

# Responsible Practice and Ethics Review in Research AD-014

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Executive Director, Research Innovation and Entrepreneurship	Jamie Doran	
Approver	Print Name	Date (07/09/2021)

#### **Purpose**

This policy establishes procedures for those wishing to undertake research involving human participants under the auspices of Georgian College to ensure that research completed at Georgian College meets the standard for integrity as defined by the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC).



**RATIONALE:** The general goals of research involving human participants are defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due. Because researchers seek to understand something not yet revealed, research often entails risks to participants and others. These risks can be trivial or profound, physical or psychological, individual or social. Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting research participants in order to try to prevent such occurrences.

#### Scope

All research involving human participants that is associated with Georgian College, including that conducted by external organizations or individuals shall be subject to the policies and procedures described within this policy.

The range of research activities involving human participants includes all research, regardless of whether the research is funded or non-funded, is performed by Georgian College students, faculty, support staff, or administrative staff, is a collaborative research undertaking with strategic college or university partners, or is for commercial or information purposes. This also includes individuals not associated with Georgian College who wish to complete research that involves Georgian College staff, students or community members. The scope of this policy encompasses ethical responsibility to human participants as well as responsible research practices.

## RESEARCH ACTIVITIES REQUIRING GEORGIAN COLLEGE RESEARCH ETHICS BOARD (GCREB) REVIEW AND APPROVAL:

All research that involves living human participants, human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells requires review and approval by the Georgian College Research Ethics Board (GCREB) in accordance with this policy statement, before recruitment or data collection begins, including:

- Research involving human participants recruited at Georgian College
- Research using the college's name
- Research sponsored by the college through professor classroom release time, sabbatical (study leave), or direct funding
- Research accessing college facilities, resources, employees, machines, and other college services or resources
- Research for which the college administers a grant from an outside agency or individual (private or government)



- Research using data formally collected, through whatever means or methods, from college students, employees or other members of the college community, or from any database containing information about the aforementioned groups
- Research involving human participants undertaken by Georgian College and Georgian College University Partnership Centre students, including course-based research activities, the primary purpose of which is pedagogical

## ACTIVITIES EXEMPT FROM GEORGIAN COLLEGE RESEARCH ETHICS BOARD (GCREB) REVIEW AND APPROVAL:

- Research about a living individual involved in the public area or about an artist, based exclusively on publicly available information
- Research involving the observation of people in public places in which the individuals targeted for observation have no reasonable expectation of privacy; receive no intervention or direct contact from the researcher; and cannot be identified in any disseminated research results
- Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively by Georgian College for assessment, management or improvement purposes, including:
  - Data collection, management, and reporting for routine administrative purposes by Georgian College departments
  - National or provincially mandated studies such as Key Performance Indicators (KPIs) or Colleges Ontario studies
  - Primary data collection (such as surveys or focus groups) designed and administered by the Institutional Research department for review and renewal of college programs and services
- Georgian College student information gathering activities classified as skill development and not research where the intent is to:
  - Use the information to provide advice, diagnosis, identification of appropriate interventions, or general advice for a client;
  - Develop skills which are considered standard practice within a profession (e.g. observation, assessment, intervention, evaluation, auditing); and/or collect information as part of the normal relationship between a student and the participants (e.g. classroom teacher and students, nurse and patient, lawyer and client).



