**George Brown College Research Ethics Policy**
Policy No. 14

## OVERVIEW

This document outlines the policy of George Brown College for ethical research involving human participants conducted under the auspices of the College. It applies to all researchers who may wish to use George Brown College employees, students and/or College equipment and facilities for study and research purposes.

In addition to adherence to College policies, all research projects must follow ethical guidelines on research involving human participants as contained in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.[1] The TCPS was revised and updated resulting in a 2nd edition (December 2010). These guidelines can be found at http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

## PHILOSOPHY & STATEMENT OF PRINCIPLES

The College endorses the ethical principles set out in the Tri-Council Policy Statement 2nd Edition (TCPS2). These principles include:

- Respect for human dignity
- Concern for welfare
- Justice

Please refer to the TCPS2 (http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter1-chapitre1/#toc01-1b) for definitions of the core principals.

## ACKNOWLEDGEMENTS

This policy is based on policy documents relating to ethical research created by Fanshawe College and Niagara College.

## DEFINITIONS

**Research** –An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation[2].

**Participant** – a person who, by virtue of his/her involvement in a data-gathering situation or activity, is a source of primary data or information. Research participants bear the risks of the research in any study involving humans.

[1] This document was produced and is maintained by the three major research granting agencies in Canada as members of the Tri-Council (Natural Sciences and Engineering Research Council, the Canadian Institutes of Health Research and the Social Sciences and Humanities Research Council (December 2010).
[2] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.

**Principal Researcher** – a person designated as the primary representative of a research project by virtue of their involvement and scholarly merit. The Principal Researcher bears responsibility for the research project and the reporting process.

**Minimal Risk** – occurs when 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 participant in those aspects of his or her everyday life.

**Capacity –** the ability of prospective participants to give informed consent in accord with their own fundamental values. It involves the ability to understand information presented, appreciate the potential consequences of the decision, and provide free and informed consent.

**Legal Incompetence –** a legal state defined by provincial law, that an individual is unable to consent for him or herself.

**Authorized Third Party –** a representative of an individual who is not competent to provide free and informed consent. The authorized third party acts in the interest of that individual.

**Free and Informed Consent –** the dialogue, information sharing, and general processes through which prospective participants choose to participate in research.

## Table of Contents

1. **Purpose**

1.1. George Brown College (GBC) is committed to the highest ethical and academic standards for its students, faculty and staff. It is committed to respect for academic freedom for all research conducted under the auspices of the College, as well as to ensuring this research meets the highest academic standards. Not without limits, these academic freedoms include freedom of inquiry and the right to disseminate the results thereof, freedom to challenge conventional thought, freedom from institutional censorship, and the privilege of conducting research on human participants with public monies, trust and support. George Brown is also committed to ensuring that research conducted involving George Brown College employees, students and/or College equipment and facilities is carried out using ethical and moral research practices. For these reasons, the College requires that all research using GBC employees, students and/or College equipment and facilities, irrespective of the source of financial support or location of the project, undergo a Research Ethics Review, as set out below.

2. **Scope**

2.1 Research projects affiliated with GBC fall within the jurisdiction of a committee called the **George Brown College Research Ethics Review Board** (REB). The main purpose of the REB is to ensure that ethical principles are applied to research. The REB endorses, and takes as its guide, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010.*If there are any issues or discrepancies while in the process of review, the researcher and REB shall refer to the *TCPS* at all times. The procedures in this policy may be amended from time to time to accommodate future approved amendments to the Tri-Council Policy or as otherwise deemed appropriate.

2.2 This policy applies to all faculty, staff and students regardless of where the research is conducted. Projects conducted by researchers from outside the GBC community who access College resources (either equipment or personnel), will also fall within the jurisdiction of the REB.

2.3 GBC considers any violation of this policy a serious offence, subject to severe penalties, including but not limited to the withdrawal of privileges to conduct research or disciplinary action. For any allegations of scholarly misconduct, including non-compliance with this policy, please refer to the *George Brown College Integrity in Research and Scholarship Policy.*

2.4 Prior ethics review and approval by the REB is required for all research projects involving human participants conducted at, or under the auspices of George Brown College. This applies to:

2.4.1 All research involving human participants conducted by the College's academic, administrative or support staff, persons with adjunct appointments, visiting instructors, visiting professional associates, and research associates.

