pub., 2009: 205-217
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Lock, Margaret
Testing for susceptibility genes: a cautionary tale
In: Rehmann-Sutter, Christoph; Müller, Hansjakob, eds. Disclosure Dilemmas: Ethics of Genetic Prognosis after the 'Right to Know/Not to Know' Debate. Farnham, England; Burlington, VT: Ashgate Pub., 2009: 65-83
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Porz, Rouven
The need for an ethics of kinship: decision stories and patients' context
In: Rehmann-Sutter, Christoph; Müller, Hansjakob, eds. Disclosure Dilemmas: Ethics of Genetic Prognosis after the 'Right to Know/Not to Know' Debate. Farnham, England; Burlington, VT: Ashgate Pub., 2009: 53-64
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Chadwick, Ruth
The right to know and the right not to know -- ten years on
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Watts, Geoff
United Kingdom. Academy of Medical Sciences; United Kingdom. Medical Research Council; United Kingdom. Science Media Centre; United Kingdom. Wellcome Trust
Hype, hope and hybrids: science, policy and media perspectives of the Human Fertilisation and Embryology Bill

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In her: Biomedical Ethics: A Canadian Focus. Don Mills, Ont.: Oxford University Press, 2009: 283-362
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Developing Stakeholder Involvement for Introducing Public Health Genomics into Public Policy.
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Genetic screening: programs, principles, and research -- thirty years later. Reviewing the recommendations of the Committee for the Study of Inborn Errors of Metabolism (SIEM).
Public Health Genomics 2009; 12(2): 105-111
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Steinbock, Bonnie; London, Alex John; Arras, John D., eds.
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Call number: R724 .E788 2009

de Jonge, Bram
Between sharing and protecting: public research on genetic resources in the year of the potato
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Potter, Beth K.; O'Reilly, Natasha; Etchegary, Holly; Howley, Heather; Graham, Ian D.; Walker, Mark; Coyle, Doug; Chomy, Yelena; Cappelli, Mario; Boland, Isabelle; Wilson, Brenda J.
Exploring informed choice in the context of prenatal testing: findings from a qualitative study.
Health Expectations 2008 December; 11(4): 355-365
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Doctor Atomic and Doctor Genomic [editorial]
Gender Medicine 2008 December; 5(4): 351-353
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U.S. scientists' role in the eugenics movement (1907-1939): a contemporary biologist's perspective
Zebrafish 2008 December; 5(4): 243-245
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Godard, Béatrice; Ozdemir, Vural
Nutrigenomics and personalized diet: from molecule to intervention and nutri-ethics [editorial]
Omics 2008 December; 12(4): 227-228
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Pendergast, Mary K.
**Regulatory agency consideration of pharmacogenomics**
Experimental Biology and Medicine 2008 December; 233(12): 1498-1503
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McGuire, Amy L.; Colgrove, James; Whitney, Simon N.; Diaz, Christina M.; Bustillos, Daniel; Versalovic, James
**Ethical, legal, and social considerations in conducting the Human Microbiome Project.**
Genome Research 2008 December;18(12): 1861-1864
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Document 445
Ryan-Harshman, Milly; Vogel, Ellen; Jones-Taggart, Holly; Green-Johnson, Julia; Castle, David; Austin, Zubin; Anderson, Kristin
**Nutritional genomics and dietetic professional practice.**
Canadian journal of dietetic practice and research = Revue canadienne de la pratique et de la recherche en diététique 2008 Winter; 69(4): 177-182
Georgetown users check [Georgetown Journal Finder](#) for access to full text

Document 446
Zhang, Xinqing
**Ethical reflection on human gene therapy in the Chinese context**
**Abstract:** Although China SFDA approved Genedicine as the first commercial approved gene therapy product, worldwide in 2003, the scientific basis together with the ethical review capacity building is not so strong. Firstly, the author briefly introduces the history of ethical and regulatory thinking on gene therapy in China. Secondly, the author argues that: although significant progress had been made in disseminating gene therapy knowledge to the general public, gene therapy is in many cases accepted as a routine medical intervention for a variety of diseases in China. A fundamental root of such a therapeutic misconception is financial conflict of interest in the field of gene therapy. Finally, the author points out that the balance between "to benefit" and "no harm" is both a scientific evaluation and a moral judgment. "Do no harm" should be the priority in gene therapy clinical trials as long as there are major technical problems unsolved.
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Document 447
Fan, Chien Te; Wu, Chunyan; Shi, Zhiyuan
**Impact of development of population-based study in biomedical field on laws and regulations: a cross-strait experience on biobank development**
**Abstract:** Together with the completion of the Human Genome Project, biomedical research has marched into the "Post-Genomic Era." In order to take advantage of these extracted gene related information extensively and precisely so as to realize the human being's biological phenomena as well as the mechanism of pathogenesis, consequentially, large scale sample collection of different geological areas and/or ethnic group becomes necessary
for the future population based genetic research of a country and, in turn, the construction of population-based genetic database (Biobank). In recent years, both mainland China & Taiwan have not only made great progress in information & computation technologies but have also gradually taken a close look into the quality of medicine delivery. Thus, it becomes unavoidable for both sides to create each one's population-based genetic databases (Biobank). Theoretically speaking, the Biobank development shall benefit the study on the correlation between genes and disease and, also, the solution for disease treatment. At the same time, medical diagnosis technology has also been significantly improved. It is believable that the population-based genetic database might be utilized to promote medical quality and to reduce the cost of public health delivery. Furthermore, in the near future, it might become the "raw materials" for medical research application. However, when taking the public welfare promotion as the premises for a Biobank development, severe and multi challenges occurred against traditional legal rules in terms of the privacy protection, public trust development, the compliance of informed consent principle, the implementation of a benefit-sharing doctrine and the possible discrimination concern on the population/participants selection and some other ELSI issues. In this paper, the major legal issues encountered by the Biobank development will be firstly reviewed accompanied with the background information concerning the Biobank development scenario crossing the Taiwan Strait. Also, mainly following the realm of comparative policy or legal approaches, the paper, learning from the fruits of this comparative study, tries to propose some recommendations for future legislative consideration by both mainland China & Taiwan. It's been this author's wish that, when establishing a large scale population based Biobank, the promotion of public trust shall be placed as the primary goal together with the emphasis on the supporting publicity and transparency on the administrative practices, so as to encourage the public participation in observing the principle of altruism and, in turns, benefit the future biomedicine development.

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text
Document 452
Savulescu, Julian; Skene, Loane
The kingdom of genes: why genes from animals and plants will make better humans.
American Journal of Bioethics 2008 December; 8(12): 35-38; reply by Françoise Baylis W4-W6

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http://bioethics.net (link may be outdated)

Document 453
de Melo-Martín, Inmaculada
Ethics, embryos, and eggs: the need for more than epistemic values.
American Journal of Bioethics 2008 December; 8(12): 38-40; reply by Françoise Baylis W4-W6

Georgetown users check Georgetown Journal Finder for access to full text

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Document 454
Crawford, Lyle; Laforce, Daisy; Master, Zubin
A problematic principle.
American Journal of Bioethics 2008 December; 8(12): 40-42; reply by Françoise Baylis W4-W6

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Document 455
Benham, Bryan; Haber, Matt
Moral confusion and developmental essentialism in part-human hybrid research.
American Journal of Bioethics 2008 December; 8(12): 42-44; reply by Françoise Baylis W4-W6

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http://bioethics.net (link may be outdated)

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Chapman, Audrey; Hiskes, Anne L.
Unscrambling the eggs: cybrid research through an Embryonic Stem Cell Research Oversight Committee (ESRC) lens.
American Journal of Bioethics 2008 December; 8(12): 44-46; reply by Françoise Baylis W4-W6