### **Definitions**

Word/Term	Definition	
Co-investigator(s)	Researcher(s) who collaborate on the research project.	
	The Georgian College Research Ethics Board (GCREB) serves to approve the ethical integrity of proposed or ongoing research involving human participants that is conducted within, or by members of, Georgian College.	
Georgian College Research Ethics Board	International consensus and the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or 'the Agencies', require that a duly constituted and functioning independent committee review and approve all research projects involving human participants before the first potential research participant is invited to participate. Independent review reinforces the ethical standards that the researcher and institution strive to meet.	
	The GCREB is composed of Georgian College employees and community members knowledgeable in research content and methodology, ethics and law.	
Minimal Risk Research	"Research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research" (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 – TCPS 2 (2018), Glossary).	
Participants	"For the purposes of this Policy, "human participants" (referred to as "participants") are those individuals whose data, biological materials, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question(s)." (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 – TCPS 2 (2018), Article 2.1)	
	"The researcher who is responsible for the ethical conduct of the research, and for the actions of any member of the research team at a local site" (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 – TCPS 2 (2018), Glossary).	
Principal Investigator (PI)	For multi-site studies, there must be a "Lead principal investigator – The designated principal investigator who is responsible for the ethical conduct of the study for all sites" (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 – TCPS 2 (2018), Glossary).	
	For student research, the faculty member supervising the research serves as the study's Principal Investigator.	
Research	"An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation." (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 – TCPS 2 (2018), Glossary)  For the purposes of this policy, "research" refers to research involving human participants.	
Researcher	Person who undertakes a project "intended to extend knowledge through a disciplined inquiry and/or systematic investigation" (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 – TCPS 2 (2018), Glossary). Also known as "investigator".  See also "Principal Investigator (PI)" and "Co-investigator".	



Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS or the Policy) "The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS or the Policy) is a joint policy of Canada's three federal research agencies — the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or "the Agencies."

This Policy expresses the Agencies' continuing commitment to the people of Canada to promote the ethical conduct of research involving humans. It has been informed, in part, by leading international ethics norms, all of which may help, in some measure, to guide Canadian researchers, in Canada and abroad, in the conduct of research involving humans" (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 – TCPS 2 (2018)).

#### Responsibility

- As the highest body within the institution, the Georgian College Board of Governors is responsible under the TCPS for establishing the Georgian College Research Ethics Board (GCREB), defining an appropriate reporting relationship with the GCREB and ensuring the GCREB is provided with the necessary and sufficient ongoing financial and administrative resources to fulfill their duties.
- The Vice President (VP), Academic has been delegated the authority to approve the membership of the GCREB on behalf of the Georgian College Board of Governors.
- The Georgian College Research Ethics Board (GCREB) is accountable to the Georgian College Board of Governors, and is responsible for independent decision-making regarding "the ethical acceptability of research on behalf of the institution, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans". (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 TCPS 2 (2018), Article 6.2)
- GCREB Members are responsible for:
  - Demonstrating respect for ethics and responsible practice in research and fostering ethical research practices at Georgian College;
  - Attending meetings and learning opportunities;



- Updating their knowledge of current research ethics policies and best practices;
- Responding to requests for review in a timely manner;
- Participating and/or contributing to effective discussion and decision making at the GCREB;
- Maintaining the confidentiality of any and all information, discussions or proceedings at meetings of the GCREB which were closed to the public; and
- Observing and performing the Members' fiduciary duty to the GCREB by acting with honesty, in good faith and in the best interests of the GCREB.
- The **GCREB Chair** is responsible for:
  - Ensuring that the GCREB review process conforms to the requirements of this Policy;
  - Ensuring that ethics reviews are both thorough and timely;
  - Advise GCREB members on any matters that arise from their review of a proposal;
  - Using consultative and participative decision-making practices;
  - o Encouraging ethical research practices; and
  - Educating the GCREB members concerning matters of research ethics as needed; organizing an orientation for incoming members of the GCREB; and conducting at least one educational seminar during his or her term. The Chair shall explain procedures and guidelines, and give general instruction on the nature of research ethics and professional standards.
- All researchers conducting research at or on behalf of Georgian College must follow the standards and procedures set out in this policy.
- The **Principal Investigator** is responsible for:
  - Ensuring all researchers working on their project complete the TCPS 2 Tutorial Course on Research Ethics (CORE);
  - Submitting a completed Georgian College Application for Research Ethics
     Approval (or other ethics review forms approved by GCREB) to the Chair of the GCREB for review;
  - The ethical conduct of all researchers working on the project;
  - Immediately notifying the GCREB of any changes or problems that occur during the study; and
  - Submitting a Renewal Request or Final Report before the expiry date of the GCREB ethics approval.
- Course Instructors who are authorized by GCREB to conduct course-based ethics review shall serve as the Principal Investigator for their students' projects and shall ensure all course-based research documents are filed with the GCREB in a timely manner.



