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TRI-COUNCIL POLICY STATEMENT

Ethical Conduct for Research Involving Humans

2014

Canadian Institutes of Health Research
Natural Sciences and Engineering Research Council of Canada
Social Sciences and Humanities Research Council of Canada

Government of Canada Gouvernement du Canada

Canada

Final reports shall be made available to the territorial or organizational community or community of interest participating in the research. Researchers and communities should clarify the extent to which research findings will require translation, plain language summaries or oral presentations to community members, in order to make the research findings accessible to the community.

An Aboriginal community, and those who participated in the research, should have the option to participate in deciding how collective or individual contributions to the research project will be acknowledged and credited in the dissemination of results (e.g., acknowledgement of co-authorship in research reports or at conferences and seminars).

Intellectual Property Related to Research

Article 9.18 In collaborative research, intellectual property rights should be discussed by researchers, communities and institutions. The assignment of rights, or the grant of licences and interests in material that may flow from the research, should be specified in a research agreement (as appropriate) before the research is conducted.

Application Researchers, communities and institutions should be aware that all knowledge and information is not necessarily protected under the existing law. Existing intellectual property legislation generally protects works and inventions. Strict criteria are used to define intellectual property rights. Understanding and communicating what qualifies, or does not qualify, as intellectual property for the purposes of research under this Policy is a joint responsibility of communities, researchers and institutions.

When undertaking research guided by community engagement, researchers, institutions and communities may need to first address issues regarding access to data, and the use of data for the purpose of the research or in the dissemination of research findings. Regarding access to and use of data, a research agreement may set out any limits on the disclosure of personal or privileged information (subject to applicable legal and regulatory requirements and the guidance in Chapter 5 of this Policy). It might include provisions to review reports and publications regarding the research prior to publication, or limits on the release of, or access to, research results (subject to applicable laws). Provisions for any anticipated secondary use of the information or human biological material, and associated data collected, should also be addressed and documented in this agreement. It may also set out any interests, licences or assignments in copyright flowing from publications about, or based on, the research (see Articles 9.8, 9.11 and 9.16).

Some knowledge collected as a result of the research may have commercial applications, and lead to the development of marketable products. With respect to commercialization of results of collaborative research, researchers and communities should discuss and agree on the use, assignment or licensing of any intellectual property (e.g., any patents or copyright), resulting from the marketable product,

and document mutual understandings in an agreement. If the proposed research has explicit commercial objectives, or direct or indirect links to the commercial sector, researchers and communities may want to include provisions related to anticipated commercial use in research agreements. These provisions should be clearly communicated to all parties in advance, consistent with the consent process.

Researchers should consult the research office of their institution before entering into a research agreement that includes intellectual property provisions. Researchers should also consult the program literature or policies on intellectual property and copyright adopted by the federal research agencies CIHR, NSERC and SSHRC (available on their websites), and seek legal advice where appropriate.

Collection of Human Biological Materials Involving Aboriginal Peoples

Article 9.19 As part of community engagement, researchers shall address and specify in the research agreement the rights and proprietary interests of individuals and communities, to the extent such exist, in human biological materials and associated data to be collected, stored and used in the course of the research.

Application Canadian law does not provide clear recognition of property rights in human biological materials. Researchers should be aware, however, that Aboriginal people and communities may seek to maintain control over, and access to, data and human biological materials collected for research. This is in accordance with Aboriginal world views about "full embodiment," in which every part and product of the human body is sacred and cannot be alienated. Consistent with Articles 9.8 and 9.11 and Chapter 12, researchers and communities should address and specify in the research agreement:

- the objectives for collection, use and storage of human biological materials;
- the roles and responsibilities regarding custodianship of the data and the human biological materials; and
- any future use of these human biological materials and associated data, including material transfer agreements to third parties, and any subsequent requirements for community engagement.

Researchers must seek consent, in accordance with Articles 12.1 and 12.2, from individuals who are invited to donate their biological materials.

Secondary Use of Information or Human Biological Materials Identifiable as Originating from Aboriginal Communities or Peoples

Ongoing sensitivity about secondary use of data collected for approved purposes arises from experiences with misrepresentation of Aboriginal peoples; use of data or human biological materials without appropriate engagement with the source community or consent of participants; and lack of reporting to communities on research outcomes. For example, members of Nuu-chah-nulth communities in British Columbia provided blood samples for research on rheumatic disease.

influencing disease, and evaluating health services and interventions. However, data linkage also raises separate privacy issues, discussed in Section E of Chapter 5.

E. Research Involving Materials Related to Human Reproduction

Researchers who conduct research involving human biological materials related to human reproduction shall follow applicable guidance expressed in other chapters of this Policy. This section provides further guidance for research involving embryos, fetuses, fetal tissue, and reproductive materials. For the purposes of this Policy the following definitions apply:[3]

- Embryo means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being.
- Fetus means a human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth.
- Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus.
- Human reproductive materials means a sperm, ovum or other human cell, or a human gene, and includes a part of any of them.

