HUMBER

Procedure Manual

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Ethical Conduct for Research Involving Humans

Purpose:

The purpose of this procedure is to complement the Humber College Institute of Technology & Advanced Learning's (hereafter referred to as "Humber" or "the College") policy on the *Ethical Conduct for Research Involving Humans* and to articulate a clear and defined process that will allow the review of research applications in a fair and transparent manner.

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Definitions:

Competence: The ability of the participant to comprehend the information, to appreciate the consequences of the decision and to make an informed judgment about their participation in the research project.

Confidentiality: The legal and ethical obligation that arises from one person entrusting another with personal and private information. It is recognized that data collected about characteristics and responses may have identifiable private information, which is confidential and must be protected by the researcher.

Harm: Anything that has a negative effect on the welfare of participants. The nature of the harm may take a social, behavioural, psychological, physical or economic form.

Human participants: Individuals whose data or responses to interventions, stimuli or questions by the researcher are relevant to answering the research question.

Human participation: The nature of human participation in research will vary from one project to the next depending on the degree of involvement and an individual's consent. Under a broad definition, human participation may take place:

- Directly through physical participation; may include both active and/or passive involvement;
- Indirectly through the provision for or access to personal data and/or biological material;
- On behalf of others (parents/legal guardians for those without the capacity to give informed consent, and supervisors of individuals under controlled environments).

Naturalistic observation: Is a research technique, which involves observing subjects in their natural environment.

Principal investigator: Person designated as the primary representative of a research project and bears the responsibility for research design, conduct of research, data handling and storage, and reporting of findings.

Proportionate approach: Involves consideration of the foreseeable risks, the potential benefits and the ethical implications of the research.

Research Ethics Board (REB): The Humber Research Ethics Board (REB) is an arm's-length body, which oversees ethical screening and conducts a full review of research projects involving human participants. The REB endorses, and takes as its guide, the *Tri-Council Policy Statement: Ethnical Conduct for Research involving Humans -- TCPS 2*

(2018). The REB evaluates all research involving humans and ensures it is conducted in a manner that is consistent with the TCPS and its aligned provisions.

Procedures:

1. Submission Review Procedure

1.1. General

A completed Application for the Ethical Review Involving Human Participants must be submitted. Researchers may contact the REB administrator/coordinator for assistance in the process. Meetings between the REB and researcher may occur to clarify aspects of the application or to expedite the process but shall not substitute for the formal review process.

Humber recognizes there is a range of risk to human participants associated with research. The proportionate approach to the research ethics assessment is categorized in two levels of review:

- Full review (default) by the entire REB
- Delegated review by the REB Chair or subgroup of the REB.

Research to be conducted by any member of the Humber community who is outside the jurisdiction or country shall undergo an ethics review by the Humber College REB and by the REB that has authority in the jurisdiction where the research is to take place.

Certain studies are exempt from REB review under the TCPS 2 (2018) Article 2.5 governing quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes. These studies do not fall within the scope of REB review. When such applications are submitted to the REB, the Chair reviews the applications and confirms their exempt status through formal correspondence.

Studies that involve Humber College faculty and staff, including personnel data and communication utilizing Humber College coordinates, require institutional approval from the Office of the Senior Vice-President, Academic. This approval does not fall within the scope of the REB and is not contingent on REB approval. Conversely, REB approval is not contingent on institutional approval. The two reviews are independent. The Humber REB coordinator handles the liaison between the applicant and the Senior Vice-President, Academic, as part of their administrative duties and may consult with the REB Chair for clarification depending on the circumstance.

Humber College assignments and courses that involve research projects with humans that are outside of the normal scope of the profession require REB review and designation. Course-designation applications are reviewed by the REB Chair, who may delegate the review to one REB member who has specific expertise in the field of study.

The Humber REB does not review individual student research projects. Students (current and/or graduates) conducting research that involves Humber faculty, administrative staff member and/or students must be aligned with a Humber College faculty/administrative staff member who must submit the REB application.

1.2. Full Review

1.2.1. The Chair will convene regular meetings of the REB to review all submitted applications that require full reviews. Research proposals shall be sent to the members of the REB at least 10 business days in advance of each meeting.