#### **Policy**

- 1.1 Standards and Procedures for Research Involving Human Participants
  - 1.1.1 All Georgian College standards and procedures for research involving human participants shall be in accordance with the 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 TCPS 2 (2018). This includes research involving:
    - a. living human participants; and/or
    - b. human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

(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 – TCPS 2 (2018), Article 2.1).

- 1.1.2 Researchers and the GCREB shall refer to and be guided by Georgian College's Intellectual Property, Research Integrity, and Conflict of Interest policies, in addition to the 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 TCPS 2 (2018).
- 1.1.3 Risks in research are not limited to participants. In their conduct of research, researchers themselves may be exposed to risks that may take many forms (e.g., injury, incarceration). Risks to researchers may become a safety concern. The GCREB shall raise concerns about the safety of researchers as part of its communication to the researchers, and to their supervisors. Based on the level of risk, the GCREB may refer these concerns to the Vice-President, Academic or designate at the VP level.
- 1.2 Georgian College Research Ethics Board (GCREB) Structure
  - 1.2.1 Composition of the GCREB

The criteria for GCREB membership are founded upon the principle that competent research ethics review requires ethics expertise, a multidisciplinary perspective, and GCREB independence. Guided by these criteria, the GCREB must consist of at least five members, including:

Both men and women;



- At least two members with expertise in relevant research disciplines, fields and methodologies covered by the GCREB;
- At least one member who is knowledgeable in ethics;
- At least one member who is knowledgeable in the relevant law but who is not the college's legal counsel or risk manager; and
- At least one community member who has no affiliation with the institution.

To ensure the independence of GCREB decision making, institutional senior administrators shall not serve on the GCREB.

#### 1.2.2 Selection and Term of the GCREB Chair

The Chair shall be appointed by the VP, Academic. The Chair shall hold the position for a two-year term (renewable for up to two more years).

In order to be appointed to the position of Chair, an individual must possess a background in the area of research, which includes a demonstrable knowledge of research ethics, appropriate qualifications and research experience.

If the Chair must assume another role during an ethics review, or if the Chair would be in conflict of interest during a vote, the GCREB shall choose by majority vote a member to perform the duties of the Chair. If the Chair is unable to perform their role as Chair for an extended period of time, the VP, Academic shall appoint a new Chair or Interim Chair.

#### 1.2.3 GCREB Membership Criteria

- 1.2.3.1 Members of the GCREB shall be appointed by the VP, Academic and the Chair of the GCREB.
- 1.2.3.2 Criteria for membership are:
  - Respect for ethics and responsible practice in research;
  - Willingness to learn and follow college policies and guidelines;
  - Willingness to attend meetings, and learning opportunities;
  - Willingness to read learning materials related to ethics and responsible practice in research;
  - Ability to work with a team;
  - Ability to respond quickly to requests for review; and
  - Demonstrated commitment to fostering ethical research practices.
- 1.2.3.3 Members shall be required to assume a two-year term that is renewable for a maximum of four consecutive years. Departing members shall be replaced at the end of their terms, ensuring the membership representation stated above. Former GCREB members may be invited to rejoin GCREB following a one-year break from the GCREB.
- 1.2.3.4 GCREB members are expected to be versed in the procedures and the language of the policy and to read any relevant information provided to



them by the Chair (This includes any documents provided by the researchers in support of their proposals). GCREB members may consult with the Chair at any point in the review process. All GCREB members shall complete, in a timely manner, the TCPS 2 Tutorial Course on Research Ethics (CORE), and shall read the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) and the highlights of changes. All GCREB members shall actively audit the current literature on research, particularly in the area of research ethics and professional standards.

#### 1.2.4 GCREB Meetings and Attendance

- 1.2.4.1 To ensure adequate discussion, the GCREB is required to meet face-to-face to discuss research proposals and for the collective education of the GCREB. Videoconferencing, web-conferencing, teleconferencing or use of other technologies may be used as necessary for meetings when "members are geographically dispersed and there is no other way of holding an effective REB meeting, or when exceptional or exigent circumstances significantly disrupt or limit the feasibility of face-to-face REB meetings." (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 TCPS 2 (2018), Article 6.10). Quorum must be held throughout the meeting, and the Chair shall ensure active participation of members not physically present.
- 1.2.4.2 The meeting schedule shall be determined by the Chair. The GCREB should hold general meetings, retreats and educational workshops to allow members to take advantage of opportunities that improve the functioning of the GCREB.
- 1.2.4.3 Regular attendance by GCREB members is essential to the adequate functioning of the board. Frequent unexplained absences shall be treated as a notice of resignation.