While research involving materials related to human reproduction has great promise for assisting the development of healthy pregnancies, curing illness, and repairing or rebuilding tissue, it raises special ethical considerations. Accordingly, this research has provoked vigorous debate. Discussion and reflection should continue as our scientific understanding develops.

Significant ethical issues include consent to research involving materials related to human reproduction, privacy concerns, the risk of harm to those who provide reproductive materials, an embryo or fetus, and potential commodification of reproductive capabilities and materials related to reproduction. Researchers and REBs have a continuing duty to remain mindful of the public interest in these issues, and to respect policy, legal and regulatory requirements. In particular, researchers and REBs shall be aware of the detailed requirements and prohibitions set out in the *Assisted Human Reproduction Act.*

Article 12.6 In addition to requirements in this chapter that apply to all research involving human biological materials, the following guidelines apply to research involving materials related to human reproduction:

(a) Research using materials related to human reproduction in the context of an anticipated or ongoing pregnancy shall not be undertaken if the knowledge sought can reasonably be obtained by alternative methods.

(b) Materials related to human reproduction for research use shall not be obtained through commercial transaction, including exchange for services.

Application Because of the risk of harm to the woman or the fetus, Article 12.6(a) requires that the use of these materials be avoided where pregnancy is anticipated or ongoing, if research goals may be accomplished in some other way.

Article 12.6(b) reflects concerns about the commercialization or commodification of human reproduction. Exchange for services refers, for instance, to trading a service, such as a medical treatment, for an in vitro embryo or gamete.

Research Involving Human Embryos

Article 12.7 Research on in vitro embryos already created and intended for implantation to achieve pregnancy is acceptable if:

(a) the research is intended to benefit the embryo;

(b) research interventions will not compromise the care of the woman, or the subsequent fetus;

(c) researchers closely monitor the safety and comfort of the woman and the safety of the embryo; and

(d) consent was provided by the gamete donors.

Application Research potentially altering the embryo by chemical or physical manipulation shall be distinguished from research directed at ensuring normal fetal development. For example, the evaluation of potential teratogens and their effects on certain cell lineages may use early embryos, but those embryos must not be implanted for an ongoing pregnancy.

The *Assisted Human Reproduction Act* prohibits the creation of a human embryo specifically for research purposes, with the limited exception of creating an embryo for the purpose of improving, or providing instruction in, assisted reproduction procedures.

Article 12.8 Research involving embryos that have been created for reproductive or other purposes permitted under the *Assisted Human Reproduction Act*, but are no longer required for these purpose*s*, may be ethically acceptable if:

(a) the ova and sperm from which they are formed were obtained in accordance with Article 12.7;

(b) consent was provided by the gamete donors;

(c) embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and

F. Genetic Material Banks

Article 13.7 (a) Researchers who propose research involving the collection and banking of genetic material shall indicate in their research proposal, and in the information they provide to prospective participants, how they plan to address the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, possibility of commercialization of research findings and withdrawal by participants as well as future contact of participants, families, communities and groups.

(b) Researchers who propose research involving the secondary use of previously collected and banked genetic material shall, likewise, indicate in their research proposal how they plan to address associated ethical issues.

Application Collection of human biological materials including genetic materials, and their retention in biobanks provides an increasingly important research resource. Guidance for research involving human biological materials (see Chapter 12) applies to banking of genetic material. Chapter 12, Section D, provides guidance for the creation of biobanks of genetic material, and Section C addresses access to, and use of, previously collected genetic material. Researchers who intend to bank genetic material shall inform participants of the potential for secondary use. See Chapter 5 for guidance regarding secondary use.

G. Gene Transfer

Guidance set out in Chapter 11 applies to clinical trial research involving gene transfer, and Article 12.9 is applicable to gene transfer in utero. In the context of gene transfer research, researchers and REBs shall pay careful attention to the need to assess safety, minimize risk, and minimize therapeutic misconception (see Chapter 11, Section C). Researchers have obligations to share with participants new information that may be relevant to ongoing consent, and to follow up with former participants to inform them of issues that may affect their welfare.

Gene alteration involves the transfer of genes into cells to induce an altered capacity of the cell. Viruses are commonly used vectors (carriers) to introduce the gene into the host genome. Gene alteration is irreversible – the cell and its descendants are forever altered and introduced changes cannot be removed. The possible use of germ line alteration implies changes that could be transmitted to future generations.

Gene transfer research that involves alteration of human germ line cells is governed in Canada by the *Assisted Human Reproduction Act*[2] and its regulations. Researchers should be aware of how this law applies to their work, such as the Act's prohibition on knowingly altering the genome of a cell of a human being, or in vitro embryo, such that the alteration is capable of being transmitted to descendants.