ABSTRACTS

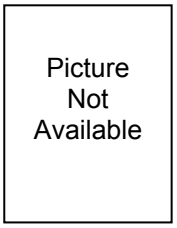
Picture Not Available

Author(s): Ayesha Ahmad, *PhD. (c)*

Affiliations: *Peninsula Medical School, University of Exeter*

Ambiguity in the Name of the Embryo

What is an embryo? A quick scout through embryology textbooks will yield a definition of embryology; i.e. “embryology is the study of the development of an organism from fertilisation of the ovum-the single cell stage-through the period of organogenesis, when primordial of the organ systems are established.” However with regard to the embryo as an organism, there is no definition provided. The embryo may be referred to as a subject in need of protection or as something that may be of therapeutic use, yet these two possibilities are seemingly at odds. Policies regarding embryonic research, for example, are designed to prevent vulnerable embryos from being exploited. Yet these same policies permit research at specific, early stages in embryonic development while creating barriers at further stages. Developmental biology demonstrates that the embryo at day one is different from the embryo at week one, and the week-old embryo is different from a month- old embryo. The differences are displayed in terms of physiological features, among other things. Arguments for protecting the embryo stress the embryo as human life from the moment of fertilisation. Indeed, many embryology textbooks use the terminology of “embryo death”. There are plenty of descriptions referring to the embryo’s size, rate of cell cycles, organ development, even the circumstances under which embryonic death can occur. Thus, if the embryo is synonymous with human life, how can a research policy justify embryonic experimentation or manipulation?



Author(s): Sarah E. Ali-Khan, *Ph.D.*[1]; Beatrice Seguin, P*h.D.*[1]; Peter A. Singer *MD, MPH, FRCPC & FRSC*[1,3,4]; & Abdallah S. Daar*, FRS* (c)[1,2,3]

Affiliations: *[1] McLaughlin-Rotman Centre for Global Health, University of Toronto; [2]Department of Public Health, University of Toronto; [3]McLaughlin Centre for Molecular Medicine, University of Toronto [4]Department of Medicine, University of Toronto and UHN*

Human Genomic Variation: Best practices in mapping differential disease susceptibility in sub-population groups- An African American Multiple Sclerosis Genetics case study

The implications of genomic differences between population groups, and their potential medical applications, are increasingly a topic of great interest. Despite the idea being controversial in some quarters, genetic differences between population groups do exist, and it is possible with some degree of accuracy to determine an individual's ancestry by studying genetic variation at a small number of loci. Admixture mapping is a powerful genome scanning strategy to pinpoint risk factors for complex diseases, but because it takes advantage of the genetic differences between sub-population groups it has heightened potential for GE^{3}LS implications. This qualitative study examines a large-scale Admixture scanning project being run by the International Multiple Sclerosis Genetics Consortium (IMSGC) that is mapping genes predisposing African Americans to getting Multiple Sclerosis (MS), a disease that is practically non-existent in Sub-Sahara Africa but that increases with genetic admixture with people of European ancestry. We are interviewing scientists, clinicians, ethicists, African American interest groups and other stakeholders in order to identify the actual GE^{3}LS issues that are emerging in this early example of admixture mapping for differential disease susceptibility and acquired disease predisposition in a sub-population group. Some of the topics we are focusing on are subject recruitment strategies, obtaining of informed consent, benefit sharing, and the management of DNA samples. We are also looking to uncover the utility of such studies in 'looking beyond' race to a more biologically-relevant appreciation of differences between populations of different geographical ancestry. Interviews are being systematically analyzed by qualitative methodologies to uncover important themes, and distill best practices and ethical guidelines. Ultimately, we hope this product will be a resource that can be built on by other groups studying the genomic basis of health and disease between different sub-population groups.

Author(s): Bita Amani, *LL.B., S.J.D*.

Affiliation: Assistant Professor, *Faculty of Law, Queen's University*

Biopatenting after the Supreme Court of Canada: Some Unhappy Compromises and Unintended Consequences

Recent findings by the Supreme Court of Canada on the patentability of higher life forms leave the law in this area unsettled. A judicial extension of patent rights seems contrary to strict doctrinal requirements for patentability and confuses significant distinctions between product and process patents. This paper reviews relevant case law and literature and examines the current Canadian position. The Supreme Court of Canada has recognized that higher life forms are not patentable, but has also extended a patentee's exclusive "right to use" to achieve similar protection over higher life forms through an infringement analysis. This provides backdoor protection to that which has directly been held to be unpatentable. This has created skewed incentives toward greater patentability of genes and DNA fragments arguably of lesser inventive merit as a means of securing patent rights to their embodiment in higher life. Public consultation, co-operation, and co-ordination amongst the public and private sectors, and governmental agencies and ministries, are needed to optimize public welfare and balance these interests against those of industry. In the United States, efforts are underway to legislate a ban on human gene patents. In Canada, a similar legislative response is needed but there is no indication that it is forthcoming. Where patenting life is concerned, the failure to legislate regulatory coherence into biopatenting cannot be exclusively attributed to international trade obligations that prescribe minimum protection requirements for WTO members.

Author(s): Cindy L. Baldassi, *LL.B, LL.M, Ph.D. (c)*

Affiliations: *University of British Columbia Faculty of Law*

The Rise of the Genetic Family and the Implications for Generation Reprotech

Building on Janet Dolgin's observation that American law is beginning to recognize the "genetic family" over the traditional family and families of choice, this paper considers the implications for Canada's reproductive technology users and resulting children. While Canadian legislatures and courts have gone much further than those in the United States in acknowledging families of choice (e.g., same sex couples and their children), the traditional family (heterosexual couples and their children) still holds sway in many circumstances. If the law now begins to define family as those related by genes, what will that mean for the other modes of family, and for the ever-growing group of gamete-donation offspring who can fall into either of those modes? Children born of egg, sperm and embryo donation rarely have access to their genetic relatives in Canada, and the law has not even changed as much as in adoption, where permanent records of identifying information and medical and social background are sometimes available to adopted people upon adulthood. If there is a right to be informed about genetic diseases running in one's genetic family, how will this obligation to inform affect anonymous gamete donors, since they may only become aware of a heritable disease years after donating? Would such a right lead to the ability to demand continuing updates from one's gamete donors, a right also potentially applicable to adoptees? And would gamete donation offspring and their parents have an obligation to track down the gamete source to inform them of genetic conditions that develop post-birth? The traditional deference legal authorities pay to adoptive and donation families may be on the wane, since a right to such information would mean that these children also have the right to be told of their origins - a right that is currently denied.

Author(s): Christian Bök, *M.A, PhD*

Affiliations: Assistant Professor*, Department of English, University of Calgary*

The Xenotext Experiment

"The Xenotext Experiment" is an artistic exercise to be undertaken by the poetic technician, Christian Bök, and the expert geneticist, Stuart Kauffman—two innovators who propose to create an example of "living poetry" by composing a short verse about language and genetics, translating this poem into a sequence of DNA for subsequent implantation into the genome of a bacterium (in this case, Deinococcus radiodurans). The two researchers plan to document the progress of their experiment for publication in a poetic manual that showcases the text of the poem, followed by an artfully designed monograph about the experiment, including, for example, the chemical alphabet for the cipher, the genetic sequence for the poetry, the schematics for the protein, and even a photograph of the microbe, complete with other apparati, such as charts, graphs, images, and essays, all outlining the results. The collaborators also expect to include (at the end the book) a slide with a sample of the microbe for scientific inspection by the public. The researchers also foresee creating related artwork for subsequent exhibition, including a sculpture of the gene made from toy molecules, plus a sequence of giclée images generated through the DNA-fingerprinting of the organism. The researchers hope that their unorthodox experiment might serve to integrate science and poetics—two domains that might not have otherwise had any reason to interact, except under the innovative conditions of this artistic exercise. Not only do the two thinkers hope to explore the aesthetic potential of a "literary genetics," but they also hope to refine methods for the biological encryption of data—methods that might be applied to domains as varied as cryptography, epidemiology, and agrobusiness. The researchers hope to demonstrate that, if scientists can perfect the process for implanting lengthy, texual information into an organism, we might not only provide a secure method for delivering secretive documents, but we might also "watermark" cells in order to track the movement of microbial diseases or botanical products. In the future, genetics might lend a possible, literary dimension to biology, granting every geneticist the power to become a poet in the medium of life.

