Procedure Manual

Procedure #	AC200P1
Related Policy Name & #	Ethical Conduct for Research Involving Humans
Approved by:	Vice-President Academic
Approval Date:	June 15, 2011
Replaces Procedure Dated:	
Admin. Contact(s):	Chair, Research Ethics Board
Review Date:	June 2017

Procedures For Ethical Conduct For Research Involving Humans

Purpose:

The purpose of this procedure is to complement the Humber College Institute of Technology & Advanced Learning (hereafter referred to as "Humber" or "the College) Ethical Conduct for Research Involving Humans Policy document and to articulate a clear and defined process that will allow the Research Ethics Board (REB) to review applications in a fair and transparent manner. This procedure will determine whether the design of a research project is over a minimal risk threshold, whether the research is capable of addressing the questions being asked in the research, and identify the requirements for a fully detailed research proposal, progress reports for ongoing research, and a summative report at the end of the research.

Definitions:

Competence: refers to 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: is the legal and ethical obligation that arises from one person entrusting another with personal and private information.

Harm: anything that has a negative effect on the welfare of participants. The nature of the harm may take a social, behavioral, 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.

Under a broad definition, the research may include human participation:
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

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. 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.

Principal investigator: the individual who submits the research application and accepts the responsibility for ensuring the ethical treatment of every human participant for the duration of the research.

Privacy: the right of an individual to be free from intrusion or interference by others and to be secure from unauthorized disclosure of personal information that is contained in documents.

Protocol: refers to the description of the project that is included in the application submitted to the REB.

Research Ethics Board (REB): The Humber College Research Ethics Board oversees ethical screening and conducts a full review of research projects involving human participants. One REB will be established to evaluate all research and ensure the research is conducted in a manner that is consistent with the policy. (See policy, p. XX).

Risk: a function of the magnitude or seriousness of the harm and the probability that it will occur, whether to participants or third parties.

Minimal risk: occurs when potential participants can reasonably expect the probability and extent of possible harms to the participant in the research project will be no greater than the risks encountered by the participant in their everyday lives that relate to the research.

Procedures:

1.0 Submission Review Procedure

1.1. General

Research projects involving human participants should be submitted on a completed Application for Ethical Review Involving Human Participants form. Researchers may contact the Research Department 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 and the proportionate approach (See Policy, 2.7) to research ethics assessment is categorized into two levels of review:

- Full review (default);
- Expedited review by the chair or subgroup of the REB.

Research to be conducted by any member of the Humber community outside the jurisdiction or country by the principal investigator 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.

1.2. Full Review

1.2.1. The Chair will convene regular meetings of the REB to review all submitted documentation. 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 Ethical Review of Research Involving Human Participants. This application includes:

- 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 disclosure of any conflict of interest; any relevant correspondence including any comments from the public;
- all relevant supporting documents;
- if required, a justification for withholding or misrepresenting significant facts (deception) when informing the participant about the research and a plan for providing full upon completion of the project.

1.2.3. The REB will accommodate reasonable requests from researchers to participate in discussion about their proposals. The REB will function impartially and hold a full discussion, without the researcher present, when reaching a decision. 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 endeavor to reach consensus on decisions; however, if this is not achievable, a majority vote will decide the issue. A record of decisions will be maintained including requirements for revisions, along with the reasons for them 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 15 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 and the REB has an obligation to reconsider its decision.

1.2.8. Appeal

If the principal investigator and 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 of the REB 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 REB will be notified in writing, with reasons, no later than 40 business days after receiving the appeal.

1.3. Expedited Review

The principal investigator may choose to request an expedited review on the application by selecting the appropriate box. The REB Chair will review the application to assess the level of risk of harm to the human participant.

1.3.1. Criteria

If 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), does not involve vulnerable populations, sensitive information (e.g. legal, social or employability risk) or physically or psychologically invasive procedures and raises no other substantive ethical concerns, then the proposal may be referred to expedited REB review. If it does not meet the criteria for an expedited review then it is referred to the REB for a full review.

An expedited review may also be considered if a duly constituted REB under another institution that complies with the TCPS has formally approved the research.

1.3.2. Process

The principal investigator will be responsible for ensuring that the research protocol is reviewed by all institutions when a multi-centre research project is undertaken. The participating REBs may choose to co-ordinate the ethics review process and share relevant documents to facilitate the review.

The REB may delegate the expedited review of the submission to two individuals who have 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 can't come to a resolution through discussion with the assistance of the chair, the submission will again be referred for a full REB review. Submissions that meet the minimal risk criterion and comply with ethical standards, or which require only minor modifications and are subsequently revised, the REB Chair may approve on behalf of the REB.

Any requested expedited reviews and the results are reported by the Chair to other members of the REB. All expedited reviews will be ratified by the REB. This permits REB members to continue their responsibility and maintain surveillance over decisions made on their behalf.

1.4. Review for Ongoing Research

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 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. 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 are has been little or no change to the protocol, an expedited review may be considered.

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.

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 rigor of the review will be in accordance with proportionate approach.

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 his/her own authority. The REB has the authority to terminate an approved research protocol that deviates and no longer complies with the policy.

1.5. Records

A record of all decisions at all REB and REAB meetings shall clearly document decisions, dissents and reasons, and be kept in a file. 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 and then has 30 business days to submit a Research Study Completion Report. At that time, the file shall be "closed" and maintained in a secure location in the Research Department for a period of five years as a record 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.

2.0 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 through the use of 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 of the purpose of the research, what it entails, its risks and potential benefits, both to the participant and to others. 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

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 and become part of a dialogue before being invited to participate in the study. Participants are given the opportunity to discuss and reflect on their participation prior to giving free and informed consent once they understand the following:

- The purpose of the research, the identity of the principal investigator and research team members, and the contact information for a person 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 Humber College and any potential for commercialization of the research;
- Whenever possible and appropriate, additional information will be provided;
- Information on any costs, payment reimbursement for expenses or compensation.
- The potential risks and benefits that may arise from participation in the research include any consequences of non-action, treatment or where there is a potential for physical, psychological or social impacts.

2.3 Voluntariness

That 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 that none of the data or biological materials previously collected will be included in the research findings.

2.4 Confidentiality

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 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 verbal consents that are witnessed and confirmed by a neutral third party. Alternately 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 in these cases so 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 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, 2nd edition (TCPS 2)

Acknowledgments:

Durham College

Appendices:

Application for Ethical Review Involving Human Participants form