HUMAN RESEARCH ETHICS

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PURPOSE

The University of the Fraser Valley (UFV) requires and supports the highest ethical standards in conducting research involving human participants to ensure the rights of human participants are respected and protected. Researchers at or associated with UFV are required to follow research ethics protocols to ensure their research protects human participants.

Primary institutional responsibility for reviewing research involving humans at UFV rests with the UFV Human Research Ethics Board (HREB) and individually with the researchers themselves. This Policy applies to all faculty members, staff, students, and all other research personnel associated with UFV. This policy is in compliance with the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* (2010). The policies on conflict of interest and responsible conduct of research and scholarship are also applicable.

DEFINITIONS

In this policy, the following definitions apply:

1.1 Research:
Research involves systematic investigation to establish facts, principles, or generalizable knowledge

1.2 Researcher:
A researcher is defined as any person associated with UFV who undertakes to conduct research as defined above. This includes faculty, staff, and students, as well as any individuals from the community who are associated with a UFV generated research project.

1.3 Research Participants:
Human research participants are living individuals or groups of living individuals about whom a scholar conducting research obtains (1) data through intervention or interaction with the individual or group, or (2) identifiable private information.

POLICY

All research that involves living human participants requires review and approval by a Human Research Ethics Board (HREB) or designated department research ethics committee (DREC) in accordance with this policy and the *Tri-Council Policy Statement 2nd Edition (TCPS 2) ‘Ethical Conduct for Research Involving Humans’, before the research is started. UFV expects all researchers to adhere to the principles described herein.
The following core principles are outlined in the Tri Council Policy Statement (TCPS, 2010). These are principles that UFV will follow. The three core principles are: respect for persons, concern for welfare, and justice.

- Respect for persons refers to the recognition of the intrinsic value of human beings and the respect and consideration due to them as human participants. Autonomy is a consideration when considering respects for persons,

- Concern for welfare takes into the account the quality of the person’s experiences. This includes the impact on their physical, mental, spiritual health, and their physical, economic and social circumstances.

- Justice refers to fairness and equitable treatment. No specific populations should be burdened as specific recipients of the harms in research, or denied the benefits of research or research knowledge.

REGULATIONS

SECTION 1 – ETHICS REVIEW

A. Research Requiring Ethical Review

Article 1.1

a. All research that involves living human participants requires review and approval by a Human Research Ethics Board (HREB) in accordance with this policy and the Tri-Council Policy Statement ‘Ethical Conduct for Research Involving Humans’, before the research is started, except as stipulated below. A researcher is any faculty, student or community member employed directly by, or otherwise affiliated with, UFV who undertakes to conduct research. It also includes anyone who enlists UFV faculty, staff, students or departments as participants. The onus is on the researcher to clarify whether or not their research is subject to UFV HREB review.

b. Research involving humans includes the use of human remains, cadavers, tissues, biological fluids, embryos, or fetuses and shall be reviewed by the HREB

c. Research involving the files or case data of human individuals, where there is identifying information attached to those files or case data shall be reviewed by the HREB.

d. Exceptions:

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 Article 2.1 and 2.2 of the Tri-Council Policy.

Research that does not present any ethical issues, or is making use of data obtained from pre-existing or archival data-bases that are in the public domain with no identifying information being used is exempt from review.
Public information or databases with identifying information usually requires only citation of the source to meet appropriate ethical standards.

If the researchers are unsure of the exempt nature of their research, they should review the scope of research requiring ethical review below or contact a member of the Human Research Ethics Board (HREB) for advice.

e. Quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to HREB review

f. For research involving non-human animal participants, ensuring the application of ethical principles is the responsibility of the institutional Animal Care Committee (ACC). Researchers should contact this committee when this condition applies.

B. Human Research Ethics Board (HREB)

Ensuring the ethical principles are applied to research involving human participants is the responsibility of the UFV Human Research Ethics Board.