1.2.2. The REB review will be based upon fully detailed submissions that will include an application for the Ethical Review of Research Involving Human Participants. This application includes:

- A full list of the researchers and associates involved with the study, with their academic and professional designations and affiliations, from the Principal Investigator to research assistants and contractors;
- A description of the research, including methodology;
- The individuals/population required for the investigation;
- Specific planning for risk management;
- A plan for the collection and maintenance of confidentiality of data;
- A plan for the handling of data, including storage and disposal;
- Disclosure of any conflict of interest; any relevant correspondence including any comments from the public;
- All relevant supporting documents, including information letters to prospective participants, consent forms, questionnaires, promotional and other communication materials;
- If required, a justification for withholding or misrepresenting significant facts (deception) when informing the participant about the research;
- A plan for providing full information upon completion of the project; and
- The TCPS 2 (2018) certificate of completion for each researcher and research assistant involved with the study

1.2.3. The REB will accommodate reasonable requests from researchers to discuss their proposals with the REB Chair in advance of submission. The REB will function impartially and hold a full discussion without the researcher present. In addition, if there are follow-up questions or concerns raised by the REB, the Principal Investigator will address them, either in person or in writing, at the discretion of the REB.

1.2.4. The REB will endeavour to reach consensus on decisions. However, if this is not achievable, a majority vote will decide the issue. In the event of a tie vote, the Chair will “break the tie” with their final determination. A record of decisions will be maintained, including requirements for revisions, along with the reasons for the revisions and dissents.

1.2.5. Under most circumstances, applications will be reviewed within 30 business days from receipt of the application. The REB shall deliver its decision on the research application in one of the following categories:

- Approve as submitted;
- Conditionally approve with recommendations for minor changes or subject to revisions;
- Not approve.

1.2.6. Applicants will be notified of the decision in writing, including the reasons for the decision, within five business days of the meeting. Requests for modifications will be explained and once the application is revised, shall be reviewed by the REB Chair. If REB requirements have been met, approval shall be granted. When considering a negative decision, the REB shall provide the Principal Investigator with reasons and give the researcher an opportunity to reply before making a final decision.

1.2.7. Reconsideration: Principal Investigators have the right to request reconsideration of decisions affecting a research protocol. If the REB does not approve the submission based on ethical reasons of the research activity or if in the Principal Investigator's opinion, the REB imposes conditions that compromise the research, the Principal Investigator will be given an opportunity to refute the reasons in writing or in person. The REB has an obligation to reconsider its decision.

1.2.8. Appeal: If the Principal Investigator and the REB cannot reach agreement through discussion and reconsideration, the Principal Investigator may apply in writing within 30 business days to the Chair of the Research Ethics Appeal Board (REAB) requesting an appeal of the negative decision with a copy forwarded to the Chair of the REB. Upon granting an appeal, the documentation will be sent to the REAB within 10 business days of receiving the request for an appeal.

1.2.9. Research Ethics Appeal Board (REAB) The membership of the REAB will consist of a minimum of five members who are not members of the REB and reflect the range of background and expertise similar to that of the REB (i.e. research, community representation, knowledge of ethics and of law). They will operate under the same reporting and administration structure as the REB. The REAB shall review the submission in a fair and impartial manner, rendering a decision that is considered final and binding and not subject to further appeal.

The decision will:

- Confirm the original REB decision;
- Modify the decision;
- Impose specific conditions for approval; or
- Reverse the decision.

The Principal Investigator and the REB will be notified in writing, with reasons, no later than 40 business days after receiving the appeal.

1.3. Delegated Review

1.3.1. Criteria

The proposal may be referred to a delegated REB review under the following conditions:

- The proposed research is deemed to pose no greater than "minimal risk" to the research participants (i.e. where the probable level of risk is reasonably anticipated to be no greater than what the participants may encounter in everyday life);
- It does not involve vulnerable populations, or sensitive information (e.g. legal, social or employability risk);
- It does not involve physically or psychologically invasive procedures;
- It does not raise other substantive ethical concerns.

If it does not meet these criteria for delegated review, then it is referred to the REB for a full review.