2.4.2 All research involving human participants that occurs on College premises or using College facilities, equipment, or human, financial or material resources.

2.4.3 All research involving human participants conducted in a location not associated with George Brown but involving College equipment, human, financial or material resources.

2.4.4 All types of research conducted with human participants. This includes:

2.4.4.1 Human biological materials which includes tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids. Materials related to human reproduction include: embryos, fetuses, fetal tissues and human reproductive materials.

2.4.4.2 Information collected through intervention or interaction with a living individual;

2.4.4.3 Information collected through naturalistic observation of humans, except as stipulated below in item 4.1.3.

2.4.4.4 Written or recorded information derived from individually identifiable human participants;

2.4.4.5 Identifiable private information about individuals in a research study that would not require the individual's active involvement.

2.5 Prior ethics review and approval from the College REB will not normally be required for:

2.5.1 Quality assurance studies, performance reviews or testing within normal educational requirements. If data are collected for the purposes of such activities but later proposed for research purposes, at that later time, an REB review may be required in accordance with this Policy.

2.5.2 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. REB approval should only be sought if the participant 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.

2.5.3 Naturalistic observation of participants in, for example, political rallies, demonstrations or public meetings where it can be expected that participants are seeking public visibility.

2.5.4 Class research projects which involve human participants and which are conducted by students on other members of the class as exercises to learn how to conduct research.

2.5.5 Research conducted over the internet that is non intrusive, and does not involve direct interaction between the research and individuals, does not require REB review.

2.5.6 REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.

2.6 For research where the Principal Researcher is uncertain whether REB review is required, it is the responsibility of the Principal Researcher to obtain the written opinion of the Chair of the REB as to whether the research should be subjected to prior ethics

review and approval. The Principal Researcher shall submit an *Uncertainty about the Need for Review* form to the Chair (See Appendix A for form).

## 3 Free and Informed Consent

3.1 Free and Informed Consent must be obtained from all prospective participants, or Authorized Third Parties, prior to commencing research activities (see Appendix F for sample Consent Form). It is the responsibility of the Principal Researcher to ensure that Free and Informed Consent has been given and is maintained throughout a participant's participation in the research. When seeking free and informed consent the researcher must ensure that:

3.1.1 Free and Informed Consent is voluntarily given, without coercion, and may be withdrawn at any time.

3.1.2 Full and frank disclosure of all relevant information is provided, and enough time is given for prospective participants to contemplate their participation.

3.1.3 Evidence of Free and Informed Consent be obtained in writing and stored in a secure location. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek consent shall be documented.

3.1.4 Prospective participants have the ability to understand the information presented and have the Competence to give Free and Informed Consent.

3.2 Free and Informed Consent is required with modification in the following instances:

3.2.1 Naturalistic observation studies do not normally require informed consent since the participants are unaware they are being observed. This type of research requires REB review to ensure that the research records protect the identity and dignity of the participants. REB review is not required for research observing political rallies, public demonstrations, or public meetings.

3.2.2 Participants who participate in randomizing and blinding clinical trials are still required to provide informed consent and are informed of the probability of being randomly assigned to one arm of the study or another.

3.3 An REB may approve a consent procedure which does not have all the elements of informed consent, or may waive the requirements to obtain informed consent, provided the REB finds and documents certain requirements as set out below:

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

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

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

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

3.3.5 The waivered or altered consent does not involve a therapeutic intervention.

3.4 Research Involving Individuals with reduced capacity

3.4.1 For research involving individuals with reduced capacity, the REB shall ensure that the Principal Researcher shows how the Free and Informed Consent was obtained by the Authorized Third Party, and how the participants' best interests will be protected. The Principal Researcher or any member of the research team may not act as an Authorized Third Party. If during the research the participant becomes Competent to give Free and Informed Consent, this shall be obtained as a condition of continuing participation.

3.4.2 Subject to applicable legal requirements, individuals with reduced capacity shall only be asked to become research participants when:

3.4.2.1 The research question can only be addressed using individuals within the identified group(s);

3.4.2.2 Free and Informed Consent will be sought from their authorized representative(s); and

3.4.2.3 The research does not expose them to more than Minimal Risks without potential direct benefits.

3.4.3 When Free and Informed Consent has been obtained from an Authorized Third Party, and in those circumstances where the individual with reduced capacity understands the nature and consequences of the research (for example, children whose capacity for judgment and self-direction is maturing, those who are losing, but have not completely lost, capacity, such as Alzheimer's patients, and those whose capacity remains only partially developed), the Principal Researcher shall seek to ascertain the wishes of the potential participant. The potential participant's dissent will preclude his or her participation.