#### 1.2.5 Grounds for Removal

The Chair may terminate any GCREB member's membership at the Chair's discretion if:

- The member fails to uphold any of the membership requirements or responsibilities;
- b) Without making prior arrangements for alternate participation, a GCREB member fails to attend at least seventy-five percent (75%) of the regular meetings of the GCREB in any twelve (12) month period or two (2) consecutive meetings of the GCREB; or



- c) The Member has committed one of the following grounds of misconduct and in consequence would, if such Member were to continue as a Member, adversely affect the image and/or operations of the GCREB:
  - Harassment (including activities that would constitute harassment under College policies);
  - ii. Violence (including activities that would constitute violence under College policies);
  - iii. Conviction of a criminal offence;
  - iv. Conduct unbecoming of a Member; or
  - v. Discrimination as defined under the Ontario *Human Rights Code* (including activities that would constitute discrimination under College policies).

#### 1.3 Ad Hoc Advisors

If the GCREB does not have the required expertise or community representation required for review of a particular project, the GCREB may invite experts to consult with the GCREB for the duration of that review. The ad hoc advisor is not a member of the GCREB and as such is not counted in the quorum or participate in GCREB decisions.

1.4 Research Ethics Review During Publicly Declared Emergencies

GCREB shall conduct ethics reviews during publicly declared emergencies in accordance with the requirements of the TCPS, and shall follow the Network of Networks and Canadian Association of Research Ethics Boards (N2 and CAREB) Standard Operating Procedure (SOP 501.003) for REB Review During Publicly Declared Emergencies.

1.5 Scholarly Review as Part of Ethics Review

The GCREB shall briefly evaluate the merit and the scholarly standards of a research proposal. The GCREB shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research. The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out.

#### 1.6 Review of Multi-centred Research

- 1.6.1 Principles of institutional accountability require the GCREB to be responsible for the ethical acceptability of research undertaken within Georgian College. Therefore, Georgian College requires GCREB review of all research proposals that fall under the scope of this policy, even if the research ethics board of another institution has previously approved them.
- 1.6.2 Multi-centred research that conforms to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), and has been approved



by a REB of another institution that is eligible to apply for and administer research funding from the Canadian Institutes of health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and/or the Social Sciences and Humanities Research Council (SSHRC), may be eligible for delegated GCREB review. It is the responsibility of the Principal Investigator seeking Georgian College research ethics approval to provide documentation confirming that the other approving REB is from a CIHR-, NSERC- or SSHRC-eligible institution.

1.7 Review of Research in Other Jurisdictions or Countries

Research to be performed outside the jurisdiction or country of the institution that employs the Principal Investigator shall undergo prospective ethics review both (a) by the REB within the Principal Investigator's institution; and (b) by the REB, 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.

- 1.8 Proportionate Approach to Ethics Assessment
  - 1.8.1 Georgian College follows a proportionate approach to ethics assessment. This approach is founded upon the principle that the more invasive the research the greater the care in assessing the research. It is Georgian College's practice that all research must be reviewed adequately by the GCREB. Proportionate review refers to the practice that the most ethically challenging research must receive the greatest scrutiny. The most extensive GCREB review is reserved for research that involves potential harm to human participants or is highly invasive from the perspective of human participants. Georgian College recognizes that research can also be of minimal risk to human participants. Given the range of risk associated with research, Georgian College has adopted a proportionate approach to research ethics assessment, allowing for the following levels of ethics review:
    - 1.8.1.1 The default requirement for research requiring ethics approval is full review by the GCREB.
    - 1.8.1.2 The GCREB may delegate research ethics review to an individual or individuals. Delegates shall be selected from among the GCREB membership with the exception of the ethics review of student course-based research. Minimal risk course-based research can be delegated to the department, faculty or equivalent level as indicated below.
    - 1.8.1.3 To ensure accountability, regardless of the review level, the GCREB is responsible for the ethics of all Georgian College research involving human participants. Therefore, all ethics decisions must be reported to the GCREB in a timely manner to ensure that the GCREB is fully informed on all ethics decisions made on its behalf.



