POLICY ON ETHICAL RESEARCH INVOLVING HUMANS

Preamble

Ambrose University has adopted the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)2 which can be found at: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

The following policy statement is for the most part an abridgement and adaptation of that document.

Guiding Principles

Ambrose University will integrate the following guiding ethical principles so that research involving human beings at Ambrose is sure to fall within the accepted parameters of Canadian research. These principles must function as a whole, so that human beings are protected from any violation that might occur if certain of the following principles were considered in isolation.

1. Respect for Human dignity: This principle is to be foremost in the researchers' minds so that the integrity of the persons involved in the research may be preserved.
2. Respect for Free and Informed Consent: Ambrose researchers will ensure that all consent is free and informed.
3. Respect for Vulnerable Persons: Any research that involves vulnerable subjects should include special procedures to ensure that the interests of the individual are protected.
4. Respect for Privacy and Confidentiality: Ambrose researchers will endeavor to respect the privacy and confidentiality of the subjects of their research so that the subjects' human dignity, as defined by themselves, is not violated. Other cultures being studied may have different standards of privacy and confidentiality than Canadian society; therefore, research must balance the subjects' standards with the interests of the researcher.
5. Respect for Justice and Inclusiveness: All research will follow the principles and ethics of justice. Therefore ethical reviews will be fair and equitable. As well, research will seek to follow the principles of distributive justice by not discriminating against individuals or groups.
6. Balancing Harms and Benefits: Research at Ambrose must give thought to "Harms-benefit analysis" so that the human benefit of a given research project outweighs any possible harm. It is understood that the effects of research upon individuals cannot always be predicted with certainty; however, respect for human beings imposes ethical obligations on the design and conduct of research. Although these concerns apply most particularly to biomedical and health research, they also have implications for the social sciences and the humanities. For example, even apparently innocuous research projects, such as biographies, may include statements that harm reputations, and so they, too, need to be subjected to harms-benefit analysis.
7. Minimizing Harm: Research subjects must not be exposed to unnecessary risks, and so their participation must be essential to the research being undertaken. Thus, the researcher will subject them to the smallest number of tests required to ensure scientifically valid data.
8. Maximizing Benefit: Researchers will ensure that their data yield the maximum possible benefit for society.

Articles

Research Requiring Ethics Review

1.1 All research that involves living human subjects, human remains, cadavers, tissues, biological fluids, embryos, or foetuses is subject to review by the Ambrose Research Ethics Board (REB), with the following exceptions:

1. Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to section 2.3 of this policy.
2. Quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review.

Section 1: Ambrose Research Ethics Board (REB)

Authority of the Research Ethics Board

1.2. The REB is mandated to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects which is conducted within, or by members of, Ambrose University, using the considerations set forth in this policy as the minimum standard. The REB will have the necessary financial and administrative independence to enable it to fulfill its duties.

1.2.1 Ambrose as an institution may not overrule a negative decision by the REB made on ethical grounds without following the formal appeal process as set out below.

1.2.2 Ambrose as an institution may prohibit certain research within its jurisdiction, even though the REB has found it ethically acceptable.

Membership of the Research Ethics Board

1.3. The REB shall consist of at least five members, including both men and women, of whom: (a) at least two members have broad expertise in the methods or in the areas of research that are covered by the REB; (b) at least one member is knowledgeable in ethics; (c) for biomedical research, at least one member is knowledgeable in the relevant law; and (d) at least one member has no affiliation with Ambrose University. Appointments to the REB will be staggered from year to year to ensure continuity within the board.

1.4 Ambrose University has one REB. The appropriate members of the REB shall be appointed by the General Faculties Council of Ambrose University in August of each year.

Analysis of potential harm and benefit

1.5 The standard of minimal risk is commonly defined as follows: if potential subjects can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk. Above the threshold of minimal risk, the research warrants a higher degree of scrutiny and greater provision for the protection of the interests of prospective subjects.

The REB shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research. The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out. Research in the humanities and the social sciences which poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed.

Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, *in extremis*, through action in the courts for libel.

Review Procedures

1.6 The REB will adopt a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research.

1.7 The REB will meet face-to-face on a regular basis to discharge its responsibilities. A quorum for the REB will consist of a majority of its members. Where there is less than full attendance, decisions requiring full review will be adopted only if the members attending the meeting possess the range of background and expertise stipulated in article 1.3.

1.8 Minutes of all REB meetings shall be prepared and maintained by the REB. The minutes shall clearly document the REB's decisions and any dissents, and the reasons for them. These minutes will be retained by the General Faculties Council and made available, when requested, to researchers and funding agencies. Decisions of the REB will be made by majority vote.

1.9 REB reviews shall be based upon fully detailed research proposals or, where applicable, progress reports. The REB shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions. The REB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but those researchers may not be present when the REB is making its decision. When an REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

Reconsiderations

1.10 Researchers have the right to request, and the REB has an obligation to provide, reconsideration of decisions affecting a research project.

Appeals

1.11 In cases when researchers and the REB cannot reach agreement through discussion and reconsideration, the REB of The Ambrose University will conduct an appeal, provided that:

(a) The principal investigator (PI), who is responsible to file a written request for an appeal with Ambrose's REB setting out the basis for appeal as well as providing supporting evidence, had done so.

(b) Appeals on the grounds that the PI disagrees with the REB on the ethics of the research project not be allowed. An appeal will only be considered if the PI can show evidence of a perception of bias, a lack of due process, an apparent conflict of interest, or some other failure of the systematic part of the review process.

Conflict of Interest
1.12 If the REB is reviewing research in which a member of the REB has a personal interest in the research under review (e.g., as a researcher or as an entrepreneur), conflict of interest principles require that the member not be present when the REB is discussing or making its decision. The REB member may disclose and explain the conflict of interest and offer evidence to the REB provided the conflict is fully explained to the REB, and the proposer of the research has the right to hear the evidence and to offer a rebuttal.

Review Procedures for Ongoing Research
1.13 Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment. As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project. Continuing review shall consist of the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes.

Review of Multi-centred Research
In multi-centred research, when several REBs consider the same proposal from the perspectives of their respective institutions they may reach different conclusions on one or more aspects of the proposed research. In such cases, the researcher may wish to distinguish between core elements of the research, i.e., those that cannot be altered without invalidating the pooling of data from the participating institutions, and those that can be altered to comply with local requirements without invalidating the research project. The REB will attempt to coordinate its review of multi-centred projects, and to communicate any concerns that it may have with other REBs reviewing the same project. The researcher will provide to the REB information on the institutional REBs that will consider the project.

Review of research in other jurisdiction or countries
1.14 Research to be performed outside of Canada shall undergo prospective ethics review both (a) by the Ambrose REB; and (b) by the appropriate REB, where such exists, in the country where the research is to be done.

Section 2: Free and informed consent

2.1 Research governed by this Policy (see section1.1) may begin only if (1) prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation, and (2) their free and informed consent has been given and is maintained throughout their participation in the research. Sections 2.1, 2.3 and 2.8 provide exceptions to section 2.1. Evidence of free and informed consent by the subject or authorized third party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented. The REB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to

obtain informed consent, provided that the REB finds and documents that: a) The research involves no more than minimal risk to the subjects; b) The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects; c) The research could not practicably be carried out without the waiver or alteration; d) Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and e) The waivered or altered consent does not involve a therapeutic intervention. In studies including randomization and blinding in clinical trials, neither the research subjects nor those responsible for their care know which treatment the subjects are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if subjects are informed of the probability of being randomly assigned to one arm of the study or another.

2.2 Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

2.3 REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings, should not require REB review since it can be expected that the participants are seeking public visibility.

2.4 Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the free and informed consent process, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in section 2.1, at the commencement of the free and informed consent process, researchers or their qualified designated representatives shall provide prospective subjects with the following: (a) Information that the individual is being invited to participate in a research project; (b) A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures; (c) A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm; (d) An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and (e) The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, Ambrose, or sponsors.