Author(s): Yvonne Bombard[1], Lauren Currie[1], Gerry Veenstra[2], Jane Paulsen[3], Joan Bottorff[4] and Michael Hayden[1] on behalf of the Canadian Respond-HD collaborative research group*

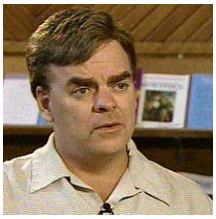
Affiliation(s): *[1] Department of Medical Genetics, University of British Columbia, [2] Department of Sociology, University of British Columbia, [3] Departments of Psychiatry, Neurology and Psychology, University of Iowa, [4] Faculty of Health and Social Development, University of British Columbia – Okanagan.*

One Origin, One Race but is There Equal Treatment? Experiences of Genetic Discrimination Among Individuals at Risk for Huntington Disease

Genetic discrimination (GD) is the perceived differential treatment of asymptomatic individuals on the basis of their actual or presumed genetic differences. Anecdotal instances of GD exist. Most recently, a young German teacher was denied a job because she was at risk for developing Huntington disease (HD), an inherited neuropsychiatric disease. A genetic test predicting risk of HD has been available since 1986; however some of the legal and social implications associated with having this knowledge have not been explored.

GD is a potential risk associated with genetic testing and the fear of GD has prevented individuals from undergoing genetic testing and participating in genetic research, thus hindering potentially beneficial engagement with genetic medicine and development of important scientific advances. Although concern for GD is widespread, there is limited evidence indicating whether GD exists in general and with respect to HD in particular.

To examine the nature and extent of GD, a cross-sectional, self-report survey of 293 asymptomatic individuals at risk for HD was undertaken. The sample comprised 233 tested and untested individuals (response rate of 79.5%). Discrimination was reported by 93 respondents (40%) and occurred most often in reference to life insurance, disability insurance, making reproductive decisions, friends and establishing relationships. GD did not differ in overall prevalence between the tested and not-tested respondents. Interestingly, family history rather than genetic test result was reported as the major reason for GD. As the first study to report the nature and prevalence of GD in Canada, these results may inform policy and identify areas were more education and counseling may be needed to support individuals identified as being at risk for developing a genetic disease.



Author(s): Kerry Bowman,[1] *PhD* and Michael Szego, [2] *B.Sc*.

Affiliations: [1] Bioethicist*, Mount Sinai Hospital*
University of Toronto
[2] *Department of Molecular and Medical Genetics, University of Toronto, Hospital for Sick Children*

Ethical Implications in Genetic Testing: Promise and Peril

The use of preimplantation genetic diagnosis (PGD) to screen embryos and pre natal diagnosis (PND) to screen the fetus for genetic anomalies is growing exponentially. Both PND and PGD are often used to identify chromosomal abnormalities (such as Down's Syndrome) and single gene disorders (such as Cystic Fibrosis). Society already expresses great concern in this area, however, new uses of PGD have been reported that are more ethically contentious. For example, embryos can be screened for susceptibility to cancer, for disorders that manifest later in life such as Huntington's Disease, and to identify an embryo that is tissue matched for a child (a future sibling) afflicted with a serious disease requiring a transplant. This is likely only the beginning. With time, PGD and PND will identify a pre-disposition to a host of disorders such as depression or autism. These emerging applications are raising profound social and ethical questions.

Although the same genetic tests currently available for PND can also be applied to PGD, significant ethical differences exist between them. While PND may lead to the termination of pregnancy for genetic reasons, PGD raises profound questions about the moral status of the embryo and the greater potential for eugenics.

This paper will review some of the ethical and social implications of these technologies, and give clinical examples from our practice to illustrate the moral complexities that have emerged. The implications of genetic testing in relation to attitudes toward people with disabilities will be explored. Furthermore, with the changing demographics of Canada, we will review the cultural differences in attitudes toward these technologies. We conclude with recommendations.

Author(s): Karen Eltis, *LL.B. /B.C.L., LL.M.*

Affiliations: Law Professor (Civil Law*), Law and Technology, University of Ottawa*

Genetic Determinism and Discrimination: A Call to Re-Orient Prevailing Human Rights Discourse to Better Comport with the Public Implications of Individual Genetic Testing

Genetic testing can not only provide information about diseases but also respecting their prevalence in ethnic, gender or other vulnerable populations. While offering the promise of significant therapeutic benefits and serving to highlight our commonality, genetic information also raises a number of sensitive human rights issues touching on identity and the perception thereof, as well as the possibility of discrimination and social stigma. Moreover, the stoicism with which the public tends to greet genetic information is of particular relevance to its eventual impact on rights in the genomics age. It stands to reason that the results of individual screening could haplessly be used to make *general* assumptions about entire ethnic or gender groups. In this manner, genetic information can directly influence identity; impacting and perhaps even reframing conceptions of group rights and dimensions of self-identification, thus importing constitutional scrutiny on questions of dignity and discrimination in particular. Is there a risk of collective stigmatization deriving from discrete testing of self-identified individuals? Would such stigmatization impinge on individual dignity by the exogenous imposition of ethnic or gender/sexual identify? If so, what norms can most adequately respond if and when individual and group interests diverge? These questions will be examined from a comparative perspective.

Author(s): Aphra Green[1], Richmond Wee[2], and B. Henaghan[3]

Affiliations: [1]Research Fellow, [2]Project Manager, [3]Dean of Law and Project Leader,
Law Foundation-sponsored Human Genome Research Project, Faculty of Law, University of Otago

Biotechnology Patents and the New Zealand Health and Research Sectors

The Law Foundation-sponsored Human Genome Research Project has just begun investigating the effects of patents on New Zealand's health and research sectors. An online survey of health services and research organizations in New Zealand is being undertaken to find out:

- the impact of patents, and particularly human gene patents, on the provision of and access to clinical genetic testing services in New Zealand;
- the patenting and licensing practices of the New Zealand research sector, particularly in the area of biotechnology; and
- the impact of patents, and particularly human gene patents, on the commercial success of the New Zealand research sector.

The issue of granting patents over gene sequences came to a head in New Zealand in 2003 when an Australian biotechnology company, Genetic Technologies Ltd (GTG), approached the New Zealand health sector and a number of life science organizations, and demanded license fees for the use of its patents on non-coding DNA analysis and mapping. Litigation with GTG was eventually settled. However, the lingering question for New Zealand has been whether GTG was a one-off case, whether key factors of the case are suggestive of broader issues and challenges within the health/research sectors, or even more possibly, whether it foreshadows what could be expected next in this area.

Despite a proliferation of opinion on the topic internationally, only a handful of empirical studies exist on the substantive effects of gene patents. No such studies have been undertaken in New Zealand until now.