#### 1.9 Decision Making

- 1.9.1 Quorum for the GCREB shall be three members and must include the GCREB Chair and a community member. The quorum should also possess "the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration" (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 TCPS 2 (2018), Article 6.9).
- 1.9.2 The GCREB shall endeavour to reach decisions by consensus, and may wish to request external advice and/or representation in person from a researcher prior to decision-making. If a consensus cannot be reached, a decision shall be made by majority vote. Decisions may be to approve an application, request modification, or deny the application. The final decision of the GCREB shall be made in writing and signed by the Chair.
- 1.9.3 GCREB review shall be based upon fully detailed research proposals. The GCREB shall function impartially, provide a fair hearing to those involved and provide reasoned and appropriately documented opinions and decisions. The GCREB shall accommodate reasonable requests from researchers to participate in discussions about their proposals. Researchers may not be present when the GCREB makes decisions. When the GCREB is considering a negative decision, it shall provide the Principal Investigator with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision. Researchers shall be given the opportunity to reapply if there is a negative decision. The GCREB shall work with the Principal Investigator, within reason, to modify the research methodology to ensure that the research complies with the Tri-Council standards.

#### 1.10 Record Keeping

Minutes shall be prepared and maintained by the GCREB for all meetings. Minutes shall clearly document decisions and any dissents, and the reasons for them. In order to assist internal and external audits of research monitoring, and to facilitate reconsideration or appeals, the minutes from meetings must be made available to authorized representatives of Georgian College, researchers considering reconsideration or appeal, and funding agencies. Authorization for access to the minutes shall be provided by the Chair of the GCREB. Correspondence with researchers regarding final GCREB review decisions shall be made initially through email, followed by a formal letter signed by the Chair.

#### 1.11 Reconsideration

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



#### 1.12 Appeals

If the researchers and GCREB cannot reach agreement through discussion and reconsideration, the established Research Ethics Appeal Board (REAB) shall review the decision. The formal Memorandums of Agreement for the REAB are attached in Appendix A.

#### 1.13 Ongoing Research Ethics Review

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

#### **Procedures**

#### 2.1 Membership

- 2.1.1 Appointment of GCREB Members
  - 2.1.1.1 The GCREB issues calls for new members as needed to ensure the required membership criteria are satisfied.
  - 2.1.1.2 Applicants submit the required documentation to the GCREB. To avoid conflict with other duties, Georgian College employees must obtain permission from their manager before applying to become a GCREB member.
  - 2.1.1.3 The Chair reviews the applicants' documents and select members ensuring the needs of the GCREB are met.
  - 2.1.1.4 The Chair submits a list of members annually to the VP, Academic for confirmation.

#### 2.1.2 Removal of GCREB Members

- 2.1.2.1 In the event that a GCREB member's behaviour presents grounds for removal, the Chair and/or the GCREB member shall pursue reasonable means to rectify the situation.
- 2.1.2.2 If the attempt to rectify the situation does not result in a satisfactory solution, the member may be removed at the Chair's discretion, in which case the Chair shall notify the GCREB member in writing of their removal from the GCREB and the reasons for their removal. The Chair shall send a copy of the letter to the VP, Academic and, if the member is a College employee, to their direct supervisor.



#### 2.2 Applications for Research Ethics Approval

- 2.2.1 Prior to applying for research ethics approval, researchers are advised to seek permission for access to the resources they will require for research. Such resources may include access to target populations and/or Georgian College employee support and property beyond the researchers' normal entitlement.
- 2.2.2 To apply for research ethics approval, the Principal Investigator completes the required forms and submits them with all required attachments to the <u>GCREB</u>.
- 2.2.3 Unless otherwise directed by the Chair of the GCREB, each researcher must provide proof that he or she has completed the TCPS 2 Tutorial Course on Research Ethics (CORE).