2.5 Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when: (a) the research question can only be addressed using the identified group(s); and (b) free and informed consent will be sought from their authorized representative(s); and (c) the research does not expose them to more than minimal risks without the potential for direct benefits for them.

2.6 For research involving incompetent participants, the REB shall ensure that, as a minimum, the following conditions are met: (a) the researcher shall show how the free and informed consent will be sought from the authorized third party, and how the subjects' best interests will be protected. (b) The authorized third party may not be the researcher or any other member of the research team. (c) The continued free and informed consent of an appropriately authorized third party will be required

to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent. (d) When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.

2.7 Where free and informed consent has been obtained from an authorized third party and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation.

2.8 Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party if ALL of the following apply: (a) A serious threat to the prospective subject requires immediate intervention; and (b) Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and (c) Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject; and (d) The prospective subject is unconscious or lacks capacity to understand risks, methods, and purposes of the research; and (e) Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and (f) No relevant prior directive by the subject is known to exist.

Section 3: Privacy and Confidentiality

3.1 Researchers at Ambrose shall safeguard all information entrusted to them and not misuse or wrongfully disclose it.

3.2 Researchers gathering biological data subject to the exceptions in article 1.1 shall secure REB approval before commencing their research.

3.3 Subject to the exceptions in Article 1.1, researchers who intend to interview a human subject to secure identifiable information shall secure REB approval for the interview procedure used and shall ensure the free and informed consent of the interviewee as required in the Article 2.4. As indicated in Article 1.1, REB approval is not required for access to publicly available information or materials including archival documents and records of public interviews or performances.

Accessing Private Information: Surveys, Questionnaires, and the Collection of Data
3.4 Subject to Article 3.1, 3.2, and 3.3 above, researches shall secure REB approval for obtaining identifiable information about subjects. Approval for such research shall include such considerations: (a) the type of data to be collected; (b) the purpose for which the data will be used; (c) limits on the use, disclosure and retention of the data; (d) appropriate safeguards for security and confidentiality; (e) any modes of observation (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that allow identification of particular subjects; (f) any anticipated secondary uses of identifiable data from the research; (g) any anticipated linkage of data gathered in the research with other data about subjects, whether those data are contained in public or personal records; and (h) provisions for confidentiality of data resulting from the research.

3.5 If identifying information is involved, REB approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that: (a) identifying information is essential to the research; (b) they will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to the subjects; and (c) individuals to whom the data refer have not objected to secondary use.

3.6 The REB may also require that a researcher's access to secondary use of data involving identifying information be dependent on: (a) The informed consent of those who contributed data or of authorized third parties; or (b) an appropriate strategy for informing the subjects; or (c) consultation with representatives of those who contributed data.

3.7 Researchers who wish to contact individuals to whom data refer shall seek the authorization of the REB prior to contact.

3.8 The implications of approval data linkage in which research subjects may be identifiable shall be approved by the REB.

Section 4: Conflict of Interest Involving Researchers

4.1 Researchers and REB members shall disclose actual, perceived, or potential conflicts of interest to the REB. REB's should develop mechanisms to address and resolve conflicts of interest.

4.2 REB members will excuse themselves from reviews in which they are related to the researcher by family relationship, financial partnership, or other economic interest, or by competing interests as per article 1.12. In such a case the chair of the REB will appoint substitute members to maintain the appropriate membership profile as set out in article 1.3. In the case where the Chair of the REB is the one with a conflict of interest, the senior member of the REB will assume the chair and appoint a substitute member for the duration of the review of the research proposal pertaining to the conflict of interest.

Section 5: Inclusion in Research

5.1 Where research is designed to survey a number of living research subjects because of their activities (e.g., in many areas of health research, or in some social science research such as studies of child poverty or of access to legal clinics) that are not specific to particular identifiable groups, researchers shall not exclude prospective or actual research subjects on the basis of such attributes as culture, religion, race, mental or physical disability, sexual orientation, ethnicity, sex or age, unless there is a valid reason for doing so.