This paper will discuss initial findings from our research, explore issues for further investigation in follow-up interviews with participants from the survey, and examine implications flowing from developments in this area in New Zealand and internationally.

Author(s): Greg Hagen, *LL.M., PhD*

Affiliations: Assistant Professor*, Faculty of Law, University of Calgary*

Potency, Preformation and Patenting

In Harvard v. Canada, the Supreme Court of Canada held that higher life forms are not patentable, but said in obiter dicta that a fertilized, genetically altered oncomouse egg would be patentable subject matter, regardless of its ultimate anticipated development into a mouse. Later, in 2006, the Canadian Intellectual Property Office ("CIPO") took the position that animals at any stage of development, from fertilized eggs on, are higher life forms and are thus not patentable subject matter under section 2 of the Patent Act. Further, it said that totipotent stem cells, which have the same potential as fertilized eggs to develop into an entire animal, are considered to be equivalents of fertilized eggs and are thus higher life forms and are not patentable subject matter. The position that a single totipotent cell is unpatentable was taken despite the fact that s. 12.04.01 of CIPO's Manual of Patent Office Practice provides that unicellular life forms are patentable subject matter. This paper reviews the reasoning of CIPO and suggests that it assumes an interpretation of developmental biology which has been put into question by advances in stem cell biology.

Author(s): Marsha Hanen[1], *C.M., PhD.* &;
Kenna Miskelly[2], *B.Sc., M.A.,*

Affiliations: [1]Adjunct Professor of Philosophy*, University of Victoria*

Biobanking: Preserving Patient Privacy and Autonomy

Because research involving biobanks is essentially future oriented, donor anonymity and privacy cannot be fully protected using the traditional practice of informed consent. We examine some models that have been proposed to safeguard privacy, and offer an alternative.

Solutions focusing on coding data appear to be too narrow, as they leave information vulnerable to hackers, human error, and new technologies which could be retroactively applied to stored information. Coding is also frequently coupled with presumed consent, which, we argue, is an ethically questionable practice.

Authorization models, which enable donors to grant an extended form of consent, appear more promising for two reasons: they look to uphold the values of informed consent and they strive for a greater level of transparency than has sometimes been part of medical or research settings. One drawback, given the networking and aggregation of information involved in research, is that it may not be possible for a donor to withdraw her sample completely or to have her data destroyed, should she so decide. Perhaps more important, the practice of informed consent has never fully matched its intent, and in some respects informed consent as it is applied does not actually promote autonomy. Thus, given that the informed consent process is flawed, it would be a mistake to pass on these flaws to an alternative model.

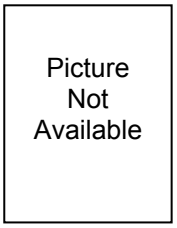
In light of the above concerns, we propose a model that empowers ethics review boards to prevent future problematic social and ethical consequences and to engender trust in patients. These boards would be composed of a broader membership than has been usual, with an emphasis on involving knowledgeable non-medical professionals in order to ensure impartiality, and to focus especially on preserving the dignity and autonomy, and thus the privacy, of donors.

Author(s): Shawn H.E. Harmon, *LL.B., LL.M.*

Affiliations: Research Fellow, *ESRC Centre for Social and Economic Research on Innovation in Genomics, University of Edinburgh, Edinburgh*

Values in Genomic Research Governance in the International Context

Genomics influences many facets of the human experience, from scientific/academic endeavour, to food production/consumption, to definitions of health and methods of healthcare delivery. In each case, it is reshaping our relationship with the world (eg: what we investigate and how we investigate it, how we view fauna/flora and the food we ingest, how we characterize disease and states of 'abnormality', etc.). The international community has issued a host of declaratory international instruments – informed by the human rights paradigm – which impact on genomics research. These instruments stress the special nature of our genetic heritage and attempt to set limits on our activities with respect to same, both investigatively and commercially. This paper examines the primary thrust and value positions of the key provisions of these instruments. Then, focusing on stem cells, an increasingly important and still controversial aspect of genomics research which is feeding our dreams of regenerative medicine, it inquires whether the control and command instruments (eg: hard regulation) applicable to research commercialization (eg: patenting) advances the same values and conforms to the same high-minded rhetoric. In particular, it examines the TRIPS Agreement together with domestic legislation from both developing and developed countries. It concludes by suggesting a course within the IP field for better realizing the values most broadly claimed.



Author(s): Matthew Herder, *LL.M., J.S.M.*

Affiliations:

Challenging the Corollaries of Commercialization: No Direct Financial Returns for Publics, Providers, & Participants in Biomedical Research?

Providers of bodily materials for research, including DNA, cells, gametes, and tissues are generally prohibited from receiving financial compensation save for personal expenses. Research participants are likewise barred from profiting regardless of the project's ultimate success. The most commonly stated rationale for this rule is that the promise of direct financial returns would coerce otherwise unwilling individuals into donation or participation, vitiating informed consent. Also lurking, however, is the view that giving direct compensation – especially shares in future profits – could undermine the commercialization of scientific discoveries into diagnostic and therapeutic products. This latter rationale has also trumped any suggestion that publics should receive direct returns from state-sponsored research programs. So-called "recoupment" or "payback" obligations are not generally incorporated into funding agreements, it is claimed, because they would create a host of disincentives, inefficiencies, and uncertainties for the range of actors – scientists, academic institutions, technology transfer officials, and private sector firms – tasked with commercializing biomedical research.

While these rules have long been enshrined in United States law and several other countries have institutionalized them as norms of practice, significant exceptions can now be observed. The aim of this paper is thus to: (1) expose the curious histories behind these norms; (2) demonstrate that each is based primarily upon a set of assumptions rather than empirical evidence about their potential impact upon commercialization; and, (3) suggest an alternative way of understanding direct financial returns, using large-scale stem cell research initiatives in the United States, particularly the California Institute for Regenerative Medicine, as a model. In the end, the value of such returns may be best conceived in democratic terms: as one means of attempting to balance a host of conflicting views and values, and preserve public trust as the many promises of biotechnology become increasingly integral to nation-building strategies and our lives.

Author(s): Anita Huntley, *LL.B., LL.M. (c)*

Affiliation: *Fasken, Martineau, DuMoulin, LLP, Toronto*

Applying a Corporate Governance Framework to Promote the Bioethics of Genetics Company Activities in Developing Countries

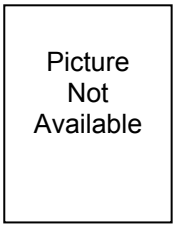
Business, including the business of genetics, has been heralded as a means for the reduction of poverty in developing countries. That said, business arrangements by pharmaceutical, biotechnology and other genetics companies in and with developing countries raise a host of complex challenges for bioethics, e.g., in the case of benefit sharing ventures and public-private partnerships. Bioethical criticisms have been launched against many of these endeavours, pointing to conflicts of interest that, real or perceived, call into question the very integrity of the science and business involved. Improperly addressed, ethical dilemmas can have dire consequences not only for developing countries, but for genetics companies and their stakeholders -- directors, officers, shareholders and experts. Are these companies equipped to be accountable for the bioethics of their activities? An analogy may be drawn to recent financial reporting scandals in the United States that have been addressed by the institution of corporate governance mechanisms to protect stakeholders, while ensuring that officers, directors and experts have the right information and support to make ethical decisions. Properly conceived, a corporate governance framework could also help promote the bioethics of genetics company activities in developing countries. Directors, officers and experts could be apprised of better information and evaluation tools to make bioethical choices. Shareholders could be educated to judge the bioethics of a genetics company's activities in developing countries and empowered to have a say. In the result, developing countries could benefit from informed bioethical analysis at all stages of business engagement.