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http://bioethics.net (link may be outdated)
Gerrek, Monica L.  
**Who really causes the lady to vanish?**  
American Journal of Bioethics 2008 December; 8(12): 46-47; reply by Françoise Baylis W4-W6  

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Murphy, Timothy F.  
**When is an objection to hybrid stem cell research a moral objection?**  
American Journal of Bioethics 2008 December; 8(12): 47-49; reply by Françoise Baylis W4-W6  

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Cooke, Sarah; Crawford, Gillian; Parker, Michael; Lucassen, Anneke; Hallowell, Nina  
**Recall of participation in research projects in cancer genetics: some implications for research ethics**  
Clinical Ethics 2008 December; 3(4): 180-184  

**Abstract:** The aim of this study is to assess patients' recall of their previous research participation. Recall was established during interviews and compared with entries from clinical notes. Participants were 49 patients who had previously participated in different types of research. Of the 49 patients, 45 (92%) interviewees recalled 69 of 109 (63%) study participations. Level of recall varied according to the type of research, some participants clearly recalled the details of research aims, giving consent and research procedures. Others recalled procedures (e.g. DNA testing) but were unclear about their purpose. There was no significant effect of time on recall. Some types of research participation (e.g. DNA testing) may be recalled as clinical care. We argue that such misunderstandings may have the potential to undermine participants' ongoing consent, particularly in ongoing/longitudinal studies. Valid consent may be best achieved by re-assessing the scope of consent and relating it to the nature of the interventions themselves rather than the reasons for undertaking them.  

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Boys, Carol; Cunningham, Cliff; McKenna, Dawn; Robertson, Penny; Weeks, Daniel J.; Wishart, Jennifer  
**Prenatal screening for Down's syndrome: editorial responsibilities [comment]**  
Lancet 2008 November 22-28; 372(9652): 1789-1791  

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[http://www.thelancet.com/journals/lancet](http://www.thelancet.com/journals/lancet) (link may be outdated)

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Gibson, Elaine; Brazil, Kevin; Coughlin, Michael D.; Emerson, Claudia; Fournier, Francois; Schwartz, Lisa; Szala-Meneok, Karen V.; Weisbaum, Karen M.; Willison, Donald J.  
**Who's minding the shop? The role of Canadian research ethics boards in the creation and uses of registries and biobanks.**
BACKGROUND: The amount of research utilizing health information has increased dramatically over the last ten years. Many institutions have extensive biobank holdings collected over a number of years for clinical and teaching purposes, but are uncertain as to the proper circumstances in which to permit research uses of these samples. Research Ethics Boards (REBs) in Canada and elsewhere in the world are grappling with these issues, but lack clear guidance regarding their role in the creation of and access to registries and biobanks. METHODS: Chairs of 34 REBs and/or REB Administrators affiliated with Faculties of Medicine in Canadian universities were interviewed. Interviews consisted of structured questions dealing with diabetes-related scenarios, with open-ended responses and probing for rationales. The two scenarios involved the development of a diabetes registry using clinical encounter data across several physicians’ practices, and the addition of biological samples to the registry to create a biobank. RESULTS: There was a wide range of responses given for the questions raised in the scenarios, indicating a lack of clarity about the role of REBs in registries and biobanks. With respect to the creation of a registry, a minority of sites felt that consent was not required for the information to be entered into the registry. Whether patient consent was required for information to be entered into the registry and the duration for which the consent would be operative differed across sites. With respect to the creation of a biobank linked to the registry, a majority of sites viewed biobank information as qualitatively different from other types of personal health information. All respondents agreed that patient consent was needed for blood samples to be placed in the biobank but the duration of consent again varied. CONCLUSION: Participants were more attuned to issues surrounding biobanks as compared to registries and demonstrated a higher level of concern regarding biobanks. As registries and biobanks expand, there is a need for critical analysis of suitable roles for REBs and subsequent guidance on these topics. The authors conclude by recommending REB participation in the creation of registries and biobanks and the eventual drafting of comprehensive legislation.
Document 465
My genome. So what? Research is needed into the way individuals use their genomic information, and into protection from its abuse by others [editorial]
Nature 2008 November 6; 456(7218): 1

Document 466
Sheehan, Mark
Is gene therapy for the treatment of male infertility ethical?

Document 467
Woodcock, Janet
The human genome and translational research: how much evidence is enough?
Health Affairs 2008 November-December; 27(6): 1616-1618

Document 468
Haas, David M.; Renbarger, Jamie L; Meslin, Eric M.; Drabiak, Katherine; Flockhart, David
Patient attitudes toward genotyping in an urban women's health clinic
Obstetrics and Gynecology 2008 November; 112(5): 1023-1028

Document 469
Murphy, Juli; Scott, Joan; Kaufman, David; Geller, Gail; LeRoy, Lisa; Hudson, Kathy
Public expectations for return of results from large-cohort genetic research.
Supported by: HNGRI-funded publication; Grant UG1HG004206
Abstract: The National Institutes of Health and other federal health agencies are considering establishing a national biobank to study the roles of genes and environment in human health. A preliminary public engagement study was conducted to assess public attitudes and concerns about the proposed biobank, including the expectations for return of individual research results. A total of 141 adults of different ages, incomes, genders, ethnicities, and races participated in 16 focus groups in six locations across the country. Focus group participants voiced a strong desire to be able to access individual research results. Recognizing the wide range of possible research results from a large cohort study, they repeatedly and spontaneously suggested that cohort study participants be given ongoing choices as to which results they received.
Document 470
Meyer, Michelle N.
**The kindness of strangers: the donative contract between subjects and researchers and the non-obligation to return individual results of genetic research.**
American Journal of Bioethics 2008 November; 8(11): 44-46

Document 471
Wilfond, Benjamin S.
**The Genetic Information Nondiscrimination Act: fear factor or fantasy island?**
Hastings Center Report 2008 November-December; 38(6): 11-12

Document 472
Rodriguez, Henry
**International summit on proteomics data release and sharing policy [editorial]**
Journal of Proteome Research 2008 November; 7(11): 4609

Document 473
Cottingham, Katie
**Proteomics researchers now agree on some aspects of data sharing.**
Journal of Proteome Research 2008 November; 7(11): 4612

Document 474
Dure, Leon S.; Quaid, Kimberly; Beasley, T. Mark
**A pilot assessment of parental practices and attitudes regarding risk disclosure and clinical research involving children in Huntington disease families.**
Genetics in Medicine 2008 November; 10(11): 811-819
Supported by: NHGRI-funded publication; P50 HG003390
Subjects matter: a survey of public opinions about a large genetic cohort study.

Kaufman, David; Murphy, Juli; Scott, Joan; Hudson, Kathy

Genetics in Medicine 2008 November; 10(11): 831-839

Supported by: NHGRI-funded publication; 1 U01 HG004206-0

Ethical rhetoric: genomics and the moral content of UNESCO's "universal" declarations.

Harmon, S.H.E.


Abstract: Genomic research is an expanding and subversive field, leaking into various others, from environmental protection to food production to healthcare delivery, and in doing so, it is reshaping our relationship with them. The international community has issued various declaratory instruments aimed at the human genome and genomic research. These soft law instruments stress the special nature of genomics and our genetic heritage, and attempt to set limits on our activities with respect to same, as informed by the human rights paradigm. This paper examines the primary thrust and, more importantly, the joint value position of the Universal Declaration on the Human Genome and Human Rights and the Universal Declaration on Bioethics and Human Rights, concluding that, though important legal instruments from the human rights paradigm, these instruments, or rather the values contained therein, must find a more influential hard law voice and a broader policy environment.