The HREB has two primary roles - educative and review. In its educative role, the HREB serves the UFV research community as a consultative body and thus, contributes to education and understanding of research ethics. In its review role, the HREB has the responsibility for independent, multidisciplinary review of the ethics of research to determine whether the research should be permitted to start or to continue.

The HREB is considered a delegation of the President’s Office at UFV. The President has the authority to dismiss or appoint HREB members at his or her pleasure. The Board has the authority to approve, reject, propose modifications to, or terminate all proposed or ongoing research involving humans within the institution’s jurisdiction based on the ethical considerations as set forth in the Policy.

B(1) – Authority of the HREB

Article 1.2

a. For research involving human participants, UFV mandates the HREB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants which is conducted within, or by members of, the institution, using the considerations set forth in the HREB Terms of Reference.

b. Department Research Ethics Committees (DRECs) will conduct ethics reviews of research that is carried out by their undergraduate students as part of their course work, as outlined in 1.6c below and the DREC Terms of Reference, and will comply with this policy.

UFV has set criteria for determining which categories of research proposal are suitable for consideration through this means, and established such procedural issues as to who will be responsible for implementing and overseeing the approval mechanisms. As with other levels of review, proper accountability demands appropriate record keeping. Each research proposal and records of the decision will be sent to the Chair of the HREB who will provide a Certificate of Approval. Only the Chair of the HREB has the authority to sign Certificates of Approval. In cases where the Chair is the researcher, the Vice-Chair may be given the authority to sign the Certificate of Approval. In cases where the Chair or Vice-Chair is unavailable in person, but has given approval,
a pdf signature may be used.

Departmental level review should not be used for research in which an undergraduate student is carrying out research that is part of a faculty member’s own research program. Such research should be reviewed by UFV’s regular institutional HREB procedures.

C. Analysis, Balance and Distribution of Harms and Benefits

C(1) - Minimal Risk

Article 1.6

a. The HREB 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 minimal risk checklist is used as a guide for researchers.

b. 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.

c. Research in the humanities and the social sciences which poses, at most, minimal risks shall not normally be required by the HREB to be peer reviewed.

d. 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.

In evaluating the merit and the scholarly standards of a research proposal, the HREB should be concerned with a global assessment of the degree to which the research might further the understanding of a phenomenon, and not be driven by factors such as personal biases or preferences. HREBs should not reject research proposals because they are controversial, challenge mainstream thought, or offend powerful or vocal interest groups. The primary tests to be used by HREBs should be ethical probity and high scientific and scholarly standards.

D. Review of Procedure

D(1) - Proportionate Approach to Ethics Assessment

Article 1.7

a) The HREB utilizes a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing the research.

Potential harms are usually understood in relation to risks, which are defined in terms of the magnitude of harm and the probability of its occurrence. Both potential harms and benefits may span the spectrum from minimal through significant to substantial. A proportionate approach to ethics review thus starts with an assessment, primarily from the viewpoint of the potential participants, of the character, magnitude and probability of potential harms inherent in the research. The concept of minimum risk provides a foundation for proportionate review.
The standard of minimal risk is commonly defined as follows:

If potential participants 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 participants. There is a similar threshold regarding undue or excessive offers of benefit. As an offer of payment in relation to research participation exceeds the normal range of benefits open to the research subject, it is increasingly likely to amount to an undue incentive for participation.

All levels of ethical reviews of research must meet the requirements of this policy and of the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans.

D1.1 Course-Based Research

Researchers may wish to use the research ethics checklist to assist them in determining if their research is of minimal risk.

b. For a course that involves research, research methods or some aspect of research for the primary purpose of teaching and is of minimal risk, the instructor may request a designation of the course as a HREB approved course by applying to the HREB for ethical approval, assuming no substantial changes to the assignments are made. Substantial changes would include those that may affect the status of minimum risk, change the involvement of participants, or change the methodology / research design impacting participants.