3.5 Researchers shall provide prospective participants or Authorized Third Parties with the following information (for a sample information letter please see Appendix E):

3.5.1 Information that the individual is being invited to participate in a research project;

3.5.2 A statement of the research purpose, identity of the Principal Researcher, the expected duration and nature of participation and a description of the research procedures;

3.5.3 A description of the 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;

3.5.4 An assurance that prospective participants are free not to participate and 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

3.5.5 The possibility of commercialization of the research findings, and the presence of any apparent, actual, or potential conflict of interest on the part of researchers, their institutions or sponsors;

3.5.6 Information on how the research will be stored.

## 4 Research in Emergency Health Situations

4.1 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 the 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 participant or of his or her Authorized Third Party if ALL of the following apply:

4.1.1 A serious threat to the prospective participant requires immediate intervention; and

4.1.2 Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care; and

4.1.3 Either the risk of harm is not greater than that involved in standard efficacious care, or it is not clearly justified by the direct benefits to the participant; and

4.1.4 The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research; and

4.1.5 Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and

4.1.6 No relevant prior directive by the participant is known to exist.

4.1.7 When a previously incapacitated participant 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.

## 5 George Brown College Research Ethics Board of Review

5.1 The George Brown College Research Ethics Board of Review has been mandated by the President of George Brown College 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, as per the policies and guidelines set forth in this document. The REB shall report to the President. By this mandate, the President affirms that:

5.1.1 The REB, and the appeal process as outlined in section 7.10 of this policy, is the final authority for the ethical approval of research involving human participants, and the College may not override REB decisions on the grounds of ethics without going through the formal appeal mechanism. The College may however refuse to allow certain research within its jurisdiction even though the REB has found it ethically acceptable.

5.1.2 The REB will be provided with the appropriate financial and administrative independence to fulfill their primary duties. The REB will be supported by the College's Office of Applied Research.

5.2 In this context the REB is responsible for:

5.2.1 Developing policies regarding ethical issues relating to the use of human participants in research and experimental teaching protocols;

5.2.2 Reviewing all protocols requiring the participation of human participants for ethical approval;

5.2.3 Reviewing annually all policies regarding ethical issues relating to the use of human participants in research projects to ensure that policies remain consistent with the Tri-Council Policy Statement;

5.2.4 Preparing an annual report for submission to the President of George Brown College;

5.2.5 Holding an annual meeting open to all College staff, students, and external stakeholders;

5.2.6 Participating in continuing education organized by George Brown College research administrators and staff development in matters relating to ethics and the use of human participants.

5.3 Composition of the Board

5.3.1 The REB shall consist of five members, both men and women, of whom:

5.3.1.1 At least two members have expertise in the areas of research covered by the board;

5.3.1.2 At least one member is knowledgeable in the area of ethics

5.3.1.3 At least one community member with no affiliation to the College

5.3.1.4 At least one is a lawyer, who is not George Brown's legal counsel

5.3.1.5 In the case of biomedical research at least one member who is knowledgeable in the area of biomedical research law

5.3.2 In the event that the REB is reviewing a project that requires particular community or research participant representation, or a project that requires specific expertise not available from its regular members, the REB Chair shall nominate appropriate *ad hoc* members for the duration of the review. Should this occur regularly, the membership of the REB should be modified.

5.3.3 Substitute members to the REB may be nominated so that Boards are not paralyzed by illness or unforeseen circumstances. Such substitute members shall be nominated in advance to avoid the potential for *ad hoc* substitutes. The appointment of nominated substitute members for a specific review shall not alter the membership structure.

5.3.4 The normal term of office for REB members is two years, with no more than one-third being replaced each year; shorter or longer terms may be necessary from time to time. Members may not serve more than three consecutive terms, but may be eligible for re-appointment after an interval of one year.