Author(s): Tom Keenan, *Ed,D., FCIPS, I.S.P.*

Affiliations: Professor*, Faculty of Environmental Design, Adjunct Professor, Dept. of Computer Science, Unviersity of Calgary*

On the Internet, Things Never Really Go Away: The Looming Challenge of Data Persistence of Bio-Information

The phenomenal rise of the Internet elevated the problem of Data Persistence to a public issue, as the "private" emails of public figures such Oliver North and Bill Gates were introduced in court proceedings. Search engine spiders, caching sites (both documented and secret) mirror sites, web mail and web storage have led to a situation where, unless specific precautions are taken, one should essentially assume that data placed on the Internet can never be completely recaptured and may be viewed by others. New technologies,from 3D virtual worlds, to camera phones to video sharing sites, give the question of "Where Has My Data Gone and How Do I Really Know?" some new and frightening dimensions. Future developments like "signature by DNA biometric" will make the issue even more urgent and more complex.



Author(s): Aneal Khan, *M.D., FRCPC*

Affiliation: *Alberta Children's Hospital, University of Calgary*

Challenges to Clinical Medicine in the new era of Genetics:
The Elephant in the Living Room

In just over 50 years since the discovery of DNA, genetics has become a dominant force in clinical medicine. Out of the 3 X 10^9 base pairs in the human genome, so far close to 18, 000 disorders of proven or suspect genetic basis are catalogued on Online Mendelian Inheritance in Man (OMIM) and over 1 million entries involving genes exist in PubMed. Today, a diagnosis of cancer almost universally involves genetic testing to identify prognostic and treatment factors. Screening for genetic disorders in newborn infants for dozens of conditions is possible before any symptoms of disease arise. To date, resources have been directed towards screening technologies yet the impact of having all those children with positive screens seen by community and hospital clinicians is overlooked. Despite attempts using genetic tests to identify which disease(s) an individual is likely to suffer from, health care coverage has been denied to people on the basis of their genetic predisposition, not whether or not they have a disease. Testing for all genetic disorders is beyond the capability of any private or public institution and considerable expense can be involved sending for testing around the world. Furthermore, emerging therapies targeted at rare genetic disorders, some costing as much as $500, 000 per patient per year for life, easily outstrip the resources of the individual patient and most small jurisdictions. As genetics has emerged from a study of rare metabolic disorder to affecting the health of every individual, clinical medicine and the health care system must be designed to cope with the ethical and resource challenges in this new era of Genetics.

Author(s): Bartha Maria Knoppers, *LL.B, PhD*

Affiliations: Project Director of HumGen International, *University of Montreal*

Population Genomics, Biobanking and Informed Consent: CARTaGENE

Since the Nuremberg Code, an autonomous and informed consent has been the bedrock of voluntary participation in research. While a sign of respect for persons, their individuality and their values, an over-emphasis on the principle of autonomy has unwillingly fostered certain anomalies in biobanking and population genomics research.

The first is the equation of the person with their tissue especially now that such tissues are perceived as holding “the code of life”. Paradoxically, the second is the paternalism of ethics committees, as they constrain competent adult participants from providing DNA and data for future research so as to “protect” them from their own freely made decisions. Between the sacralisation or the reification of tissues and data, how can prospective policies frame population genomics? Will Quebec’s CARTaGENE project meet these challenges?

Author(s): Jerzy Koopman, *LL.M., Ph. D. Researcher*

Affiliations: *Centre for Intellectual Property Law, Molengraaff Institute, Utrecht University, The Netherlands*

Exploitation of Human Genetic Material: Towards Human Rights-Proof Patent Laws

The increasingly complicated manner in which biotechnological inventions are attained, the growing number of participants in the process of innovation, and the accelerated use of the patent system by them throughout all phases of R&D, has rightly called for attention. Central is the question of how the process of innovation should be structured, facilitated and regulated to enhance the development of useful products such as biopharmaceuticals – the subject matter in this presentation – while simultaneously respecting social, ecological, cultural and human rights and interests of the groups (such as indigenous communities and families) and individuals that contribute to R&D processes (e.g. by handing over materials). Outcomes of R&D are often patented to allow recouping of investments, and patent systems have been developed according to economic parameters. This has spurred a certain kind of technological progress. However, it becomes clear that the mere economic make-up of these regimes negates other aspects of these inventions. Several human rights instruments may be implicated by patenting. These include rights conveyed pursuant to, for example, the Convention on Human Rights in Biomedicine and the International Covenant on Economic, Social and Cultural Rights. Several countries are pursuing amendments to their patent regimes and patentability requirements (e.g. disclosure, art. 29(1) TRIPS) and exceptions (e.g. public order and morality, art. 27(2) TRIPS). This results in additional obligations for patent applicants (e.g. the obligation to handover proof of the prior informed consent of donors). In this presentation, these initiatives are discussed. The focus is on the European Patent Convention, but comparisons are provided. Whereas contemporary patent laws and their workings may negatively touch upon human rights instruments, one can often not speak of violations but rather of ethical and legal asymmetries. These initiatives to align patent laws with human rights instruments may complicate things even further though. Therefore, suggestions on how to move forward are provided.

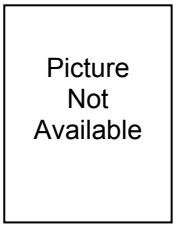
Author(s): Michael J. Malinowski*, B.A., J.D.*

Affiliations: Biotechnology and Bioethics Professor, *Paul M. Hebert Law Center,* Louisiana State University, Baton Rouge

Dealing with the Reality of Race and Ethnicity: A Bioethics-Centered Argument in Favor of Race-Based Genetics Research

Considerable race, ethnicity, and ancestry-based genetics research has been undertaken in recent years, and more is underway. Race and ethnicity are social constructs, and many – drawing from a bouquet of disciplines that includes science, medicine and law – argue that the human population groupings they form are inconsistent with the scientific reality of human genetics. Their reasoning is that genetics will group us differently, often dramatically so, and it is scientifically and socially misguided and inconsistent with U.S. law and policy against discrimination to approach contemporary population genetics with methodologies that embrace these constructs. While the debate over race-based research has been of mixed opinion in the natural science and medical disciplines, there is a considerable majority opinion among law academics that race-based research is wrong on multiple levels.

This article proposes that responsible race-based research, both basic and clinical, is possible and even desirable. The article emphasizes that race and ethnicity are as real socially and culturally as genetics is scientifically, and it promotes approaching race-based genetics with the mindset of affirmative action rather than anti-discrimination. The article concludes that applied bioethics and scientific pragmatism favor full recognition of and responsiveness to race and ethnicity as a preferred methodology for population genetics. This conclusion is based on several observations, the first of which is that the proposed approach is most sensitive to communication with members of groups under study, the realization of individual informed consent, recognition and assessment of group impact, and the development and realization of group consent in population genetics. The second is that responsible race and ethnicity-based research may prove a means of access to the genomics revolution for racial and ethnic groups left out thus far. The third is science-based. Should the science critics of race and ethnicity-centered research prove to be correct, research outcomes and associated health care applications will transcend the groups under study to benefit the human species in general, and doing this research will accelerate establishing scientifically that race and ethnicity are not genetic realities. To the extent the critics are incorrect, the groups under study will benefit disproportionately through scientific understanding and greater likelihood of medicinal applications tailored to their genetic idiosyncrasies. The article's proposal intends to promote several important goals, including heightened sensitivity towards people's self-identification, group identification, and group impact in the context of population genetics research on human subjects; an increase in the rate of translation of the map of the human genome into medical meaning through more group participation in biomedical research; an increase in participation in the genomics revolution by groups organized socially and culturally by race and ethnicity; and a lessening of negative, documented disparities in the delivery of health care for these groups.