These types of research assignments are instructor-led, assigned to the whole class, and have uniformity in the assignment. If changes are made then the revisions must be sent to the chair of the HREB. In the 4th year, a new course application must be submitted.

c. For a course that involves research, research methods or some aspect of research for the primary purpose of conducting research and is of minimal risk, student-led, and, significantly different and varied within the class, students will submit a Request for Ethical Review to the Department Research Ethics Committee (DREC) which will deem whether the research is of minimal risk. If the research is deemed minimal risk, the DREC will review the research. If the research is not minimal risk, the DREC will refer the researcher to the HREB.

d. Research conducted by students for faculty is considered faculty research and must follow the procedures for faculty.

D1.2 Faculty / Graduate Student / Institutional Research

Researchers may wish to use the research ethics checklist to assist them in determining if their research is of minimal risk.

e. Faculty, graduate students and other members of the university who wish to conduct research must submit a Request for Ethical Review to the HREB. The chair and vice-chair of the HREB will determine the level of review required depending on the assessment of the level of risk - under, equal or beyond minimal risk. If the research is deemed to be of minimal risk, the proposal will
have a delegated review, conducted by the chair and vice-chair. In some cases a designate HREB member may be part of a delegated review. If the research is deemed not to be of minimal risk, the request will be sent to the HREB for a full review.

**D1.3 Multi-jurisdictional Research**

Research involving human participants that may require the involvement of multiple institutions or multiple HREBs includes (but is not limited to):

a. A research project conducted by a team of researchers affiliated with different institutions;
b. Several research projects independently conducted by researchers affiliated with different institutions, with data combined at some point to form one overall research project;
c. A research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting participants at different institutions.
d. A research project conducted by a researcher who has multiple institutional affiliations.
e. A research project conducted by a researcher at one institution that requires limited collaboration of individuals affiliated with different institutions or organizations.
f. A research project that researcher(s) working under the auspices of a Canadian research institution conduct in another province, territory or country.

An HREB may approve alternative review models for research involving multiple HREBs and/or institutions, in accordance with the Tri Council Policy Statement on Ethical Conduct for Research Involving Humans.

**D(2) - Meetings and Attendance**

**Article 1.8**

The HREB shall meet regularly to discharge its responsibilities.

A schedule of when the HREB will sit to review research proposals will be communicated to the faculty, staff and students of UFV. The HREB and researchers may request informal meetings with each other prior to the formal review process, in order to expedite and facilitate the review process. Such informal meetings cannot, however, substitute for the formal review process.

The HREB will hold general meetings, retreats, and educational workshops for members for educational, discussion of issues, or revision of policies. The HREB will also promote and communicate the policy of Human Research Ethics to and provide educational opportunities for the faculty, staff and students at UFV.

**D(3) - Record Keeping**

**Article 1.9**

Minutes of all HREB meetings shall be prepared and maintained by the Research Office on behalf of the HREB. The minutes shall clearly document the attendance at the meeting, HREB’s decisions - listing the number of votes for, votes against, abstentions, and absences for all votes cast, providing the reasons for the decisions, and actions taken by the HREB. In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the minutes must be accessible to authorized representatives of UFV, researchers and funding agencies.
UFV and its HREB shall prepare and maintain adequate documentation of HREB activities, including the following:

(1) Copies of all research proposals reviewed, certificates of approval, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants.
(2) Records of continuing review activities.
(3) Copies of all correspondence between the HREB and the investigators.
(4) A list of HREB members
(5) Written procedures for the HREB

The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All minutes shall be accessible for inspection and copying by authorized representatives of UFV, researchers, sponsors, funding agencies, Government ministries, or departments at reasonable times and in a reasonable manner.

**D(4) - Decision-making**

**Article 1.10**

In a timely manner, HREBs shall meet face-to-face on a regular basis to review proposed research that is not delegated to expedited review. HREB review shall be based upon fully detailed research proposals or, where applicable, progress reports. The HREB shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions. The HREB shall accommodate reasonable requests from researchers to participate in discussions about their proposals, but researchers shall not be present when the HREB is making its decision. When an HREB 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.

Final decisions in the full review of projects that are based on a majority quorum will be adopted only if the members attending the meeting possess the range and background outlined in the HREB Terms of Reference.