1.3.2 Delegated Review Process

The REB may delegate the review of the submission to two individuals with appropriate expertise. After completing the review, they will provide a written assessment on whether or not there are additional risk factors in the research that constitute greater than minimal risk. If both reviewers determine the risk is greater than minimal, the ethics submission will be referred to the REB for a full review. If the two reviewers disagree and are unable to reach a resolution with the assistance of the Chair, then the submission will also be referred for a full REB review. Submissions that meet the minimal risk criteria and comply with ethical standards, or that require only minor modifications and are subsequently revised, the REB Chair may approve on behalf of the REB.

Delegated reviews and the results are reported by the Chair to other members of the REB.

1.4. Ontario Colleges Multi-College Ethics Review Process (Expert REB Panel)

The multi-college review process coordinates the ethics review of applications among participating colleges. Researchers may submit minimal risk applications to the Expert REB Panel (herein referred to as 'Expert Panel') for review. The Expert Panel will work with the researcher to make changes. Once the Expert Panel is satisfied with the application, the researcher will be issued a letter of recommendation. The letter of recommendation is submitted to any of the necessary participating colleges, along with all final application documents. Humber College is a participant of the Multi-College Ethics Review Process and accepts recommendations from the Expert Panel. The Humber REB Chair reviews the application and recommendation from the Expert Panel. The Chair determines the ethical acceptability, and if appropriate, issues the certificate of

ethical approval to the researcher, or determines that a separate review will need to be completed.

When a multi-college research project is undertaken, the Principal Investigator is responsible for ensuring that all institutions review the research protocol. The participating REBs may choose to co-ordinate the ethics review process and share relevant documents to facilitate the review.

1.5. Review of Ongoing Research

1.5.1. In accordance with a proportionate approach to ethics review, the REB shall make the final determination as to the nature and frequency of the continuing ethics review. At a minimum, an annual status report with sufficient details to make a judgment about the ethical acceptability of the research will be submitted by the Principle Investigator to the Chair of the REB. However, reports may be requested at shorter intervals and/or additional requirements may be imposed depending on the risks and probability of harm.

1.5.2. If research that is expected to be completed within one year continues, the Principal Investigator must submit a request for an extension prior to the expiration of the current approval. Where there has been little or no change to the protocol, an expedited review may be considered.

1.5.3. Any adverse effects suffered by the participants are to be reported immediately to the REB by the Principal Investigator and resolved within seven business days of their occurrence. This report will enable the REB to better protect research participants in future research projects. Depending on the nature of the event or issue, the REB may require adjustments to the protocol to prevent a reoccurrence.

1.5.4. Contemplated changes to the research protocol must be submitted to the REB with an explanation and are subject to an ethics review before the changes are implemented. The only exception is when changes are necessary to eliminate an immediate hazard to the research participants. The rigour of the review will be in accordance with proportionate approach.

1.5.5. The Chair has the discretion to refer the matter for the opinion of the REB if the change is substantial or to approve it on their own authority. The REB has the authority to terminate an approved research protocol that deviates and no longer complies with the policy.

1.5.6. On an annual basis, the REB will provide the Research Integrity Officer (normally the Associate Vice-President Academic), with a report on all REB activity throughout the year.

1.6. Records

A record of decisions at all REB and REAB meetings shall clearly document decisions, dissents and reasons, and be stored on file on a Humber secured main database administered by the Humber REB coordinator. Plans for continuing ethics review, timelines and any conditions or limitations attached to the approval will also be documented. At the conclusion of the project, the Principal Investigator will notify the REB promptly that the project has been completed. The Principal Investigator must submit a Research Study Completion Report within 30 days of project completion to the REB. At that time, the file shall be "closed" and maintained in a secure location in a Humber administrative area for a period of seven years following completion to demonstrate compliance with the policy. The files will remain the property of Humber College—subject to audit by authorized representatives of the College, members of appeals boards and funding agencies.