Author(s): Rhiannon Noble[1], *B.Sc., M.Sc.*;
Tania Bubela[2], *LL.B, PhD.;*
Andreas Strotmann[3], *PhD.*

Affiliations: [1]*University of Alberta Scientific Patent Office*;
[2]Assistant Professor, *School of Business, University of Alberta*
[3]Post-Doctoral Fellow, *University of Alberta*

Examining Patents of Basic Research Tools and their Downstream Effects

There has been a trend in governmental and institutional policies toward the commercialization of science, especially biotechnology. This has lead to a rush to patent basic research tools at the expense of open access alternatives. In particular, a plethora of patents on upstream methods and products may impact the ability to establish public research resources such as the international knock-out mouse projects, KOMP, EuCOMM and NorCOMM, which aim to make knock out mice or Embryonic stem cell lines publicly available for every gene in the mouse genome. Our study develops a patent landscape of a quintessential biomedical research tool, the mouse, to obtain a quantitative measure of how this model organism is being privatized and from there examine the cause and effect of this phenomenon. We performed a search of the USPTO database using Delphion for patents including DNA sequences (Cook-Deegan Algorithm) and mouse (or common variations) in the claims. This provided 6,979 US granted patents, which we systematically analyzed, and found that the majority are method or process patents, and only 30% were relevant to our research question. An in-depth examination of these patents, which claim mouse cells, DNA or the whole organism, revealed that the majority are assigned to pharmaceutical companies followed by public universities. Approximately half of the patents are held by private companies, which can make it difficult for public resource organizations to gain access to necessary research tools. For example, intellectual property issues and access to resources have had an impact on the Knockout Mouse Project (KOMP) in the US, where the NIH has had to license knockout mouse lines from two biotechnology companies, Lexicon and Deltagen, to make them available to researchers. Our study aims to examine the effects of the commercialization of the mouse using various scientometirc analyses of research output, such as publications and collaboration patterns in fields of mouse genomics that are heavily patented versus those which are not. These results will provide a more accurate picture of the effect of commercialization of research tools.

Picture Not Available

Author(s): Noelle C. Orton[1], *MSc,* Edna F. Einsiedel[2], *PhD*

Affiliations: [1]GELS Project Manager
[2] Professor of Communication Studies
Faculty of Communication and Culture, University of Calgary

Access to Data and Materials in the Life Sciences- A Study of the *Caenorhabditis elegans* Knockout Project as a Model for the North American Conditional Mouse Mutagenesis (NorCOMM) Project

With the availability of whole genome sequence for many organisms several groups have begun on the next stage of genomic research –systematically disabling every gene within an organism's genome. Started in 1998, the *Caenorhabditis elegans* Gene Knockout project is well on its way to being the first complete knockout of a multicellular organism. We are interested in studying the effects of policies regarding access to data and materials generated by this project.

The mission of the *C.elegans* Knockout project is to facilitate the genetic research of this model system. To do this, several unique policies have been adopted by the project such as: 1) ease of access to mutants and data: all mutants are stored in one central repository, the Caenorhabditis Genetics Centre at the University of Minnesota and all experimental data for the mutants is deposited in Wormbase. 2) No withholding of mutants: Researchers are able to request the knockout of a specific gene but once a mutant is created it is made available to all researchers without delay. 3) Low Cost: All mutants are distributed for a flat fee of $7/strain to academic users ($100 for non-academic research). 4) No Restrictions on Use: Investigators are only requested to acknowledge the source of mutants in any publications; no material transfer agreements are used.

The North American Conditional Mouse Mutagenesis (NorCOMM) project is aiming to improve access to mouse models for researchers. In collaboration with the American (KOMP) and European (EUCOMM) knockout projects, it aims to provide universal access to the mutant mice and ES cells to researchers for a minimal cost.

Our study of the *C.elegans* project through interviews with key players in the *C.elegans* and broader research community will give us insight into the impact of the policies adopted by this project. We hope to use the *C. elegans* project as a model for NorCOMM as it further develops its own policies regarding access to research materials.

Author(s): Cathy Anne Pachnowski, *LL.M*.

Affiliations: Information and Security Privacy Officer,
Alberta Cancer Board

The Alberta Research Tumor Bank - Privacy Best Practices

We live in remarkable times. With patient consent, small vials of tumor specimens from cancer surgery can be stored at very low temperatures and used for research for years to come. The potential for conducting leading-edge research and eradicating cancer is enormous, but how do we balance that potential with ensuring that individual patient privacy is protected?

This presentation will offer the Canadian Breast Cancer Foundation Alberta/NWT Chapter Alberta Research Tumor Bank (Tumor Bank) as an example of how best practices regarding privacy are being followed. The Alberta Cancer Board developed and operates the Tumor Bank -- a comprehensive collection of cancer specimens and related clinical information. Provincial, national and international researchers with ethical and administrative approval can obtain specimens and information from the Bank. The Canadian Breast Cancer Foundation Alberta/NWT Chapter provides financial support for this initiative.

This paper outlines proactive measures being taken to protect patient privacy. It focuses on the Alberta Cancer Board's voluntary submission of a Privacy Impact Assessment to the provincial Office of the Information and Privacy Commissioner. Although a Privacy Impact Assessment was not mandatory under Alberta's *Health Information Act*, one was submitted in the spirit of ensuring that the Cancer Board has exercised due diligence in addressing privacy and security concerns. The Privacy Commissioner's Office accepted the Privacy Impact Assessment, which included a series of administrative, technical and physical safeguards for the Tumor Bank information. This paper explores these safeguards and explains how best practices regarding privacy are being actively followed.

Author(s): Verónica B. Piñero, LL.M., PhD. (c)

Affiliations: *C.I.R.C.E.M., Université d'Ottawa*

**Can Children Consent to Medical Treatment?
An International Legal Exploration from a
Children's Rights Perspective**

The *Convention on the Rights of the Child* (*CRC*), ratified by Canada in 1991, meant a paradigmatic shift in notion of childhood. Children were no longer seen as objects to be protected, but as subjects who were able to express their perspectives and willingness. In an attempt to augment the autonomy of children, article 12(1) of the *CRC* notes that "States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the chid." However, a question arises: does this article regulate children's ability to consent to medical treatment? The answer is not clear, and the *CRC* principle of the "best interest of the child", does not necessarily let an affirmative answer.

The *International Covenant on Civil and Political Rights*, along with other international guidelines, has regulated consent to medical experimentation; however, the issue of consent to medical treatment is left by aside. Having examined the body of international law that regulates consent during medical decision making, the author highlights a legal lacuna concerning the regulation of children's consent to medical treatment. Next, and focusing on the *CRC* principle of the "evolving capacities of the child", she discusses whether a child has the capacity to consent to medical treatment, and whether the persons legally responsible for the child should be notified about the medical treatment. Finally, she discusses if such notification infringes the child's right to privacy regulated in article 16 of the *CRC*.

Author(s): Adit Pujari, *B.A./B.Sc., LL.B. (h) student*

Affiliation: *National University of Juridical Sciences, Kolkata, India*

Protecting Traditional Knowledge in India: Creating a Future Based on Past Projections?