5.3.5 The Chair shall be elected by the REB on a two year appointment, and may be re-elected for one additional term. The Chair is responsible for:

5.3.5.1 Calling and chairing regular meetings of the REB and other meetings as required

5.3.5.2 Maintaining and coordinating communication with REB members and the Office of Applied Research

5.3.5.3 Communicating decisions to the research applicant

5.3.5.4 Assisting in determining delegated reviews of proposed research

5.3.5.5 Recommending experts and *ad hoc members* to the REB where appropriate

5.3.5.6 Ensuring that appropriate documentation of REB meetings and decisions are kept and submitted to the Office of Applied Research.

5.4 Conflict of Interest

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

5.4.2 REB members are under conflict of interest when they have an actual or perceived personal interest in the research. 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 Principal Researcher has the right to hear the evidence and to offer a rebuttal.

5.4.3 It is the responsibility of the REB to assess the likelihood that the researchers' judgment may be influenced, or appear to be influenced, by private or personal interests.

5.5 Quorum

5.5.1 The quorum shall consist of 50% plus one of duly appointed members of the REB. When there is less than full attendance, decisions requiring full review should be adopted only if the members in attendance possess the range of background and expertise stipulated in section 5.3.1

5.6 Meetings

5.6.1 The REB shall meet monthly, at dates and times that are publicly announced in advance. The REB will endeavor to announce REB meetings for the upcoming academic year by June 30 of the year previous. Regular REB meetings may not be required at certain times of the year (July and August). Regularly scheduled REB meetings may be cancelled if no protocols have been received by the submission deadlines.

5.7 Research Ethics Appeal Board

5.7.1 The REAB, similar to the REB, will be comprised of at least five members, appointed by the President of the College, including both men and women, of whom:

5.7.1.1 none are members of the REB

5.7.1.2 at least two members have broad expertise in the areas of research covered by the REB at the College

5.7.1.3 one member is knowledgeable in ethics

5.7.1.4 in the case of biomedical research at least one member must be knowledgeable in the area of biomedical research law

5.7.1.5 one is a lawyer, who is not the College legal counsel

5.7.1.6 one is a community member with no affiliation to the College.

5.7.2 The George Brown REAB shall follow the protocol for appeal as outlined in section 7.1 of this policy.

5.8 Record Keeping

5.8.1 Minutes of all REB and REAB meetings shall be prepared and maintained by the REB. The minutes shall clearly document the decisions and any dissents, and the reasons for them. The minutes will be accessible to authorized representatives of the institution, researchers and funding agencies through the Office of Applied Research. Availability of these minutes shall be made available in order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals.

## 6 Responsibility of REB

6.1 The REB shall adopt a proportionate approach to ethics review, as laid out in section 7.2 of this policy.

6.2 The REB is responsible for scholarly review as part of the ethics review process. 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. In the event that the REB membership does not contain the necessary expertise, the Chair shall establish an *ad hoc* independent external peer review. REB peer review is not normally required if a research proposal has previously undergone a professional peer-review assessment, provided the researcher submits full documentation of those reviews.

6.3 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.

6.4 Research in the humanities and social sciences that poses Minimal Risk at most is not normally required by the REB to be peer reviewed.

6.5 REB review 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 the Principal Researcher to participate in discussions about their proposals, but 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.

6.6 It is the responsibility of the REB to uphold the principle of *distributive justice*: “members of society should neither bear an unfair share of the direct burdens of participating in research, nor should they be unfairly excluded from the potential benefits of research participation.” For example, those who do not have the capacity 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.

## 7 Procedural Guidelines

### 7.1 Submission

7.1.1 While it is not necessary for the REB to review a research proposal before it is submitted to a funding agency, REB approval must be obtained before the work begins. Visiting researchers should contact the chair of the George Brown College REB well in advance of the anticipated start date of research. Submissions for review should be submitted to the REB using the appropriate forms and by following the instructions on those forms. Prospective applicants may approach the Office of Applied Research for assistance in selecting the appropriate forms for submission.

### 7.2 Guidelines for Proportionate Review

7.2.1 The REB will use a proportionate approach based on the general principle of risk. Risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to participants or to third parties (as outlined below). A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk. Proportionate review shall be evaluated by assessing the character, magnitude and probability of potential harms inherent in the research, from the point of view of the potential participants. Following this initial assessment, the REB may choose from the following possible levels of review:

7.2.1.1 Full REB review (default level)

7.2.1.2 Delegated REB review by an individual or sub-group of the REB

7.2.1.3 Faculty/Divisional (Departmental) level review of undergraduate projects carried out within formal course requirements and posing no more than minimal risk.