#### 2.3 GCREB Review

- 2.3.1 The GCREB Chair, or a GCREB member designated by the Chair, reviews each GCREB submission to assess whether the proposed research will pose no greater than minimal risk to research participants.
- 2.3.2 If, in the sole opinion of the GCREB Chair or designate, the research poses no more than minimal risk or has been approved by another REB as described in section 1.6.2 of this policy, and raises no other substantive ethical concerns, the GCREB Chair or designate may refer the proposal to delegated review.
  - 2.3.2.1 If the Chair or designate refers the proposal to delegated review, two GCREB members assess its ethical acceptability and each provide a written assessment to the Chair or designate. The delegated reviewers determine in their assessments whether there are risk factors that constitute greater than minimal risk and evaluate compliance with ethical standards. If either delegated reviewer determines that the risk is greater than minimal risk, the Chair or designate refers the ethics submission to full GCREB review.
  - 2.3.2.2 For proposals that have been determined to meet the minimal risk criterion or have been approved by another REB as described in section 1.6.2 of this policy, and which meet relevant standards of ethical acceptability, the GCREB Chair may approve the project on behalf of the GCREB or may grant approval conditional on certain changes being made to comply with relevant standards of ethical acceptability. The Chair may grant approval once conditions are met.
  - 2.3.2.3 If, the Chair, designate or a delegated reviewer determine that the proposed research poses more than minimal risk or raises substantive ethical concerns, the GCREB Chair or designate will refer the application for full ethics review by GCREB members at a GCREB meeting.
- 2.3.3 At the meeting, members present their individual assessments of the proposal. GCREB discusses concerns and decides whether the proposal is in compliance



- with ethical standards. They may vote to approve an application, request modification, or deny the application.
- 2.3.4 The Chair communicates all GCREB decisions to the Principal Investigator in a timely manner, first via email followed by a final decision signed by the Chair.

#### 2.4 Reporting Requirements

- 2.4.1 The Principal Investigator promptly must report any adverse affects to the GCREB.
- 2.4.2 If the length of the study is to be extended, the Principal Investigator must submit a Renewal Request to GCREB at least two weeks before their ethics approval expires.
- 2.4.3 If any changes will be made to the study protocol, the Principal Investigator must first submit a Change Request to GCREB for approval.
- 2.4.4 When the research is complete or when ethics approval expires, the Principal Investigator must submit a completed Final Report to GCREB.
- 2.5 Review of Student Projects Carried Out Within Formal Course Requirements
  - 2.5.1 Course instructors with current authority from the GCREB to conduct course-based research ethics review may approve their students' research involving humans only if:
    - The objective is to provide students exposure to research methods in their field of study;
    - The research poses no more than minimal risk;
    - The research participants are drawn from the general adult population, capable of giving free and informed consent, and may not include vulnerable participants such as children or persons who are not legally competent to consent;
    - The research does not involve any personal, sensitive or incriminating topics or questions which could place participants at risk;
    - The research does not manipulate behaviour of participants beyond the range of "normal" classroom activity or daily life;
    - The research does not involve physically invasive contact with the research participants;
    - The research does not involve deception; and
    - The research is not part of the faculty member's own research program.

Research that does not fit the description above must be reviewed by the regular procedures for GCREB review.

2.5.2 A Course Instructor seeking permission to review the ethics of their students' minimal-risk course-based research must submit a completed Request for