This article is not intended to preclude research focused on a single living individual (such as a biography) or on a group of individuals who share a specific characteristic (as a study of an identifiable group of painters who happen to be all of one sex, colour or religion, or of a religious order that is restricted to one sex).

5.2 Women shall not automatically be excluded from research solely on the basis of sex or reproductive capacity.

5.3 Subject to the provisions in Articles 2.6 to 2.8, those who are not competent to consent for themselves shall not be automatically excluded from research that is potentially beneficial to them as individuals, or to the group they represent.

Section 6: Research involving aboriginal people

Researchers involved with Aboriginal communities should consider the following "good practices."

- To respect the culture traditions and knowledge of Aboriginal groups
- To engage only in such research as can be conceived of as a partnership with said community or communities
- To consult members of the group who have relevant experience
- To involve the group in the design of the project
- To examine how the research may be shaped to addresses the needs and concerns of the group
- To provide the group with information respecting the following:
    - Protection of the group's cultural estate and other property
    - The availability of a preliminary report for comment
    - Potential employment by researchers of members of the community appropriate [verify original wording]and without prejudice
    - Researchers' willingness to cooperate with community institutions
    - Researchers' willingness to deposit data, working papers, and related materials in an agreed-upon repository.
- To acknowledge in the publication of the research results the various viewpoints of the community on the topics researched
- To give the community an opportunity to respond to the research findings before the completion of the final report.

Section 7: Clinical Trials

Pharmaceutical Research

Currently Ambrose University is not involved in pharmaceutical research. However, in the event that research capacity develops at Ambrose so that pharmaceutical research becomes a possibility, the following articles shall govern said trials.

7.1 Phase I: non-therapeutic trials shall undergo both stringent review and continuous monitoring by an REB independent of the clinical trials sponsor.

7.2 In combined Phase I/II clinical trials, researchers and REBs shall carefully examine the integrity of the process of free and informed consent. Where appropriate, the REB may require an independent monitoring process.

7.3 REBs shall examine the budgets of clinical trials to assure that ethical duties concerning conflict of interest are respected.

7.4 The use of placebo controls in clinical trials is generally unacceptable when standard therapies or interventions are available for a particular patient population.

Section 8: Human Genetic Research

8.1 The genetics researcher shall seek free and informed consent from the individual and report results to the individual if the individual so desires.

8.2 The researchers and the REB shall ensure that the results of genetic testing and genetic counselling records are protected from access by third parties, unless free and informed consent is given by the subject. Family information in databanks shall be coded so as to remove the possibility of identification of subjects within the bank itself.

8.3 Researchers and genetic counsellors involving families and groups in genetic research studies shall reveal potential harms to the REB and outline how such harms will be dealt with as part of the research project.

8.4 Genetic researchers and the REB shall ensure that the research protocol makes provisions for access to genetic counselling for the subjects, where appropriate.

8.5 Gene alteration (including "gene therapy") that involves human germline cells or human embryos is not ethically acceptable. Gene alteration for therapeutic purposes and involving human somatic cells may be considered for approval.

8.6 Though the banking of genetic material is expected to yield benefits, it may also pose potential harms to individuals, their families and the groups to which they may belong. Accordingly, researchers who propose research involving the banking of genetic material have a duty to satisfy the REB and prospective research subjects that they have addressed the associated ethical issues, including confidentiality, privacy, storage, use of the data and results, withdrawal by the subject, and future contact of subjects, families, and groups.

8.7 At the outset of the research project, the researcher shall discuss with the REB and the research subject the possibility and/or the probability that the genetic material and the information derived from its use may have potential commercial uses.

Section 9: Research Involving Human Gametes

9.1 Researchers shall obtain free and informed consent from the individual whose gametes are to be used in research.

9.2 In research, it is not ethical to use ova or sperm that have been obtained through commercial transactions, including exchange for service.