This paper addresses the position that India warrants in regard to traditional knowledge protection globally, owing to its diversity of cultures and peoples and their corresponding customary practices. Issues of access-benefit sharing shall be dealt with, concerning derivations from existing knowledge. Disclosure is a pre-requisite for the grant of patents, and certain Indigenous communities regard the revelation of their practices with derision. This viewpoint shall be analyzed and the researcher shall propose a pragmatic model that, while respecting the antipathy of certain communities to disclosure, is also advertent to a utilitarian approach that would apply the benefits of knowledge to a larger population.

The Indian government has, over the years, endeavored to make a comprehensive database of Indigenous knowledge and applications of this knowledge. This is in keeping with the verity of the statement that "present day knowledge in terms of prior art only means documented records". Prior art is essential to show the existence of the idea that the patent-applicant has used in his creation, thus, in effect, vitiating the "novelty" of the creation. Such a database has also been made in the case of *Yoga* and *Yogic Asanas* (Positions). This paper shall address the application of patents and copyrights in regard to *Yoga* and its validity in light of the existing database. Finally, the paper shall discuss how apparent setbacks[1] to the protection of Indigenous knowledge – because of awards of patents to creations based upon this knowledge – have acted in fact as stimuli for protective regulatory action.

[1]The term 'setback' may connote a negative meaning in this regard, but it is due to these 'setbacks' that awareness in the matter of Traditional Knowledge protection has spread in India, resulting in governmental action for its protection.

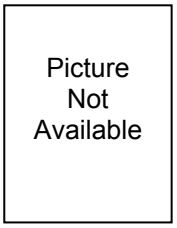
Author(s): Catherine Rhodes, *PhD*

Affiliations: Research Fellow*, Dept. of Peace Studies, University of Bradford*

Sustainable Development and Genetic Research - Reconciling the Interests of Developed and Developing Countries

The need for and utility of the sustainable development approach has been repeatedly articulated by the international community over the past thirty-five years. Sustainable development seeks to meet development needs without imposing unsustainable stresses on the environment. Sustainable development is a particularly suitable approach for the international regulation of genetic research because managed in the right way, it has great potential for improving human, animal and plant health, nutrition, food security, conservation and use of natural resources – all key elements for sustainable development. However, if genetic research is not managed within a sustainable development approach, the gap between the developed and developing worlds is likely to become further entrenched.

The key documents produced by the international community on sustainable development have all recognized the key role that science and technology, including biotechnologies, have to play in sustainable development. But the approach is only substantially used in five of the thirty-six international regulations that cover biotechnology, and is generally poorly implemented by the international community. The international community has the knowledge and many of the tools needed to reconcile the interests of developed and developing nations, but not the political will. Until it does, the interests of developed nations will continue to dominate the path of genetic research.



Author(s): Janna Rosales, M.A., *PhD*. (c)

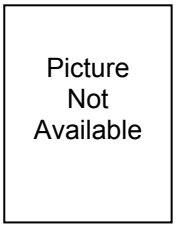
Affiliations: Junior Fellow*, Massey College, University of Toronto*

Transhumanism, Eugenics and the Principle of Procreative Beneficence

Transhumanism is a loosely organized philosophy or movement which advocates using technology to enhance and extend human capabilities, and to possibly overcome human "limitations" all together. Transhumanists advocate prolongation of life by slowing down or stopping the aging process, enhancement of oneself and one's offspring through genetic engineering, and implantation of nanotechnology and cybernetic technology into the body to extend the senses or to monitor health. In essence, transhumanists propose self-directed evolution through technology.

Some transhumanists have asserted that once genetic and reproductive technologies are proven safe and effective, parents have a *moral obligation* to select a child they judge to have the greatest potential, according to a principle known as procreative beneficence. However, the question of eugenics arises if and when technology gives us the ability to select the qualities of our offspring; we're already charting some of those waters with respect to sex selection, designer babies and saviour siblings. Some transhumanists flatly reject eugenicist correlations, while others openly admit to eugenic leanings, although they too distance themselves from association with previous notable eugenics movements.

This paper will examine transhumanist views on genetic engineering as they pertain to the principle of procreative beneficence. It will also discuss various transhumanist interpretations of and commentary on eugenics. Finally, using the lens provided by the moral philosophy of Canadian philosopher George Grant, it will raise the question of whether a transhumanist approach to self-directed evolution is an adequate moral response to the ethical issues raised by human enhancement technologies



Author(s): Victoria Seavilleklein, *PhD.*

Affiliation: Fellow, Clinical and Organizational Ethics, *Joint Centre for Bioethics, University of Toronto*

The Public Health Value of Prenatal Genetic Screening

One of the most widespread applications of genetic information arising from the Human Genome Project has been in the implementation of prenatal genetic testing technologies. The Society of Obstetricians and Gynaecologists of Canada has recently recommended that prenatal genetic screening be offered to all pregnant women regardless of age, disease history or risk status (Summers, 2007). What values is this screening thought to fulfill?

Autonomy for pregnant women is overwhelmingly cited by genetics departments, health care providers, and the public as the reason for providing these screens. Much less publicly discussed, however, is the value of public health which plays an important role in motivating screening programs. Yet for most of the conditions screened there are no treatments or cures available to improve the health of the developing fetus, and societal benefits such as improved infant mortality rates and public cost savings are presumed to accrue when fetuses with anomalies are aborted (Comis, J, 1991; Public Health Agency of Canada, 2005).

In this paper, I analyze the role of prenatal genetic screening as a public health strategy. I argue that while prenatal genetic screening, diagnosis and abortion fit in a public health framework in some ways, they differ from paradigmatic examples of public health in other significant ways, namely in the definition of 'prevention' and in the beneficiaries of the programs. I also explore the assumptions that underlie the implementation of screening programs and argue that these assumptions make the practice vulnerable to charges of devaluation brought against them by disability rights theorists. I conclude that such programs are not inherently devaluing but that in light of past and current discriminatory attitudes toward people with disabilities, changes to the practice must be made to reduce both the possibility and the perception of discrimination in this use of genetic technology.

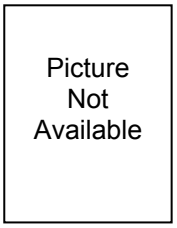
Author(s): David M. Secko[1], *M.J., Ph.D*,; Nina Preto[2], *LLB., MSc*, Simon Niemeyer[3], *Ph.D,* & Michael M. Burgess[4], *PhD*

Affiliations: [1]Assistant Professor*, Department of Journalism, Concordia University*
[2]Doctoral Trainee*, W. Maurice Young Centre for Applied Ethics, University of British Columbia;*
[3]ARC Postdoctoral Research Fellow*, Deliberative Democracy Research Group, Department of Political Science, RSSS, The Australian National University;* [4]*Chair in Biomedical Ethics, W. Maurice Young Centre for Applied Ethics, UBC*

Informed Consent in Biobanking Research:
Fresh Evidence for the Debate

The current requirements and rationales for informed consent in research have evolved through a long series of abuses, particularly in the area of health research. The primary purpose of the informed consent process is to protect the autonomy and interests of individual human subjects. However, some suggest that where the scale of impact and influence of the research reaches beyond the individual to the broader public, such individualistic protections may not be appropriate. It could be argued that potential societal benefits from medical advances made through the use of biobanks are too important to be weighed down by the current narrow focus on the individual subject. Alternatively, biobanks could support research that some fear will breach privacy, be offensive to groups such as First Nations peoples, and enable discrimination. Such arguments highlight the underlying tension between individual interests and the broader societal impacts, begging the question of how a balance might best be struck.