Fearing a non-existing Minotaur? The ethical challenges of research on cytoplasmic hybrid embryos.

Camporesi, S.; Boniolo, G.

Journal of Medical Ethics 2008 November; 34(11): 821-825

Abstract: In this paper we address the ethical challenges of research on cytoplasmic hybrid embryos, or "cybrids". The controversial pronouncement of the UK's Human Embryology and Fertilisation Authority of September 2007 on the permissibility of this area of research is the starting point of our discussion, and we argue in its favour. By a rigorous definition of the entities at issue, we show how the terms "chimera" and "hybrid" are improper in the case of cybrids, and how their use can bias the debate creating moral prejudices. After analysing the scientific aspects of cybrids research and sketching out current alternatives, we enter the ethical debate, starting from the premise that research on early human embryos is ethically permissible under some circumstances. We emphasise how research on cybrids has positive consequences in terms of scientific and therapeutic applications, since it allows the derivation of human embryonic stem cells genetically tailored to the somatic cell donor. Such cell lines offer a unique in vitro model both for studies of human pathogenesis and for drug screening and discovery. Research on cybrids also circumvents the problem of the scarcity of human oocytes and their ethically dubious donation. Finally, we object to the most common arguments against cybrids research, that is, moral repugnance, the slippery slope argument, the appeal to "nature", and the unfair distribution of economical resources.
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Holman, Christopher M.
**Trends in human gene patent litigation**
Science 2008 October 10; 322(5899): 198-199

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Sexton, Adrienne C.; Metcalfe, Sylvia A.
**Disclosing genetic research results after death of pediatric patients**
JAMA: Journal of the American Medical Association 2008 October 8; 300(14): 1693-1695

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Horch, Raymund E.; Pepescu, L.M.; Vacanti, Charles; Maio, Giovanni
**Ethical issues in cellular and molecular medicine and tissue engineering**
Journal of Cellular and Molecular Medicine 2008 October; 12(5B): 1785-1793

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Braff, Jeffrey P.; Chatterjee, Biswajit; Hochman, Meredith; Kelton, Teresa; Kennington, Jessica; Kolavala, Chandana; Layman, Katherine; Parver, Corrine; Selby, Myra C.; Washlick, John R.; Wolf, Rebecca
**Patient-tailored medicine, part one: the impact of race and genetics on medicine.**

Georgetown users check [Georgetown Journal Finder](http://www.sciencemag.org) for access to full text

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Chen, Donna T.; Meschia, James F.; Brott, Thomas G.; Brown, Robert D.; Worrall, Bradford B.;
**Stroke genetic research and adults with impaired decision-making capacity: a survey of IRB and investigator practices**
Stroke 2008 October; 39(10): 2732-2735

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Ozdemir, Vural; Graham, Janice E.; Godard, Béatrice
**Race as a variable in pharmacogenomics science: from empirical ethics to publication standards. [editorial]**
Pharmacogenetics and Genomics 2008 October; 18(10): 837-841
Document 484

Friedmann, Theodore
The ASGT and ethical codes for clinical research. [editorial]
Molecular Therapy 2008 October; 16(10): 1643-1644

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Hull, Sara Chandros; Wilfond, Benjamin S.
What does it mean to be identifiable?
American Journal of Bioethics 2008 October; 8(10): W7-W8

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Hull, Sara Chandros; Sharp, Richard R.; Botkin, Jeffrey R.; Brown, Mark; Hughes, Mark; Sugarman, Jeremy; Schwinn, Debra; Sankar, Pamela; Bolcic-Jankovic, Dragana; Clarridge, Brian R.; Wilfond, Benjamin S.
Patients' views on identifiability of samples and informed consent for genetic research.
American Journal of Bioethics 2008 October; 8(10): 62-70

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Greenbaum, Dov; Du, Jiang; Gerstein, Mark
Genomic anonymity: have we already lost it?
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McGuire, Amy L.
**Identifiability of DNA data: the need for consistent federal policy.**
Supported by: NHGRI-funded publication

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Coors, Marilyn; Mikulich-Gilbertson, Susan; Raymond, Kristen; Stover, Shannon; Crowley, Thomas; Brown, Sandra; Tapert, Susan
**Directives for retained DNA: preferences of adolescent patients with substance and conduct problems and their siblings.**

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**Wrongful deaths and rightful lives – screening for Down syndrome**

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Karp, David R.; Carlin, Shelley; Cook-Deegan, Robert; Ford, Daniel E.; Geller, Gail; Glass, David N.; Greely, Hank; Guthridge, Joel; Kahn, Jeffrey; Kaslow, Richard; Kraft, Cheryl; Macqueen, Kathleen; Malin, Bradley; Scheuerman, Richard H.; Sugarman, Jeremy
**Ethical and practical issues associated with aggregating databases**
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Berg, Paul
**Asilomar 1975: DNA modification secured**
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**Informed consent in the genomics era**
PLoS medicine 2008 September 16; 5(9): e192

Nisselle, Amy; Forbes, Robin; Bankier, Agnes; Hughes, Eilis; Aitken, Maryanne
**Consumer contribution to the delivery of genetic health services.**
American Journal of Medical Genetics. Part A 2008 September 1; 146A(17): 2266-2274

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**Transgressing borders: genetic research, immigration, and discourses of sacrifice**

Ormond, Kelly E.
**Medical ethics for the genome world: a paper from the 2007 William Beaumont hospital symposium on molecular pathology.**
Journal of Molecular Diagnostics 2008 September; 10(5): 377-382

Arnos, Kathleen S.
**Ethical and social implications of genetic testing for communication disorders.**
Journal of Communication Disorders 2008 September-October; 41(5): 444-457

Yerbury, Sally; Arran, N.; Craufurd, D.; MacLeod, R.
**PREDICT-HD: a companion study exploring attitudes of partners to predictive testing and participation in research [abstract; poster 4.12]**
Journal of Medical Genetics 2008 September; 45(Supplement 1): S105
Document 499
Development of a large-scale de-identified DNA biobank to enable personalized medicine.
Clinical Pharmacology and Therapeutics 2008 September; 84(3): 362-369

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Lavery, James V.; Harrington, Laura C.; Scott, Thomas W.
Ethical, social, and cultural considerations for site selection for research with genetically modified mosquitoes.
American Journal of Tropical Medicine and Hygiene 2008 September; 79(3): 312-318

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Kristoffersson, Ulf
Regulatory issues for genetic testing in clinical practice
Molecular Biotechnology 2008 September; 40(1): 113-117

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Kakuk, Péter
Gene concepts and genethics: beyond exceptionalism.
Science and Engineering Ethics 2008 September; 14(3): 357-375

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American Association for Cancer Research. Human Epigenome Task Force; European Union. Network of Excellence. Scientific Advisory Board
Moving AHEAD with an international human epigenome project. A plan to 'genomicize' epigenetics research and pave the way for breakthroughs in the prevention, diagnosis and treatment of human disease.
Nature 2008 August 7; 454(7205): 711-715

Document 504
Braff, David L.; Freedman, Robert
Clinically responsible genetic testing in neuropsychiatric patients: a bridge too far and too soon
Ursin, Lars Øystein

**Biobank research and the right to privacy**


**Abstract:** What is privacy? What does privacy mean in relation to biobanking, in what way do the participants have an interest in privacy, (why) is there a right to privacy, and how should the privacy issue be regulated when it comes to biobank research? A relational view of privacy is argued for in this article, which takes as its basis a general discussion of several concepts of privacy and attempts at grounding privacy rights. In promoting and protecting the rights that participants in biobank research might have to privacy, it is argued that their interests should be related to the specific context of the provision and reception of health care that participation in biobank research is connected with. Rather than just granting participants an exclusive right to or ownership of their health information, which must be waived in order to make biobank research possible, the privacy aspect of health information should be viewed in light of the moral rights and duties that accompany any involvement in a research based system of health services.