9.3 It is not ethically acceptable to create, or intend to create, hybrid individuals by such means as mixing human and animal gametes, or transferring somatic or germ cell nuclei between cells of humans and other species.

9.4 It is not ethically acceptable to create human embryos specifically for research purposes. However, in those case where human embryos are created for reproductive purposes, and subsequently are no longer required for such purposes, research involving human embryos may be considered to be ethically acceptable, but only if all of the following apply:

(a) The ova and sperm from which they were formed are obtained in accordance with Articles 9.1 and 9.2
(b) The research does not involve the genetic alteration of human gametes or embryos
(c) Embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy
(d) Research involving human embryos takes place only during the first 14 days after their formation by combination of the gametes.

9.5 It is not ethically acceptable to undertake research that involves ectogenesis, cloning human beings by any means including somatic cell nuclear transfer, formation of animal/human hybrids, or the transfer of embryos between humans and other species.

Section 10: Human Biological Material (Including fluids and tissue)

10.1 Research proposing the collection and use of human biological material requires ethics review by the REB. Among other things, the research shall demonstrate the following to the REB:

(a) That the collection and use of human biological material for research purposes shall be undertaken with the free and informed consent of competent donors
(b) In the case of incompetent donors, free and informed consent shall be by an authorized third party
(c) In the case of deceased donors, free and informed consent shall be expressed in prior directive or through the exercise of free and informed consent by an authorized third party.

10.2 For the purpose of obtaining free and informed consent, researchers who seek to collect human biological material for research shall, at a minimum, provide donors or authorized third parties information about:

(a) The purpose of the research
(b) The type and amount of biological material to be taken, as well as the location where the biological material is to be taken
(c) The manner in which biological material will be taken, the safety and invasiveness of acquisition, and the duration and conditions of preservations
(d) The potential uses for the biological material, including any commercial uses
(e) The safeguards to protect the individual's privacy and confidentiality
(f) Identifying information attached to specific biological material, and its potential traceability
(g) How the use of the biological material could affect privacy

Previously collected biological material

10.3 When identification is possible, researchers shall seek to obtain free and informed consent from individuals, or from their authorized third parties, for the use of their previously collected biological material. The provisions of Article 10.2 also apply here.

When collected biological material has been provided by persons who are not individually identifiable, and when there are no potential harms to them, there is no need to seek the donors' permission to use their biological material for research purposes, unless applicable law so requires.

Section 11: Research involving human physiological manipulation

11.1 Research proposing the collection and use of data from human physiological manipulation requires ethics review by the REB. Among other things, the research shall demonstrate the following to the REB:

(a) That the actual collection of data through human physiological manipulation will be carried out by the appropriate professional, so as to minimize risk and invasiveness of the procedure
(b) That the collection and use of data from human physiological manipulation for research purposes shall be undertaken with the documented, free and informed consent of competent donors
(c) In the case of incompetent donors, free and informed consent shall be by an authorized third party

11.2 For the purpose of obtaining free and informed consent, researchers who seek to collect human biological material for research shall, at a minimum, provide donors or authorized third parties information about:

(a) The purpose of the research
(b) The type and amount of data from human physiological manipulation to be taken, as well as the location where the data from human physiological manipulation is to be taken
(c) The manner of the human physiological manipulation in which data will be obtained, the safety and invasiveness of acquisition, and the duration and conditions of manipulation
(d) The potential uses for the data from human physiological manipulation including any commercial uses
(e) The safeguards to protect the individual's privacy and confidentiality
(f) Identifying information attached to specific data from human physiological manipulation, and its potential traceability
(g) How the use of the data from human physiological manipulation could affect privacy

Previously collected data from human physiological manipulation

11.3 When identification is possible, researchers shall seek to obtain free and informed consent from individuals, or from their authorized third parties, for the use of their previously collected data from human physiological manipulation. The provisions of Article 11.2 also apply here.

When collected data from human physiological manipulation has been provided by person(s) who are not individually identifiable, and when there are no potential harms to them, there is no need to seek the donor's permission to use their data from human physiological manipulation, unless applicable law so requires.