The HREB shall notify investigators and the institution in writing of its decision to:
- approve the proposed research activity as submitted; or
- require minor modifications to the proposed research activity. The resubmitted proposal would be reviewed by the chair and vice-chair of the HREB; or
- require significant modifications or additional information or major revisions. The resubmitted proposal would be reviewed by the HREB, or.
- disapprove of the proposed research activity.

A subcommittee consisting of the chair and vice-chair of the HREB will conduct the expedited review and will follow the same format as the full HREB in recording minutes and communicating results.

The HREB is responsible for the ethics of all research involving humans carried out within UFV and thus, must maintain surveillance over decisions made on its behalf, including those conducted by Department Ethics Review Committees and those conducted through an expedited review process. Each committee will record minutes of its meetings including decisions / recommendations made
and will send a copy of these minutes and a copy of each request for ethical review that the committee reviews to the HREB.

With respect to expedited reviews made by the Chair and Vice-Chair of the HREB, the Chair will send a copy of the minutes and decisions / recommendations made to the HREB.

**D(5) - Reconsideration**

**Article 1.11**

Researchers have the right to request, and the HREB has an obligation to provide in a timely manner, reconsideration of decisions affecting a research project.

Article 1.11, together with Article 1.1o, obligates HREBs to be guided by principles of natural and procedural justice in their decision-making. Such principles include providing a reasonable opportunity to be heard, an explanation of the reasons for opinions or decisions, and the opportunity for rebuttal, fair and impartial judgment, and reasoned and written grounds for the decisions. The researcher may seek advice from the Office of Research Services and Industry Liaison for assistance in preparing a request for ethical review.

**D(6) - Appeals**

**Article 1.12**

a. In cases when researchers and HREBs cannot reach agreement through discussion and reconsideration, UFV will permit review of a HREB decision by the UFV Research Ethics Appeal Board (REAB), whose membership and procedures meet the requirements of this Policy and the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans. The researcher and HREB must have fully exhausted the reconsideration process, and the HREB must have issued a final decision before the researcher initiates an appeal.

The REAB will have different membership than the HREB but will be constituted in the same manner and will have the authority for independent decision making. The appeal process through REAB is not a substitute for the HREB. The REAB has the authority to review negative decisions by an HREB. It may approve, reject or request modifications to the research proposal. The decision on behalf of the institution shall be final.

Researchers may request an appeal of the decisions of the HREB must notify the Office of the President who will in turn inform the HREB of the intention to appeal. The decision of the REAB will be conveyed to the President’s Office and the HREB.

**E. Conflicts of Interest**

**Article 1.13**

If an HREB is reviewing research in which a member of the HREB 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 HREB is discussing or making its decision. The HREB member must disclose actual, perceived or potential conflicts of interest. The HREB member may offer evidence to the HREB provided the conflict is fully explained to the HREB, and the proposer of the research has the right to hear the evidence and to offer a rebuttal.
Disclosure of the conflict of interest will comply with UFV’s Conflict of Interest Policy.

F. Review Procedures for Ongoing Research

Article 1.14

a. Ongoing research shall be subject to continuing ethics review. The rigor of the review should be in accordance with a proportionate approach to ethics assessment.

b. As part of each research proposal submitted for HREB review, the researcher shall propose to the HREB the continuing review process deemed appropriate for that project.

c. Normally, continuing review should consist of at least the submission of a succinct annual status report (for multi-year research projects) to the HREB. The HREB shall be promptly notified when the project concludes.

Beyond scrutinizing reports, the HREB itself should not normally carry out the continuing ethics review, except in specific cases where the HREB believes that it is best suited to intervene. For research posing significant risks, the HREB should receive reports on the progress of the research project at intervals to be predetermined. These reports should include an assessment of how closely the researcher and the research team have complied with the ethical safeguards initially proposed.