Delatycki, Martin B.

**Population screening for reproductive risk for single gene disorders in Australia: now and the future.**

Twin Research and Human Genetics 2008 August; 11(4): 422-430

Dorval, Michel; Bouchard, Karine; Maunsell, Elizabeth; Plante, Marie; Chiquette, Jocelyne; Camden, St phanie; Dugas, Michel J.; Simard, Jacques

**Health behaviors and psychological distress in women initiating BRCA1/2 genetic testing: comparison with control population**

Journal of Genetic Counseling 2008 August; 17(4): 314-326

Van Camp, N.; Dierickx, K.

**The retention of forensic DNA samples: a socioethical evaluation of current practices in the EU**

Journal of Medical Ethics 2008 August; 34(8): 606-610

**Abstract:** Since the mid-1990s most EU Member States have established a national forensic DNA database. These mass repositories of DNA profiles enable the police to identify DNA stains which are found at crime scenes and are invaluable in criminal investigation. Governments have always brushed aside privacy objections by stressing that the stored DNA profiles do not contain sensitive genetic information on the included individuals and that they reside under the statutory privacy protection regulations. However, it has been generally overlooked that the police also store the DNA samples from which the DNA profiles are derived. Although these DNA samples are actually a potential source of genetic information, they have so far scarcely been the subject of discussion. In this article we
will show that both European and national regulations offer inadequate protection to completely prevent function creep, that is, the use of these forensic DNA samples for purposes beyond those envisaged at the time of collection.

http://www.jmedethics.com (link may be outdated)
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Balls, Michael

*Experiments on humans and animals: can the ends justify the means?* [editorial]

ATLA: Alternatives to Laboratory Animals 2008 July; 36(3): 263-264

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Evans, James P.; Burke, Wylie

*Genetic exceptionalism. Too much of a good thing?*

Genetics in Medicine 2008 July; 10(7): 500-501

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Document 515

Ebbesen, Mette; Jensen, Thomas G.; Andersen, Svend; Pedersen, Finn Skou

*Ethical perspectives on RNA interference therapeutics.*

International Journal of Medical Sciences 2008 June 25; 5(3): 159-168

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This time it's personal: the next head of the US National Human Genome Research Institute will need to be equipped to deal with the scientific, political and societal challenges presented by the burgeoning era of personal genomics [editorial]

Nature 2008 June 5; 453(7196): 697

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[http://www.nature.com](http://www.nature.com) (link may be outdated)

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Ndebele, Paul; Musesengwa, Rosemary

*Will developing countries benefit from their participation in genetics research?*


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[http://www.mmj.medcol.mw/](http://www.mmj.medcol.mw/) (link may be outdated)

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Hartigan, John, Jr.

*Is race still socially constructed? The recent controversy over race and medical genetics*

Science as Culture 2008 June; 17(2): 163-193

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Turgeon, David
**Ethic and patents: immiscible realities?**
Health Law in Canada 2008 June; 28(3-4): 66-78
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Laufert, Michael
**Race and population-based medicine: drug development and distributive justice**
Georgetown Journal of Legal Ethics 2008 Summer; 21(3): 859-879
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Document 521
Hindmarsh, Richard
**Edging towards bioutopia: human folly or paradise?**
GeneWatch 2008 Summer; 21(1-2): 9-11
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Document 522
Artizzu, Federica
**The informed consent aftermath of the genetic revolution. An Italian example of implementation**
Medicine, Health Care and Philosophy 2008 June; 11(2): 181-190
Abstract: A great part of human genetics research is carried out collecting data and building large databases of biological samples that are in a non-anonymous format. These constitute a valuable resource for future research. The construction of such databases and tissue banks facilitates important scientific progress. However, biobanks have been recognized as ethically problematic because they contain thousands of data that could expose individuals and populations to discrimination, stigmatization and psychological stress if misused. Informed consent is regarded as a cornerstone in the protection of personal autonomy in research involving human subjects. Yet in recent years this fundamental concept has been overwhelmed by the genomic revolution. From a general overview of international literature, it seems evident that informed consent issues have come into sharp focus, in particular in relation to the twin issues of time extension (blanket versus specific/repeated consent) and personal extension (group consent). After an introduction on obtaining informed consent in the context of genetic research, this paper addresses the apparent lack of a single, universal model of obtaining informed consent among populations involved in genetic research and it argues for the need to develop an ethical framework tailored to the specific features of each project. In order to support this theory of contextualizing, the case of a private biotechnology company, SharDNA is presented. The present paper explores the management of its biobank, developed from a genetic research project carried out on isolated populations living on the Italian island of Sardinia. In particular, the paper highlights how the company is tackling the problem of informed consent and other ethical requirements for genetic research, such as the respect of individual privacy, the population approach and the existing Italian legal regulatory framework.
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Olde Rikkert, Marcel G.M.; van der Vorm, Anco; Burns, Alistair; Dekkers, Wim; Robert, Philipp; Sartorius, Norman; Selmes, Jacques; Stoppe, Gabriela; Vernooij-Dassen, Myrrha; Waldemar, Gunhild
Consensus statement on genetic research in dementia.
American Journal of Alzheimer's Disease and other Dementias 2008 June-July; 23(3): 262-266

Zika, Eleni; Schulte In den Bäumen, Tobias; Kaye, Jane; Brand, Angela; Ibarreta, Dolores
Sample, data use and protection in biobanking in Europe: legal issues.
Pharmacogenomics 2008 June; 9(6): 773-781

Twomey, John G.; Bove, Catherine; Cassidy, Deborah
Presymptomatic genetic testing in children for neurofibromatosis 2.
Journal of Pediatric Nursing 2008 June; 23(3): 183-194

Sexton, A.C.; Sahhar, M.; Thorburn, D.R.; Metcalfe, S.A.
Impact of genetic diagnosis of a mitochondrial disorder 5-17 years after the death of an affected child

Samuels, Mark E.; Orr, Andrew; Guernsey, Duane L.; Dooley, Kent; Riddell, Christie; Hodgkinson, Kathy; Ludman, Mark; Pullman, Daryl
Is gene discovery research or diagnosis?
Genetics in Medicine 2008 June; 10(6): 385-390

Hale, Benjamin
Open to debate: moral considerations and the lab monkey
American Journal of Bioethics 2008 June; 8(6): 53-54; reply by Autumn Fiester W1-W2

Rossi, John
Toward a zoocentric animal ethics
Thompson, Paul B.
Animal biotechnology: how not to presume

Streiffer, Robert
Animal biotechnology and the non-identity problem

Eberl, Jason T.; Ballard, Rebecca A.
Exercising restraint in the creation of animal-human chimeras

Fiester, Autumn
Justifying a presumption of restraint in animal biotechnology research
American Journal of Bioethics 2008 June; 8(6): 36-44

Abstract: Articulating the public's widespread unease about animal biotechnology has not been easy, and the first attempts have not been able to provide an effective tool for navigating the moral permissibility of this research. Because these moral intuitions have been difficult to cash out, they have been belittled as representing nothing more than fear or confusion. But there are sound philosophical reasons supporting the public's opposition to animal biotechnology and these arguments justify a default position of resistance I call the Presumption of Restraint. The Presumption of Restraint constitutes a justificatory process that sets out the criteria for permitting or rejecting individual biotechnology projects. This Presumption of Restraint can be overridden by compelling arguments that speak to a project's moral and scientific merit. This strategy creates a middle-of-the-road stance that can embrace particular projects, while rejecting others. The Presumption of Restraint can also serve as a model for assessing moral permissibility in other areas of technological innovation.
**Document 534**

Davis, Dena S.