7.2.2 Informal meetings between REBs and Principal Researchers are appropriate to expedite the process, but shall not substitute for the formal review process.

### 7.3 Full Review

7.3.1 Full review shall be the default type of review. Exceptions will be made to this as outlined in sections 7.4 and 7.5 of this policy.

7.3.2 The REB shall normally meet face to face in order to review submitted research proposals. In the case of controversial research proposals, the REB may meet face to face with Principal Researchers in order to consider the ethical solutions proposed by researchers for problems arising in their studies.

7.3.3 The REB shall accommodate reasonable requests from the Principal Researcher to participate in discussions about their proposals, but not be present when the REB is making its decision.

7.3.4 Minutes will be kept for these meetings and inserted into the appropriate case files. Meeting minutes will document the decisions and dissents of the REB and the reasons for them.

7.3.5 Research applying for ethical approval shall be kept as an “open file” in the office of Applied Research. The file shall be brought to the REB by the Chair when

sufficient information has been submitted by the researcher to start the review process. The original application, descriptions of research and methodology, correspondence, relevant documents, ethical certificates, revised materials, and any comments from the public or other information relevant to the research project shall be kept in the file.

7.3.6 It is the responsibility of the Principal Researcher to keep the file complete and up-to-date at all times. When the research project is finished, and the Principal Researcher notifies the REB, the file shall be "closed" and kept for a period of five years by the REB as records demonstrating compliance with the *TCPS*. The files remain the property of George Brown College and cannot be removed from the secure location by the researchers. These files shall be subject to audit by authorized representatives of George Brown, members of Appeal Boards, and funding agencies. The REB file on applications for ethical review shall contain the following documents:

7.3.6.1 Application form

7.3.6.2 Trial protocol and amendments

7.3.6.3 Written informed consent forms and any updates

7.3.6.4 Participant recruitment procedures

7.3.6.5 Available safety information

7.3.6.6 Information about payments and compensation available, and provided, to participants

7.3.6.7 Researcher(s) current curriculum vitae and/or other documents of qualification

7.3.6.8 Any other documents the REB may need to fulfill its responsibilities

7.3.7 All research requiring ethical approval, whether through the normal or delegated process, shall require a proper file showing compliance with the George Brown Ethics Review Policy. Insufficient information in the file is grounds for refusing or delaying ethical approval.

7.4 Delegated Review

7.4.1 Delegated review does not require face-to-face meetings with the REB members. The Principal Researcher must choose to apply for delegated or full review, by selecting the appropriate box on the *Research Ethics Protocol,* and the REB Chair may reject any application for delegated review and refer it to the REB for full review. The Chair must report requests for delegated review and results of such reviews to other members of the REB at an appropriate time.

7.4.2 Delegated review is review by two members (the Chair may be one of these) rather than the full REB. It is available only in cases which fulfill one of the following criteria:

7.4.2.1 Research which obviously involves no more than Minimal Risk, as defined in the Tri-Council Policy Statement: "research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research[3]"

[3] Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2010 (p.23).

7.4.2.2 The review is an annual renewal of a project previously approved by the REB, and the "open file" is up to date.

7.4.2.3 The research involves only review of patient records by hospital personnel

7.4.2.4 The Principal Researcher submits a letter of affirmation confirming that conditions laid down by the REB have already been approved by another institution or funding agency.

7.5 Faculty/Division/ Centre Level Review

7.5.1 This policy requires the REB to review and approve all research involving human participants. However, the REB may delegate the ethics review of research entailing no more than Minimal Risk that is carried out by undergraduate students as part of their course work, to a Faculty/Divisional/Centre level process which is in compliance with this policy and the *TCPS*. The Faculty/Divisional/Centre level process should be reviewed and approved by the REB.

7.6 Ongoing Research

7.6.1 Ongoing research is subject to continuing ethics review, the rigour of which is assessed by the proportionate approach.