In accordance with the principle of proportionate review, research that exposes participants to minimal risk or less requires only a minimal review process. The continuing review of research exceeding the threshold of minimal risk that is referred to in Article 1.14 (b), in addition to annual review (Article 1.14 (c)) might include:

- formal review of the free and informed consent process,
- establishment of a safety monitoring committee,
- periodic review by a third party of the documents generated by the study,
- review of reports of adverse events,
- review of patients’ charts, or
- a random audit of the free and informed consent process.

G. Review of Research in Other Jurisdictions or Countries

Article 1.15

Research to be performed outside the jurisdiction or country of the institution which employs the researcher shall undergo prospective ethics review both (a) by the HREB within the researcher’s institution; and (b) by the HREB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

An institution is responsible for the ethical conduct of research undertaken by its faculty, staff or students regardless of the location where the research is conducted. Thus, review of research by that institution’s HREB is required in addition to review by any agency having jurisdiction over the site of the research.

SECTION 2 – FREE AND INFORMED CONSENT
A. Requirement for Free and Informed Consent

Article 2.1

a. Research governed by this Policy (see Article 1.1) may begin only if (1) prospective participants, 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. Articles 2.1(c), 2.3 and 2.8 provide exceptions to Article 2.1(a).

b. 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.

c. The HREB 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 HREB finds and documents that:

   i. The research involves no more than minimal risk to the participants;

   ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;

   iii. The research could not practicably be carried out without the waiver or alteration;

   iv. Whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and

   v. The waived or altered consent does not involve a therapeutic intervention.

d. In studies including randomization and blinding in clinical trials, neither the research participants nor those responsible for their care know which treatment the participants are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirements for consent if participants are informed of the probability of being randomly assigned to one arm of the study or another.

B. Voluntariness

Article 2.2

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

C. Naturalistic Observation

Article 2.3

HREB 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 HREB review since it can be expected that the participants are seeking public visibility.

D. Informing Potential Participants
D(1) - General Conditions

Article 2.4

Researchers shall provide, to prospective participants 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 participants are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the free and informed consent process, researchers or their qualified designated representatives shall provide prospective participants 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 participants 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, their institutions or sponsors.

E. Competence

Article 2.5

Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research participants when:

a. the research question can only be addressed using individuals within 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.

Article 2.6

For research involving incompetent individuals, the HREB 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 participants’ 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.

F. Research in Emergency Health Situations

Article 2.7

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 HREB. The HREB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant 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.

When a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

G. Adverse Events

Article 2.8

Subject to all applicable legislative and regulatory requirements, researchers shall report any adverse events that occur during the course of conducting research. An adverse event is considered to be any undesirable experience or response that was not expected and not stated in the informed consent and original protocol. This includes anything emotional, psychological or physiological. The faculty investigator or supervisor shall report any injury or adverse event that is experienced by a participant due to the research procedures.

Endnotes
SECTION 3 – PRIVACY AND CONFIDENTIALITY

A. Accessing Private Information: Personal Interviews

Article 3.1

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

B. Accessing Private Information: Surveys, Questionnaires and the Collection of Data

Article 3.2

Subject to Article 3.1 above, researchers shall secure HREB approval for obtaining identifiable personal information about participants. Approval for such research shall include such considerations as:

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 participants;

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 participants, whether those data are contained in public or personal records; and

h. Provisions for confidentiality of data resulting from the research.

C. Secondary Use of Data

Article 3.3

If identifying information is involved, HREB 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 HREB that:

a. Identifying information is essential to the research; and

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 participants;

c. Individuals to whom the data refer have not objected to secondary use.

Article 3.4

The HREB 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 participants; or

c. Consultation with representatives of those who contributed data.

Article 3.5

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

D. Data Linkage

Article 3.6

The implications of approved data linkage in which research participants may be identifiable shall be approved by the HREB.

SECTION 4 - CONFLICT OF INTEREST FOR RESEARCHERS

Article 4.1

Researchers and HREB members shall disclose actual, perceived or potential conflicts of interest to the HREB.