**Religion, genetics and sexual orientation: the Jewish tradition**


**Abstract:** This paper probes the implications of a genetic basis for sexual orientation for traditional branches of Judaism, which are struggling with how accepting to be of noncelibate gays and lesbians in their communities. The paper looks at the current attitudes toward homosexuality across the different branches of Judaism; social and cultural factors that work against acceptance; attitudes toward science in Jewish culture; and the likelihood that scientific evidence that sexual orientation is at least partly genetically determined will influence Jewish scholars' and leaders' thinking on this issue.

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**Document 535**

Hunt, L.M.; Megyesi, M.S.

**Genes, race and research ethics: who's minding the store?**

Journal of Medical Ethics 2008 June; 34(6): 495-500

Supported by: HG2299-05

**Abstract:** BACKGROUND: The search for genetic variants between racial/ethnic groups to explain differential disease susceptibility and drug response has provoked sharp criticisms, challenging the appropriateness of using race/ethnicity as a variable in genetics research, because such categories are social constructs and not biological classifications. OBJECTIVES: To gain insight into how a group of genetic scientists conceptualise and use racial/ethnic variables in their work and their strategies for managing the ethical issues and consequences of this practice. METHODS: In-depth semi-structured interviews were conducted with a purposive sample of 30 genetic researchers who use racial/ethnic variables in their research. Standard qualitative methods of content analysis were used. RESULTS: Most of the genetic researchers viewed racial/ethnic variables as arbitrary and very poorly defined, and in turn as scientifically inadequate. However, most defended their use, describing them as useful proxy variables on a road to "imminent medical progress". None had developed overt strategies for addressing these inadequacies, with many instead asserting that science will inevitably correct itself and saying that meanwhile researchers should "be careful" in the language chosen for reporting findings. CONCLUSIONS: While the legitimacy and consequences of using racial/ethnic variables in genetics research has been widely criticised, ethical oversight is left to genetic researchers themselves. Given the general vagueness and imprecision we found amongst these researchers regarding their use of these variables, they do not seem well equipped for such an undertaking. It would seem imperative that research ethicist move forward to develop specific policies and practices to assure the scientific integrity of genetic research on biological differences between population groups.

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**Document 536**

Kauffmann, Francine; Cambon-Thomsen, Anne

**Tracing biological collections: between books and clinical trials**


**Abstract:**

Georgetown users check [Georgetown Journal Finder](http://journals.georgetown.edu) for access to full text.
Abrahams, Edward

**Right drug-right patient-right time: personalized medicine coalition.**
Clinical and translational science 2008 May; 1(1): 11-2

Georgetown users check [Georgetown Journal Finder](#) for access to full text

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Balls, Michael

**The production of admixed animal-human embryos: is it necessary, or merely desireable? [editorial]**
ATLA: Alternatives to Laboratory Animals 2008 May; 36(2): 119-121

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Borry, Pascal; Goffin, Tom; Nys, Herman; Dierickx, Kris

**Predictive genetic testing in minors for adult-onset genetic diseases**
Mount Sinai Journal of Medicine 2008 May-June; 75(3): 287-296

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Lunshof, Jeantine E.; Chadwick, Ruth; Vorhaus, Daniel B.; Church, George M.

**From genetic privacy to open consent.**

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Boon, Wouter; Moors, Ellen

**Exploring emerging technologies using metaphors--a study of orphan drugs and pharmacogenomics.**
Social Science and Medicine 2008 May; 66(9): 1915-1927

Georgetown users check [Georgetown Journal Finder](#) for access to full text

[http://www.sciencedirect.com/science/journal/02779536](http://www.sciencedirect.com/science/journal/02779536) (link may be outdated)

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Baily, Mary Ann; Murray, Thomas H.

**Ethics, evidence, and cost in newborn screening.**

Supported by: NHGRI-funded publication; Grant R01 HG002579-03

**Abstract:** When deciding what disorders to screen newborns for, we should be guided by evidence of real effectiveness, take opportunity cost into account, distribute costs and benefits fairly, and respect human rights. Current newborn screening policy does not meet these requirements.
Georgetown users check Georgetown Journal Finder for access to full text.

Document 543
Edginton, Mary E.; Selgelid, Michael J.
*Ethics and research: the case of informed consent [editorial]*
Georgetown users check Georgetown Journal Finder for access to full text.

Document 544
Peng, Zhaohui; Yu, Qing; Bao, Li
*The application of gene therapy in China.*
*IDrugs* 2008 May; 11(5): 346-350
Georgetown users check Georgetown Journal Finder for access to full text.

Document 545
Ledbetter, David H.
*Gene patenting and licensing: the role of academic researchers and advocacy groups*
*Genetics in Medicine* 2008 May; 10(5): 314-319
Georgetown users check Georgetown Journal Finder for access to full text.

Document 546
United States. Department of Health and Human Services. Secretary's Advisory Committee on Genetics, Health, and Society [SACGHS]
*Realizing the Potential of Pharmacogenomics: Opportunities and Challenges. Report of the Secretary's Advisory Committee on Genetics, Health, and Society [SACGHS]*
Bethesda, MD: Secretary's Advisory Committee on Genetics, Health, and Society [SACGHS] 2008 May: 96 p. [plus multiple appendices]
Abstract: The report explores the potential for pharmacogenomics (PGx) to advance the development of diagnostic, therapeutic, and preventive strategies to improve the safety, effectiveness, and quality of health care; identifies opportunities and critical barriers in need of the Federal Government’s attention; and makes 35 policy recommendations aimed at enhancing the development and integration of PGx applications. [from SACGHS email announcement]

[http://www4.od.nih.gov/oba/sacghs/reports/SACGHS_PGx_report.pdf](http://www4.od.nih.gov/oba/sacghs/reports/SACGHS_PGx_report.pdf) (link may be outdated)

Document 547
Trivedi, Bijal
*Betting the bank*
*Nature* 2008 April 24; 452(7190): 926-929
Georgetown users check Georgetown Journal Finder for access to full text.

[http://www.nature.com](http://www.nature.com) (link may be outdated)
Document 548
Lenzer, Jeanne; Brownlee, Shannon
Knowing me, knowing you: direct to consumer genetic testing
BMJ: British Medical Journal 2008 April 19; 336(7649): 858-860
Georgetown users check Georgetown Journal Finder for access to full text
http://www.bmj.com (link may be outdated)

Document 549
Penziner, Elizabeth; Williams, Janet K.; Erwin, Cheryl; Bombard, Yvonne; Wallis, Anne; Beglinger, Leigh J.; Hayden, Michael R.; Paulsen, Jane S.
Perceptions of discrimination among persons who have undergone predictive testing for Huntington's disease.
American Journal of Medical Genetics. Part B, Neuropsychiatric Genetics 2008 April 5; 147(3): 320-325
Supported by: NHGRI-funded publication; 1R01 HG00333001A1
Georgetown users check Georgetown Journal Finder for access to full text

Document 550
Laegsgaard, Mett Marri; Mors, Ole
Psychiatric genetic testing: attitudes and intentions among future users and providers.
Georgetown users check Georgetown Journal Finder for access to full text

Document 551
Macilotti, M.; Izzo, U.; Pascuzzi, G.; Barbareschi, M.
Legal aspects of biobanks
Pathologica 2008 April; 100(2): 86-115
Georgetown users check Georgetown Journal Finder for access to full text