Our paper will outline some of the challenges current consent requirements raise in the context of biobanking and review approaches that have been suggested as solutions. Against this backdrop, we will discuss our research team's recent public engagement event (http://biobanktalk.ca/) that brought a group of British Columbians together to deliberate on what values and interests ought to be considered in the regulation and use of biobanks for health research. We will discuss preliminary findings that draw on data collected through novel survey techniques and small and large group discussions. We use this data to track changes in opinion over the course of the event and discuss how participants balanced the tension between the individual subject's interest and broader societal interests. We end by relating participant deliberations to the ongoing debate in the literature over the place of informed consent in biobanking.

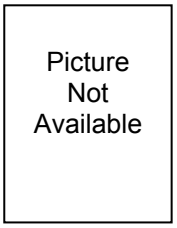


Author(s): Aaron Sheldon , *B.Sc.*

Affiliation: *Calgary Centre for Health Research*

Protecting Both Patient Privacy and Scientific Integrity:
A Technical Perspective

The ad hoc and Balkanized nature of the management of data sets in health research has failed in two important regards: first to protect the privacy of patients, and second to ensure the integrity of the scientific process. Furthermore, the complexities of the diseases being investigated have fostered the development of bio-banks and public health observatories, with the potential to match the data held in both. To address the problems raised by the development of these new health research tools the author will present a data management strategy that draws on the best practices from a diverse set of fields such as Genome Annotation projects, High Energy Particle Physics, and Experimental Cosmology. Specifically, the data management strategy will provide for the de-identification of patient data, the matching of large data sets, the enforcement of rigorous hypothesis driven blinded analysis, and the maintenance of data validity and integrity. The author will preface this by reviewing arguments for the obligatory participation in public health observatories and bio-banks, and for that information to be held in trust as a public resource. Finally the author will conclude with a brief remark on a few of the potential future effects of technological and biological research.



Author(s): Jacob J. Shelley, *LL.B.*[1] & Leia M. Minaker, *M.Sc.*[2]

Affiliations: [1] LLM Candidate, *Faculty of Law, University of Alberta & Researcher, Health Law Institute, University of Alberta*
[2] PhD Candidate, *School of Public Health, University of Alberta & Research Assistant, Centre for Studies in Health Promotion, University of Alberta*

Nutrigenomics from a Population Health Perspective

Many challenges must be overcome in order for emerging genetic technologies to be successfully incorporated into Canadian society. Nutrigenomics provides an excellent case study for contemplating some of the barriers facing the widespread acceptance of new and emerging health technologies in a Canadian context. Integrating functional genomics, nutrition and health, nutrigenomics is believed by some to hold much promise for improving population health, particularly through the prevention of chronic disease. Translating the science of nutrigenomics into health policy, however, may prove to be a process fraught with difficulties. This paper will contemplate the legal, ethical and social implications of nutrigenomics from a population health perspective as well as a public health law perspective. The aim of public health law embodies a number of essential characteristics, several of which overlap with the population health approach. For example, both public health law and the population health approach are concerned with improving the health of the entire population. Similarly, they are both concerned with power imbalances and health inequities. Health promotion, likewise, addresses disparities in health; their causes and potential solutions. Particular emphasis will be placed on theories of population health and health promotion. Determinants of health and health behaviors (particularly diet and food choice) will be explored and gaps between nutrigenomics research and ideal practice will be addressed.

Author(s): Vasudha Singh, *B.A/ B.L (h) candidate,* & Stella Joseph, *B.A./B.L (h) candidate*

Affiliations: *National Academy of LegalStudies and Research (NALSAR),Hyderabad, India*

Human Gene Patent in India: Possibility and Consequence

Human genome research is taking today's world by storm and India can no longer afford to ignore this development. In fact, India may prove to be very fertile ground for the study of human genes in the light of certain of its idiosyncratic characteristics like its large population and family size which increases the probability of the occurrence of rare genetic disorders. Furthermore, the Indian biotechnology R& D sector is burgeoning domestically and has as well enormous potential to attract foreign investment.

Therefore, at this stage the role of the patent regime in this sector becomes critical for its growth. The current picture regarding the possibility, extent and scope of human gene patenting in India, is at best, nebulous. The Indian Patents Act, even after the 2005 Amendment[2] fails to clearly address this issue. Legal development in this field is bound to occur in the light of above described scenario and this development could happen in many ways. It could take into consideration the interests of all the stakeholders (in the light of the ignorance among a lot of the population that will be exploited) or it could be one sided like the decision in *Moore* v. *Regent of the University of California*[3] in the US. So in this paper the researchers intend to chart out the various hypothetical routes this development *can* take and point out the routes that it *should* take in the light of the existing socio-legal matrix in India.

[2] The Indian Patents Act, 1970 does not directly refer to gene patenting. The only provisions which could be said to be vaguely alluding to gene patenting are S. 3 (c) and (j). These are as follows:
3 (c): the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature.
3(j) : plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.
[3] [1991] 793 P.2d. 479

Picture Not Available

Author(s): Thushi Thavaratnam, *B.Sc. (h)* Student

Affiliations: *University of Toronto*

Public Perceptions on Stem Cell Sources and Policies: A Comparison Between the Viewpoints of Young Adults & Seniors

Although stem cells have the potential to treat a variety of incurable diseases, it has been and continues to be, a very controversial area of research. The primary concerns in this field revolve around the sources from which these cells are derived. This study analyzed the views of both seniors and young adults towards different stem cell sources and policies. Two separate focus groups were held for both age groups, with a total of 12 young adults and 13 senior citizens participating. The methodology followed for each of the focus groups was similar. Five stem cell sources were employed: cord blood, adult stem cells, embryonic stem cells, somatic cell nuclear transfer or therapeutic cloning and interspecies somatic cell nuclear transfer or interspecies cloning. The stem cell policies of the United Kingdom, Canada, and the United States differing by degree of restrictiveness were also used as sample policies to gauge the reaction of these groups. Results showed that cord blood and adult stem cells were the least controversial sources for stem cells, among both the seniors and the young adults. The source that was the most controversial for both groups was embryonic stem cells. Furthermore, similar concerns and issues were addressed by the seniors and young adults towards both somatic cell nuclear transfer and interspecies somatic cell nuclear transfer methods. Differences did surface however, when the groups were faced with a policy choice: young adults were much more likely than seniors to support the policy that was least restrictive of research.

Picture Not Available

Author(s): Heather Walmsley, PhD

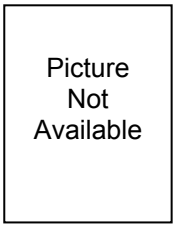
Affiliations: Visiting Doctoral Fellow, *W. Maurice Young Centre for Applied Ethics, University of British Columbia*
PhD Student, *ESRC Centre for Economic and Social Aspects of Genomics (CESAGen), Lancaster University*

From Infertile Super-Humans to a United Nations for Biobanks: Public Hopes, Fears and Innovative Design Solutions for Biobank Governance in BC

Mad scientists greedily cloning the dead and designing infertile super-humans - such dystopian fears surrounding advances in genomics are no longer novel. Utopian hopes for large independently-governed biobanks facilitating better healthcare for all and cures for orphan diseases are voiced perhaps less often. Rarer still is the opportunity for diverse members of the Canadian public to articulate such hopes and concerns, consider the latest research from varied disciplinary perspectives, deliberate over the trade-offs involved, and to formulate policy recommendations for biobank governance in their own province.