SECTION 5 - INCLUSION IN RESEARCH

Article 5.1

a. Where research is designed to survey a number of living research participants because of their involvement in generic 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 participants 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.

b. Individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or excluded from participation in research on the basis of their circumstances (e.g. individuals who are institutionalized). However, considerations on the basis of vulnerability shall be taken into account.

c. This article is not intended to preclude research focused on a single living individual (such as in a biography) or on a group of individuals who share a specific characteristic (as in a study of an identifiable group of painters who happen to be all of one sex, colour or religion, or of a
Article 5.2

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

Article 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 which is potentially beneficial to them as individuals, or to the group that they represent.

Article 5.4

a. Research involving Indigenous, First Nations Inuit, and Métis peoples of Canada requires specific consideration. Researchers and HREBs shall acknowledge the unique status of the Aboriginal peoples of Canada and in the rest of the world. Particular regard is given to the respect for human dignity that research should afford, and the core principles of: respect for persons, concern for welfare, and justice.

b. Where research involving Indigenous, First Nations Inuit, and Métis peoples is to be undertaken, the researcher should take into account the following: a requirement desirability for community engagement in the research, respect for Indigenous, First Nations, Inuit, and Métis governing authorities, recognizing diverse interests within communities, respect for community customs and codes of practice.

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

d. In collaborative research, intellectual property rights should be discussed by researchers, communities, and institutions.

SECTION 6 - CLINICAL TRIALS

A. Phases of Pharmaceutical Research

Article 6.1

Phase 1 non-therapeutic clinical trials shall undergo both stringent review and continuous monitoring by an HREB independent of the clinical trials sponsor.

Article 6.2

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

Article 6.3

HREBs shall examine the budgets of clinical trials to assure that ethical duties concerning conflict of interest are respected.
Article 6.4

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

SECTION 7 - HUMAN GENETIC RESEARCH

A. Individuals, Families and Biological Relatives

Article 7.1

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

B. Privacy, Confidentiality, Loss of Benefits and Other Harms

Article 7.2

The researcher and the HREB 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 participants within the bank itself.

Article 7.3

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

C. Genetic Counselling

Article 7.4

Genetics researchers and the HREB shall ensure that the research protocol makes provision for access to genetic counselling for the participants, where appropriate.

D. Gene Alteration

Article 7.5

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.

E. Banking of Genetic Material

Article 7.6

Though the banking of genetic material is expected to yield benefits, it may also pose potential
harm 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 HREB and prospective research participants 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 participants, families and groups.

G. Commercial Use of Genetic Data

Article 7.7

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

SECTION 8 - RESEARCH INVOLVING HUMAN GAMETES, EMBRYOS OR FETUSES

A. Research Involving Human Gametes

Article 8.1

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

Article 8.2

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

Article 8.3

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.

B. Research Involving Human Embryos

Article 8.4

It is not ethically acceptable to create human embryos specifically for research purposes. However, in those cases 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; and

d. Research involving human embryos takes place only during the first 14 days after their
formation by combination of the gametes.

Article 8.5

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 9 - HUMAN TISSUE

A. Free and Informed Consent

Article 9.1

Research proposing the collection and use of human tissues requires ethics review by an HREB. Amongst other things, the researcher shall demonstrate the following to the HREB:

a. That the collection and use of human tissues 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 a prior directive or through the exercise of free and informed consent by an authorized third party.

Article 9.2

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

a. The purpose of the research;

b. The type and amount of tissue to be taken, as well as the location where the tissue is to be taken;

c. The manner in which tissue will be taken, the safety and invasiveness of acquisition, and the duration and conditions of preservation;

d. The potential uses for the tissue including any commercial uses;

e. The safeguards to protect the individual's privacy and confidentiality;

f. Identifying information attached to specific tissue, and its potential traceability; and

g. How the use of the tissue could affect privacy.

B. Previously Collected Tissue

Article 9.3

a. 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 tissue. The provisions of article 10.2 also apply here.

b. When collected tissue has been provided by persons who are not individually identifiable (anonymous and anonymized tissue), and when there are no potential harms to them, there is no need to seek donors’ permission to use their tissue for research purposes, unless applicable law so requires.