Document 552
Henrikson, N.B.; Burke, W.; Veenstra, D.L.
Ancillary risk information and pharmacogenetic tests: social and policy implications.
Pharmacogenomics Journal 2008 April; 8(2): 85-89
Supported by: NHGRI-funded publication; Grant P50-HG003374
Georgetown users check Georgetown Journal Finder for access to full text

Document 553
Kristman, Vicki L.; Kreiger, Nancy
Information disclosure in population-based research involving genetics: a framework for the practice of ethics in epidemiology.
Annals of Epidemiology 2008 April; 18(4): 335-341
Document 554
Garrison, Louis P., Jr.; Carlson, Rick J.; Carlson, Josh J.; Kuszler, Patricia C.; Meckley, Lisa M.; Veenstra, David L.
**A review of public policy issues in promoting the development and commercialization of pharmacogenomic applications: challenges and implications.**
Drug Metabolism Reviews 2008 April; 40(2): 377-401

Document 555
Bivins, Roberta
**Hybrid vigour? Genes, genomics, and history**

**Abstract:** Is the gene ‘special’ for historians? What effects, if any, has the notion of the ‘gene’ had on our understanding of history? Certainly, there is a widespread public and professional perception that genetics and history are or should be in dialogue with each other in some way. But historians and geneticists view history and genetics very differently – and assume very different relationships between them. And public perceptions of genes, genetics, genomics, and indeed the nature and meanings of ‘history’ differ yet again. Here, in looking at the meaning, and the implications – the significance – of the gene (and its corollary scientific disciplines and approaches) specifically to historians, I will focus on two aspects of the discourse. First, I will examine the ways in which historians have thus far approached genes and genetics, and the impact such studies have had on the field. There is considerable overlap between the subject matter of genetics/genomics and many of the most widely used analytic categories of contemporary historiography – race, gender, sexuality, ethnicity, (dis)ability, among others. Yet the impact of genetics and genomics on society has been studied principally by anthropologists, sociologists and ethicists. Only two historical sub-disciplines have engaged with the rise of genetics to any significant degree: the histories of science and of medicine. What does this indicate or suggest? Second, I will explore the impact of the ‘gene’ and genetic understandings (of, for example, the body, health, disease, identity, the family, and evolution) on public conceptions of history itself.

Document 556
Caulfield, Timothy; McGuire, Amy L.; Cho, Mildred; Buchanan, Janet A.; Burgess, Michael M.; Danilczyk, Ursula; Diaz, Christina M.; Fryer-Edwards, Kelly; Green, Shane K.; Hodosh, Marc A.; Juengst, Eric T.; Kaye, Jane; Kedes, Laurence; Knoppers, Bartha Maria; Lemmens, Trudo; Meslin, Eric M.; Murphy, Juli; Nussbaum, Robert L.; Otlowksi, Margaret; Pullman, Daryl; Ray, Peter N.; Sugaman, Jeremy; Timmons, Michael
**Research ethics recommendations for whole-genome research: consensus statement.**

Document 557
Mezuk, Briana; Eaton, William W.; Zandi, Peter

**Participant characteristics that influence consent for genetic research in a population-based survey: the Baltimore epidemiologic catchment area follow-up.**

*Community Genetics* 2008 March; 11(3): 171-178

**Abstract:** BACKGROUND: The purpose of this study is to investigate the sociodemographic and health characteristics associated with the willingness to donate a DNA sample, and consent to testing and long-term storage of that sample, among participants in a longitudinal community-based survey. SAMPLE: Eighty-three percent of the 1,071 participants interviewed in 2004/5 agreed to donate a biological specimen (blood or buccal). RESULTS: Age was consistently inversely associated with the willingness to allow genetic testing (OR 0.97; p < 0.05), but was unrelated to the willingness to donate or allow storage. There was no association between race and the consent to donate a specimen, but Blacks were less likely to consent to DNA storage for future research as compared with members of other racial groups (OR 0.50; p < 0.01). Four conditions were listed on the consent form as relevant to the genes targeted for assay. Participants with a family history of 1 or more of these conditions were more likely to donate than those without (OR 1.68; p < 0.01). Participants with a personal history of 1 of the 4 conditions listed were not more or less likely to donate, allow testing or allow storage than respondents without such a history. CONCLUSIONS: Sociodemographic characteristics were unrelated to the willingness to donate a biological sample. Age, but not race, sex or education, was related to consent to genetic testing. Race, but not age, sex or education, was related to consent to storage. A family history of health conditions listed as relevant to the assays being requested was related to the willingness to donate. Factors that affect the willingness to donate a biological sample in an epidemiologic study are not the same as those associated with the willingness to allow genetic testing...
or storage of that sample for unspecified future research.

(link may be outdated)

Document 562
Cheng, Yan-Ping
A study on origin of genetic ethics problem and countermeasure
Yì chuàn = Hereditas / Zhongguo yì chuan xue hui jì 2008 March; 30(3): 380-386

Document 563
Braund, James; Sutton, Douglas G.
The case of Heinrich Wilhelm Poll (1877-1939): a German-Jewish geneticist, eugenicist, twin researcher, and victim of the Nazis.

Document 564
Schroeder, Doris; Chennells, Roger
Benefit sharing and access to essential health care: a happy marriage?
Abstract: In May 2003, one of the most important benefit sharing agreements to date was signed in South Africa. The South African San Council and the South African Centre for Scientific and Industrial Research agreed to share the benefits derived from genetic research on the Hoodia plant. Payments to the San Council started in 2005 and could reach 1.3 million US Dollars per year for approximately 15 years. Members of the San community in Southern Africa are exposed to serious poverty, resulting in malnutrition and avoidable illnesses. The question we are interested in is: could benefit sharing in compliance with the Convention on Biological Diversity be a partial solution to lack of access to essential health care? In the first part of the paper, we shall briefly introduce the legal background of benefit sharing and the San case. In the second part of the paper, we shall argue that benefit sharing and access to essential health care should not be formally linked. We shall substantiate our claim by introducing practical, normative and so-called 'bigger picture' reasons against the link.

Document 565
Lévesque, Lise; Ozdemir, Vural; Gremmen, Bart; Godard, Béatrice
Integrating anticipated nutrigenomics bioscience applications with ethical aspects

Document 566
Williams, David A.
NIH recombinant DNA Advisory Committee continues to ponder adverse event associated with AAV gene therapy trial [editorial]
Molecular Therapy 2008 March; 16(3): 427-428
Georgetown users check Georgetown Journal Finder for access to full text

Document 567
King, Nancy M.P.; Cohen-Haguenauer, Odile
En route to ethical recommendations for gene transfer clinical trials.
Molecular Therapy : the Journal of the American Society of Gene Therapy 2008 March; 16(3): 432-438
Georgetown users check Georgetown Journal Finder for access to full text

Document 568
Hall, Wayne D.; Gartner, Coral E.; Carter, Adrian
The genetics of nicotine addiction liability: ethical and social policy implications.
Addiction 2008 March; 103(3): 350-359
Georgetown users check Georgetown Journal Finder for access to full text

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Singh, Jerome Amir
Project Coast: eugenics in apartheid South Africa.
Endeavour 2008 March; 32(1): 5-9
Georgetown users check Georgetown Journal Finder for access to full text

http://www.sciencedirect.com/science/journal/01609327 (link may be outdated)

Document 570
Goering, Sara; Holland, Suzanne; Fryer-Edwards, Kelly
Transforming genetic research practices with marginalized communities: a case for responsive justice
Supported by: NHGRI-funded publication; Grant P50 HG0037-02
Abstract: Genetics researchers often work with distinct communities. To take moral account of how their research affects these communities, they need a richer conception of justice and they need to make those communities equal participants in decision-making about how the research is conducted and what is produced and published out of it.
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Document 571
Gelsinger, Paul; Shamoo, Adil E.
Eight years after Jesse's death, are human research subjects any safer?
Georgetown users check Georgetown Journal Finder for access to full text
Pharmacogenomics, ethics, and public policy
Kennedy Institute of Ethics Journal 2008 March; 18(1): 35-56

Abstract: The advent of pharmacogenomics—the study of how the human genome influences drug response within a person or population—has begun to drive the development of pharmaceuticals in Western medicine today. Although pharmacogenomics promises dramatic improvement in drug safety and efficacy, the field also raises a host of ethical questions. The need to protect informed consent and confidentiality and to promote justice and equity—both nationally and globally—requires that one approach pharmacogenomics with an enthusiastic, yet critical, eye. Drawing on the normative values of respect for persons (as both autonomous and relational), human well-being, socioeconomic justice, and human solidarity and the common good, this article offers several concrete suggestions for public policy to help ensure that pharmacogenomics develops in a way that promotes the good of both individuals and the broader society.