This paper draws from a recent exercise in deliberative democracy run by researchers at the University of British Columbia. The problem: privacy demands, commercialization fears, indigenous DNA misuse and consent burdens have all challenged the utility of existing governance frameworks for large-scale and networked 'biobanks'. The solution: draw from emerging theories of deliberative democracy; bring together 25 diverse BC residents for two weekends of small-group deliberation over the values and interests that should guide biobanking. Finally, ask them to design a BC Biobank.

This paper combines narrative analysis and participant observation by one of the focus group facilitators at this deliberative public consultation. Firstly, I present the key hopes and concerns for biobanking voiced by participants in one of three focus groups. Secondly I outline the innovative design solutions developed by this group to address their own hopes and fears. Finally, I consider the quality of 'deliberation' from the perspective of the democratic 'difference theorists'. Did the unemployed female from a rural First Nations community have 'equal' voice in deliberations to the male urban IT worker? Through what discursive events did some hopes and concerns make their way into concrete design solutions while others were discarded? What was the impact of imagination-focused versus decision-focused tasks on the content and quality of deliberation that ensued?



Author(s): Wei Wang, *M.A*.

Affiliations: *Dept. of Philosophy, University of Alberta*

Recasting an Understanding of Personhood: A Cross-Cultural Perspective on the Moral Status of the Human Embryo

Notwithstanding the great potential of stem cell research in developing new therapeutic treatments to cure many currently untreatable diseases, debates surrounding the moral permissibility of human embryonic stem (HES) cell research rest heavily on a controversial stance in regard to the moral status of the human embryo. Some hold that research using human embryos is morally acceptable as embryos are nothing but a mere cluster of cells which do not possess the moral standing of persons. However, opponents of such research insist that embryos have the moral status of persons and are thus entitled a right to life. In their view, research involving any intentional destruction of embryos cannot be morally justified. There is, though, a third position which may provide an alternative – that of the Confucian concept of personhood. The Confucian concept of personhood is closely tied with various human relationships in a social context; i.e., a person is always identified as a person-in-relations. This paper critically explores the central contentions that have defined the debate about personhood from a cross-cultural perspective. Attempts are centered on recasting an understanding of personhood that incorporates autonomous individuality into social relationships. The proposed recasting is to explore two distinct groundings, an understanding of person from the Confucian perspective and the relational perspective of personhood from the position of relational ethics, without prejudice to the question whether one or the other is true. The point here is to showcase how the proposed recasting would possibly go. So, one who responds to the appeal of relational ethics may find comfort no matter how little or how much knowledge they probably have about Confucian bioethics in terms of the Chinese conception of human personhood.

Picture Not Available

Author(s): Brandace Winquist*, BA (hons), MSc*

Affiliations: Doctoral Candidate & Strategic Training Fellow,
Community Health and Epidemiology, College of Medicine
Community and Population Health Research, University of Saskatchewan

Prenatal Screening in Saskatchewan: Impact, Uptake, and Ethics

With the help of increasingly sophisticated biomedical technology we can now detect a growing number of conditions in fetuses with more accuracy, more specificity and earlier in pregnancy. While this may be seen as an improvement in medical science, some would argue that we have not paid enough attention to population level, social, ethical and even moral implications of this rapidly growing field of prenatal screening. This study addresses several issues that have been until now under-researched and under-discussed.

Objectives: Three major questions will be examined: (1) Does Saskatchewan's prenatal screening program have a measurable impact on population health outcomes, specifically, infant mortality rates and live birth prevalence rates of major categories of congenital anomalies? (2) What are the predictors of prenatal screening utilization and prenatal diagnosis in Saskatchewan (eg. First Nations/ non-First Nations, rural/urban/north, age group, education level)? (3) How do we decide what conditions ought to be allowed for prenatal screening in a time of expanding testing options?

Methods: Data will be compiled containing information on all stillbirths, live births and terminations of pregnancies in the province of Saskatchewan from January 2000 to December 2005. Linked data will be drawn from three sources: the Provincial lab, both regional Cytogenetic labs, and Saskatchewan's administrative health databases. Infants will be followed-up for one year after birth in order to identify any congenital anomaly diagnosis. A survey of all Saskatchewan physicians providing prenatal care will be part of the inquiry into ethical implications.

Significance: National data systems such as the Canadian Congenital Anomaly Surveillance System currently do not capture most terminations of pregnancies affected by congenital anomalies, therefore provincial-level research is imperative in order to know more about the magnitude of the effect of prenatal screening and selective termination. A key deliverable will be modeling an "adjusted" infant mortality rate for the province, which has not yet been done in Canada.

Author(s): Gregor Wolbring, *PhD.*

Affiliations: *Biochemist, Dept. of Biochemistry and Molecular Biology, Faculty of Medicine, University of Calgary*

New and Emerging Sciences and Technologies and the Social Construction of Boundaries

Today's scientific news seems to become yesterday's news – fast replaced by even more astonishing news. One field of science is chased by another at an ever-increasing speed. We are just coming to grips with issues attached to advances in information and communication technology, employing among others the field of info-ethics. Then along comes biotechnology and genetics, and the field of bio-ethics. Despite the many unresolved issues around biology and genetics, we've started to hear in the last few years of nano- (N) technology, science and ethics and its convergence with bio-, info- and cogno (neuro) technology, science and ethics. The discourse around the convergence of N with BIC has barely started. But along comes the next field – synthetic biology, which is the (a) design and construction of new biological parts, devices, and systems; and (b) the re-design of existing, natural biological systems for useful purposes and synbio-ethics. This presentation will start by looking at the social construction of concepts such as genetic discrimination and line drawing exercises such as in how to use genetic testing. The presentation will then look at the impact of these social constructions on future science and technology products such as the ones enabling bodily and ability modifications and how in turn the appearance of these products impact on the social construction of concepts employed in the governance of genetic testing and discrimination.

Author(s): Anna Zadunayski, *B.A, LL.B., MSc (c)*

Affiliation: *Department of Community Health Sciences, Office of Medical Bioethics, Faculty of Medicine, University of Calgary*

Informed vs. Implied Consent:
In Search of an Ethical-Legal Screening Threshold for Clinicians

The legality of all medical treatment is founded on the existence of consent or other lawful authority. No form of medical treatment can be given without consent, and no consent is obtained without the nature and effect of the proposed treatment being communicated. Consent may be communicated in writing, orally, or it may be implied from a person's conduct.

Valid consent is a central factor in deliberations about whether medical treatment and/or interventions are right or wrong, good or bad. The ethical and legal aspects of consent must be distinguished. Although these aspects are interconnected, in reality they function very differently. At law, consent functions to head off legal liability in situations that might otherwise constitute battery. In its ethical aspects, consent is a recognition of another human as having an inherent personal worth and integrity. Clinicians need to be aware of various factors that may influence a person's decisions regarding screening. This raises critical questions about consent, autonomy and justice.

This paper explores the ethical-legal implications of obtaining consent for genetic screening and focuses upon the ethical and legal challenges inherent in screening modalities as they relate to the clinical care of women children and families. The paper queries whether genetic screening constitutes medical treatment and, in that context, discusses the ethical and legal implications of various consent models. Much of the paper is framed in terms of 'principlism', including the key ethical concepts of beneficence, non-maleficence, autonomy and informed consent, and justice, which are familiar to most clinicians. Feminist consent theory (FCT) as it pertains to screening is also reviewed.

Index of Abstracts by Author