7.6.2 Each research proposal should contain a process for continuing review appropriate to the project. Normally continuing review shall consist of at least the submission of a succinct annual status report to the REB (see App D). The annual report must be submitted to the REB prior to the anniversary date of the original protocol approval. These reports should include the status of data collection, any proposed changes to the protocol that was approved, and the details of any proposed changes. If the protocol has not changed substantially, the Chair of the REB may issue a one-year extension. If in the opinion of the REB Chair the research plan or protocol has been substantially changed, re-submission and review by the REB is required.
The REB recognizes that changes are sometimes needed after an ethics application has been approved. Researchers must report any change or modification in research design or procedures that have ethical implications or increases risk to the participants such as changes to the role of principal investigator, study recruitment process, design, protocols or consent processes. The REB will assess the modification and if changes are extensive, they may require a second formal review.

7.6.3 The continuing review of research exceeding the threshold of Minimal Risk, in addition to annual review, might include:

7.6.3.1 Formal review of the Free and Informed Consent process,

7.6.3.2 Establishment of a safety monitoring committee,

7.6.3.3 Periodic review by a third party of the documents generated by the study,

7.6.3.4 Review of reports of adverse events,

7.6.3.5 Review of patients' charts, or

7.6.3.6 A random audit of the Free and Informed Consent process.

7.6.4 The Principal Researcher shall promptly notify the REB when the project concludes by submitting a *Study Completion Report* (Appendix D)

7.6.5 Any unexpected incidents or adverse events that place study participants/and or George Brown College at risk must be reported to the Chair of the Research Ethics Board immediately using the *Adverse Event* report form (to be developed).

Sample situations that require reporting:

- An unexpected physical, psychological response during a study
- Any injury that occurs during the study
- The inadvertent release of any personal /confidential information regarding the participants

7.7 Review of Multi-Centered Research

7.7.1 It is the responsibility of the Principal Researcher to ensure that multi-centred research is reviewed by all institutions where the research is undertaken. To facilitate this type of review, the REB may share documents and findings with REBs at other institutions. The REB may also review the documents and findings of REBs of other institutions as part of its ethics review process.

7.8 Review of Research in Other Jurisdictions or Countries

7.8.1 Research under the auspices of, or involving George Brown faculty, staff or students, performed in another jurisdiction or country shall undergo ethics review by the REB and, where it exists, the equivalent REB in the country or jurisdiction where the research is to be conducted.

7.9 Decisions of the REB

7.9.1 After review by a REB, the protocol submission may be:

7.9.1.1 Approved as submitted

7.9.1.2 Approved with suggestions for minor changes

7.9.1.3 Approved with conditions that must be met before final approval is granted

7.9.1.4 Deferred, pending receipt of additional information or major revisions

7.9.1.5 Not approved

7.9.2 The REB shall notify each Principal Researcher in writing of its decision regarding his/her proposed research activity. If a protocol submission is approved with minor changes or conditions, the Principal Researcher can either accept the proposed modification or offer a counter-proposal to the Chair of the REB. To facilitate the continuing process of such research ethics protocols between meetings, the REB should specify conditions that should be met to enable the Chair to review and grant approval on behalf of the REB.

7.9.3 Researchers have the right to request, and REBs have an obligation to provide, reconsideration of decisions affecting a research project.

7.9.4 If the REB does not approve a research activity for ethical reasons, the notification shall include a statement of the reasons for its decision and the Principal Researcher shall be given an opportunity to respond in writing or in person. The REB may, at its discretion, review and reconsider its decision to not approve the research activity.

7.9.5 In the case of ongoing research, the REB has the authority to terminate research that deviates from an approved research protocol and as a result no longer complies with the criteria set forth in these policies or the TCPS.

7.10 Appeal

7.10.1 The Principal Researcher must apply in writing to the Vice-President, International and Applied Research (VP) to appeal a negative decision of the REB. A copy of the appeal letter should be sent to the REB Chair. Appeals may only be granted by the VP on procedural grounds, or when there is a significant disagreement over an interpretation of the *TCPS*. Non-compliance with the substance of the *TCPS* is a reason for refusing to grant an appeal.

7.10.2 Upon granting an appeal, the VP shall forward the appeal letter and all relevant documents to the GBC Research Ethics Appeal Board within ten days of receiving the request for appeal.

7.10.3 The Research Ethics Appeal Board shall review the appeal at their next scheduled meeting and notify the Principal Researcher in writing of their decision no later than 40 days after receiving the appeal from the VP.

7.10.4 The protocol submission may be approved or rejected in the same manner as outlined in section 7.9.1 of this policy. The decision of the Appeal Committee shall be binding.