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Document 577
Anderson, Gwen

**Ethical preparedness and performance of gene therapy study co-ordinators**
Nursing Ethics 2008 March; 15(2): 208-221

**Abstract:** Little is known about study co-ordinators of gene therapy clinical trials. The purposes of this study were to:
1. describe characteristics of co-ordinators of gene therapy (transfer) clinical trials;
2. assess differences between nurse and non-nurse study co-ordinators; and
3. identify factors indicative of study co-ordinators' role preparation that could affect their role performance.

This exploratory correlational study employed a convenience sample of 118 co-ordinators in the USA (55 participants; 47% response rate). The researcher created the Study Coordinator Role Preparedness and Performance Survey to assess factors or correlates of study co-ordinator performance. Analysis of variance was used to compare nurses and non-nurses, and men versus women on their perceived preparedness, perceived quality of orientation, and satisfaction with educational opportunities. The findings contribute to knowledge by identifying present inadequacies in the training of study co-ordinators and in recognizing the need for more effective provision of orientation and continuing education with respect to ethical issues, knowledge of genetic science, and potential research integrity challenges.

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Document 578
Hausman, Daniel

**Protecting groups from genetic research**
Bioethics 2008 March; 22(3): 157-165

Supported by: NHGRI-funded publication; Grant 1 R01 HG00303042-01

**Abstract:** Genetics research, like research in sociology and anthropology, creates risks for groups from which research subjects are drawn. This paper considers what sort of protection for groups from the risks of genetics research should be provided and by whom. The paper categorizes harms by distinguishing process-related from outcome-related harms and by distinguishing two kinds of group harms. It argues that calls for community engagement are justified with respect to some kinds of harms, but not with respect to others; and it cautions that community engagement may itself be harmful.

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text.

Document 579
Henderson, Gail; Garrett, Joanne; Bussey-Jones, Jada; Moloney, Mairead Eastin; Blumenthal, Connie; Corbie-Smith, Giselle

**Great expectations: views of genetic research participants regarding current and future genetic studies**
Genetics in Medicine 2008 March; 10(3): 193-200

Supported by: NHGRI-funded publication; Grants R01 HG0022830 and P20 HG03387

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text.

Document 580
Jenkins, Mary M.; Rasmussen, Sonja A.; Moore, Cynthia A.; Honein, Margaret A.

**Ethical issues raised by incorporation of genetics into the National Birth Defects Prevention Study**

Georgetown users check [Georgetown Journal Finder](http://bioethics.net) for access to full text.
"You're one of us now": young people describe their experiences of predictive genetic testing for Huntington disease (HD) and familial adenomatous polyposis (FAP)

Duncan, Rony E.; Gillam, Lynn; Savulescu, Julian; Williamson, Robert; Rogers, John G.; Delatycki, Martin B.


Ethical implications of including children in a large biobank for genetic-epidemiologic research: a qualitative study of public opinion

Kaufman, David; Geller, Gail; Leroy, Lisa; Murphy, Juli; Scott, Joan; Hudson, Kathy


Supported by: NHGRI-funded publication; Grant UG1HGH00406

Ethical and policy issues in pediatric genetics

Ross, Lainie Friedman


Should genetic testing for BRCA1/2 be permitted for minors? Opinions of BRCA mutation carriers and their adult offspring

Bradbury, Angela R.; Patrick-Miller, Linda; Pawlowski, Kimberly; Ibe, Comort N.; Cummings, Shelly A.; Olopade, Olufunmilayo I.; Daugherty, Christopher K.


Pre-birth testing project evaluation. Phase 2. Prepared for Toi te Taiao: The Bioethics Council

Warren, Julie; Mortlock, Sam

http://www.bioethics.org.nz/publications/ pre-birth-testing-project-evaluation-phase2-feb08/ pre-birth-testing-project-evaluation-phase2-feb08.pdf

Call number: citation only
McGuire, Amy L.; Caulfield, Timothy; Cho, Mildred K.  
**Research ethics and the challenge of whole-genome sequencing**  
Supported by: NHGRI-funded publication; Grants R01HG04333 and 5P50HG3389

Georgetown users check [Georgetown Journal Finder](http://www3.interscience.wiley.com/journal/34201/home) for access to full text

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De Paoli, P.  
**Future of biobanking in microbiology for medical research**  
Future Microbiology 2008 February; 3(1): 79-86

Georgetown users check [Georgetown Journal Finder](http://www3.interscience.wiley.com/journal/34201/home) for access to full text

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Fan, Chien-Te; Lin, Jui-Chu; Lee, Chung-His  
**Taiwan Biobank: a project aiming to aid Taiwan's transition into a biomedical island.**  
Pharmacogenomics 2008 February; 9(2): 235-246

Georgetown users check [Georgetown Journal Finder](http://www3.interscience.wiley.com/journal/34201/home) for access to full text

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Chalmers, Don; Nicol, Dianne  
**Human genetic research databases and biobanks: towards uniform terminology and Australian best practice.**  

Georgetown users check [Georgetown Journal Finder](http://www3.interscience.wiley.com/journal/34201/home) for access to full text

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Wilkins, Adam S.  
**Dr. Watson’s woeful words – and two missed opportunities [editorial]**  

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http://www3.interscience.wiley.com/journal/34201/home (link may be outdated)

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García, Elisa; Timmermans, Danielle R.M.; van Leeuwen, Evert  
**The impact of ethical beliefs on decisions about prenatal screening tests: searching for justification**  
Social Science and Medicine 2008 February; 66(3): 753-764

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Doerflinger, Richard M.
Human-animal hybrids in the U.S.? The need for anti-cloning legislation
Ethics and Medics 2008 February; 33(2): 3-4
Georgetown users check Georgetown Journal Finder for access to full text

Document 593
Quintavalle, Josephine
Human-animal hybrids under U.K. law: concerns about the HFEA's decision
Ethics and Medics 2008 February; 33(2): 1-3
Georgetown users check Georgetown Journal Finder for access to full text

Document 594
Carlson, Rick J.
Preemptive public policy for genomics
Abstract: To many, genomics is merely exploitable technology for the leviathan of biotechnology. This is both shallow and short sighted. Genomics is applied knowledge based on profound and evolving science about how living things develop, how healthy or sick we are, and what our future will be like. In health care, genomics technologies are disruptive yet potentially cost-effective because they enable primary prevention, the antidote to runaway costs and declining productivity. The challenges to integration are great, however, and many bioethical and social-policy implications are alarming. Because it is poorly understood today, we must debate genomics vigorously if we are to act wisely. Public policy must lead.
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Document 595
Singer, Peter
Should we discuss race and intelligence? [op-ed]
Free Inquiry 2008 February-March; 28(2): 21-23
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http://www.secularhumanism.org (link may be outdated)