2. Informed Consent Procedure

2.1. General

An important mechanism for respecting participants' autonomy in research is the requirement to seek their free and informed consent. This requirement reflects the commitment that participation in research, including participation using one's data, or biological materials, should be a matter of choice and that, to be meaningful, the choice must be informed. An informed choice is one that is based on as complete an understanding as is reasonably possible for the purpose of the research, what it entails, its risks and potential benefits, both to the participant and to other interested parties. Therefore, research may only proceed if:

- Potential participants have voluntarily and freely agreed to participate in the research study on the basis of well understood information about the objectives of the research and the nature of their participation; and
- Their consent is maintained throughout the duration of their participation in the research.

2.2. Competent Human Participants

Participants must be assured that they have a choice to participate and continue to participate, i.e.:

- Participation is strictly voluntary and no coercion or undue influence such as physical duress, fraudulent misrepresentation, exercise of control or abuse of power relationships will be used to gain acceptance;
- Withdrawal of consent is allowed at any time, without explanation or penalty, and
- None of the data or biological materials previously collected will be included in the research findings.

2.3. Voluntariness

Once REB approval has been granted for a research protocol, potential participants or authorized third parties must be fully informed about the nature of the research in a clear and transparent manner. Participants must be given the opportunity to discuss and reflect on their participation prior to giving free and informed consent once they understand elements such as the following:

- The purpose of the research, the identity of the Principal Investigator and research team members, and the contact information for the person leading/managing the study in the event there are concerns or complaints;
- How they will be asked to participate, the duration of the study, how much time will be required, responsibilities and how they will be selected (e.g. if randomized, the probability of participant selection);
- Full disclosure of any actual or perceived conflicts of interest on the part of the Principal Investigator or any other collaborator of Humber College and any potential for commercialization of the research;
- Information on any costs, payment reimbursement for expenses or compensation;
- The potential risks and benefits that may arise from participation in the research, which include any consequences of non-action, treatment or where there is a potential for physical, psychological or social impacts;
- Whenever possible and appropriate, additional information will be provided (e.g. survey/interview/focus group questions, recruitment and other promotional material).

2.4 Confidentiality

Participants must be informed how confidentiality will be approached including but not restricted to:

- How confidentiality will be strictly maintained and that no identifiers will be disseminated in any of the findings;
- All research findings will be kept secure, accessible only to the research team, and will be destroyed within a reasonable time frame; and
- Ways in which the outcomes of the research will be published, how participants will be informed of the results, and what opportunities will be provided for their feedback or general awareness at the end of their participation.

2.5 Documentation of Consent

Documentation of consent will be in written form, but where not appropriate, the REB may accept oral consents that are witnessed and confirmed by a neutral third party. Alternatively, they may indicate their consent by participating directly in the data collection (e.g. surveys).

2.6 Naturalistic Observation

Free and informed consent must be obtained for all prospective participants with the exception of minimal risk naturalistic observation studies that examine behaviour in a natural (not staged) environment. However, the research records must still protect the identity and dignity of the participants. Therefore, in these cases, REB review is required, and free and informed consent should be obtained from the participants after the observation whenever possible.

2.7 Vulnerable Human Participants

Some individuals may be competent but certain factors could diminish the person's ability to exercise their autonomy and effectively render them vulnerable. This would include inadequate information or understanding for deliberation, or a lack of freedom to act due to controlling influences or coercion. Sectors influenced by the nature of their relationship include students, employees, and patients dependent on caregivers or long-term care residents. Therefore, caution must be exercised and the best interests of the participant protected.

Beyond the legal requirements for obtaining free and informed consent from authorized third parties, family members and friends may provide information about the interests and previous wishes of prospective subjects. In some cases, the REB will have to determine from whom the free and informed consent should be sought.

2.8 Specific Circumstances in Obtaining Consent

The REB may approve a consent procedure that does not have all the TCPS-mandated elements or may waive the informed consent requirement in the following circumstances:

- The research is no more than minimal risk to the participants;
- The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration;
- Whenever possible and appropriate, the participants will be provided with additional pertinent information after participation;
- The waived or altered consent does not involve a therapeutic intervention.

References:

Humber Ethical Conduct for Research Involving Humans Policy

Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects – TCSP 2 (2018)

Record of Retention Schedule

Acknowledgements: George Brown College

Appendices:

Application for Ethical Review Involving Human Participants form.
https://www.humber.ca/research/reb/#hero_banner