Document 596
Atkin, Karl; Ahmed, Shenaz; Hewison, Jenny; Green, Josephine M.
Decision-making and ante-natal screening for sickle cell and thalassaemia disorders
Current Sociology 2008 January; 56(1): 77-98
Georgetown users check Georgetown Journal Finder for access to full text

Document 597
Byk, Christian
Preimplantation genetic diagnosis: an ambiguous legal status for an ambiguous medical and social practice
Georgetown users check Georgetown Journal Finder for access to full text
Document 598
Pattee, Suzanne R.
**Protections for participants in gene therapy trials: a patient's perspective.**

Document 599
Silber, Tomas Jose
**Human gene therapy, consent, and the realities of clinical research: is it time for a research subject advocate?**

Document 600
Caplan, Arthur L.
**If it's broken, shouldn't it be fixed? Informed consent and initial clinical trials of gene therapy.**
Human Gene Therapy 2008 January; 19(1): 5-6

Document 601
Kahn, Jeffrey
**Informed consent in human gene transfer clinical trials.**

Document 602
Halsey, Dale Lea
**Genetic and genomic healthcare: Ethical issues of importance to nurses**

Document 603
Gallo, Agatha M.; Hadley, Emily K.; Angst, Denise B.; Knafl, Kathleen A.; Smith, Carrol A.M.
**Parents' concerns about issues related to their children's genetic conditions**
Document 604
McGuire, Amy L.; Hamilton, Jennifer A.; Lunsroth, Rebecca; McCullough, Laurence B.; Goldman, Alica
DNA data sharing: research participants' perspectives
Supported by: NHGRI-funded publication; Grant NHGRI-ELSI R01 HG004333-01

Document 605
Bredenoord, A.L.; Pennings, G.; Smeets, H.J.; de Wert, G.
Dealing with uncertainties: ethics of prenatal diagnosis and preimplantation genetic diagnosis to prevent mitochondrial disorders

Document 606
Al Jar Allah, Murayyi’ ibn ‘Abd Allah ibn Sa’id
Kharitat al-jinum al-bashari wa al-ithbat al-jina’i, dirasah ta’siliyah tatbiqiyah = Human genome map and criminal verification, a foundational empirical study

Document 607
Dracopoulou, Marianna, ed.
Hellenic National Bioethics Commission
REFLECTIONS ON CONTEMPORARY ISSUES: OPINIONS AND REPORTS, 2000-2008

Document 608
Whitacre, Paula Tarnapol, rapporteur
National Research Council (United States). Planning Committee for the Workshop on Research to Improve the Evaluation of the Impacts of Genetically Engineered Organisms on Terrestrial and Aquatic Wildlife and Habitats
GENETICALLY ENGINEERED ORGANISMS, WILDLIFE, AND HABITAT: A WORKSHOP SUMMARY
Document 609
Elger, Bernice; Biller-Andorno, Nikola; Mauron, Alexandre; and Capron, Alexander M., eds.
ETHICAL ISSUES IN GOVERNING BIOBANKS: GLOBAL PERSPECTIVES
Call number: QH438.7 .E836 2008

Document 610
Whitmarsh, Ian
BIOMEDICAL AMBIGUITY: RACE, ASTHMA AND THE CONTESTED MEANING OF GENETIC RESEARCH IN THE CARIBBEAN
Call number: RA645 .A83 W45 2008

Document 611
Sharp, Richard R.; Marchant, Gary E.; and Grodsky, Jamie A., eds.
GENOMICS AND ENVIRONMENTAL REGULATION: SCIENCE, ETHICS, AND LAW
Call number: QH438.7 .G462 2008

Document 612
Barash, Carol Isaacson
JUST GENES: THE ETHICS OF GENETIC TECHNOLOGIES
Call number: QH438.7 .B37 2008

Document 613
Fortun, Mike
PROMISING GENOMICS: ICELAND AND DECODE GENETICS IN A WORLD OF SPECULATION
Call number: QH438.7 .F67 2008

Document 614
Hope, Janet
BIOBAZAAR: THE OPEN SOURCE REVOLUTION AND BIOTECHNOLOGY
Call number: K1519 .B54 H67 2008

Document 615
Dickenson, Donna
BODY SHOPPING: THE ECONOMY FUELED BY FLESH AND BLOOD
Call number: TP248.23 .D52 2008
**Document 616**

Cole-Turner, Ronald, ed.

*DESIGN AND DESTINY: JEWISH AND CHRISTIAN PERSPECTIVES ON HUMAN GERMLINE MODIFICATION*


Call number: RB155 .D42 2008

**Document 617**

McCabe, Linda L. and McCabe, Edward R.B.

*DNA: PROMISE AND PERIL*


Call number: RB155 .M314 2008

**Document 618**

Abu Ghuddah, 'Abd al-Sattar

*Al-wirathah al-bashariyah (wa al-jinat) wa tiknulwijiya al-takathur wa mawqif al-Shari'ah al-Islamiyah minha*  
*[The stance of the Islamic Sharia towards human genetics (and genes) and reproductive technology]*

In: Jundi, Ahmad Raja'i, ed., *Al-wirathah wa al-takathur al-bashari wa in'ikasuha: Ru'yat al-adyan al-samawiyah wa wjhat nazar al-'almaniyah* [Genetics, human reproduction and their repercussions: The vision of revealed religions and the viewpoint of secularism], Kuwait: Islamic Organization for Medical Sciences, 2008: 685-714

**Abstract:** This paper was submitted to the symposium held by the Islamic Organization for Medical Sciences (IOMS) during the period 6-9 February 2006 on human genetics and reproductive technologies. In the absence of decisive scriptural texts in the Koran and Sunna, the author argues that Islamic ethical perspectives on genetics and reproductive technologies should be based on assessing their possible harms and expected benefits.

**Document 619**

Albar, Muhammad 'Ali

*Taqniyat al-wirathah wa al-takathur al-bashari min al-manzur al-Islami*  
*[Genetic technologies and human reproduction from an Islamic perspective]*

In: Jundi, Ahmad Raja'i, ed., *Al-wirathah wa al-takathur al-bashari wa in'ikasuha: Ru'yat al-adyan al-samawiyah wa wjhat nazar al-'almaniyah* [Genetics, human reproduction and their repercussions: The vision of revealed religions and the viewpoint of secularism], Kuwait: Islamic Organization for Medical Sciences, 2008: 651-682

**Abstract:** This paper was submitted to the symposium held by the Islamic Organization for Medical Sciences (IOMS) during the period 6-9 February 2006 on human genetics and reproductive technologies. The author addresses a wide range of topics from an Islamic ethical perspective, including abortion; consanguineous marriage; preimplantation genetic diagnosis (PGD), DNA fingerprinting, cloning, genetic engineering and stem cell research.

**Document 620**

Hoeyer, Klaus

*The ethics of research biobanking: a critical review of the literature.*  
*Biotechnology & genetic engineering reviews* 2008; 25: 429-52

**Abstract:** Human tissue has been stored and used for research on a regular basis for more than 80 years. During the 1990s, collections of human tissue suddenly became framed as ethical problems in a process reflecting developments in genetic research intertwined with developments in patient rights and steps towards increased commercialization of research. This review describes the process of framing tissue storage as an ethical problem and the solutions proposed in the process. It gives an overview of the academic debate and relates this debate to empirical studies of donor attitudes and interests. It points to the clear discrepancy between the concerns of donors, legislators and ethicists. The academic debate and legislative action tend to focus on informed consent, and most of the concerns that donors have remain unattended to.
Document 621
Fadel, Hossam
Strategies to decrease the incidence of genetic disorders in Arab countries

Document 622
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