- Authority to Conduct Course-Based Research Ethics Review to the GCREB for approval.
- 2.5.3 The normal term for approval to review course-based projects is three years. The approval is conditional upon there being no changes to the course curriculum pertaining to the student research projects, and is conditional upon adherence to GCREB reporting requirements.
- 2.5.4 If changes to the course curriculum occur and the changes affect the nature of the student research projects, then the Course Instructor must re-apply for authority to conduct course-based research ethics review.
- 2.5.5 New requests must be re-submitted to the GCREB after three years.
- 2.5.6 While the Course Instructor as the Principal Investigator for student research projects is responsible for the conduct of the student researchers, the GCREB is ultimately responsible for the ethics of all research involving human participants at Georgian College.
- 2.5.7 Reporting Requirements for Course-based Research
  - 2.5.7.1 Each term there is course-based research in a course for which the instructor has authority to review course-based research ethics, the Course Instructor:
    - 2.5.7.1.1 Ensures that all students conducting the research complete the TCPS 2 Tutorial Course on Research Ethics (CORE), and that they read the latest edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) and the highlights of changes.
    - 2.5.7.1.2 Ensures students have obtained all necessary permissions for access to resources for their research, whether the research site is Georgian College or another location.
    - 2.5.7.1.3 Ensures Georgian College students planning to complete research at other institutions or agencies (such as schools, hospitals, government agencies, etc.) are aware that the research may require ethics review from both GCREB and the REB of the other institution.
    - 2.5.7.1.4 Has his or her students complete a Georgian College Application for Research Ethics Approval for each research project being undertaken by the students for the course.
    - 2.5.7.1.5 Reviews each application to determine if it qualifies for course-based approval or if it requires GCREB review. If in doubt, the instructor will refer the application to the GCREB for review.
    - 2.5.7.1.6 Ensures that proposals are complete and in compliance with all applicable ethics review requirements.



- 2.5.7.1.7 Submits all the completed ethics applications for the course, including all attachments, to the GCREB with a completed Summary of Course-based Research which lists all the research projects to be conducted by their students and identifies which studies require GCREB review. The list of projects and completed Applications for Research Ethics Approval must be submitted to the GCREB prior to the commencement of the research.
- 2.5.7.1.8 At the end of the research project or within two weeks of submitting final grades, the Course Instructor submits a completed Georgian College Research Ethics Board Final Report Form for each separate research project being undertaken by the students to the GCREB, with a completed Summary of Course-based Research which identifies any changes made to the protocols and any problems that were encountered as part of the research.
- 2.5.8 Failure to comply with these requirements will result in revocation of the Course Instructor's authority to conduct course-based research ethics review.

#### **Related Materials**

- Appendix A: Memorandums of Agreement for the Research Ethics Appeal Boards (REAB)
- Government of Canada Panel on Research Ethics website
- Network of Networks and Canadian Association of Research Ethics Boards (N2 and CAREB) Standard Operating Procedure (SOP 501.003) for REB Review During Publicly Declared Emergencies
- Georgian College Policies:
  - AD-016: Access to Georgian College Resources for Research
  - 1-130 Intellectual Property
  - AD-015 Research Integrity Policy
  - 4-126 Conflict of Interest Policy
- Forms available on the Georgian College Research Ethics Board website:
  - Georgian College Research Ethics Board Application for Research Ethics Approval
  - Georgian College Research Ethics Board Change Request
  - Georgian College Research Ethics Board Renewal Request
  - Georgian College Research Ethics Board Request for Authority to Conduct Course-Based Research Ethics Review
  - Georgian College Research Ethics Board Final Report Form
  - Georgian College Research Ethics Board Summary of Course-based Research



#### **RECORD OF PREVIOUS VERSIONS OF THIS POLICY**

**Responsible Practice and Ethics Review in Research** 

**Administration** 

**Procedure #: 2-119** 

**Prepared By:** Sylvia Barnard, Michele Beaudoin, Marie-Noelle Bonicalzi, Harvey

Briggs, Cathy Brown, Jim Bryson, Dave Duncan, Bob Emptage, Chris Frank, Bill Gordon, Gail Higginson, Rob Howard, Sue Jackson, Hal Jorch, Marie Knapp, Karen McPhatter, Barbara Marshall, Kevin McCormick, Greg Murphy, Kathryn Peet, Tony Podziemski, Janice Mawhiney-Priest, Jean Reid, Helen Sheridan, Cassandra Thompson, Judith Skuce, Heather

White, Michael Wolfe, Robert Wong

1<sup>st</sup> Revision By: Cherylyn Cameron, Bob Emptage, Elizabeth Erwin, Maryann Fifield,

Jean Reid, Richard Rinaldo, Cynthia Hare

**2<sup>nd</sup> Revision By:** Cherylyn Cameron

3<sup>rd</sup> Revision By: Richard Rinaldo, Louise Alphonse, Chantal Arpin-Cribbie, Chris Berni,

Elizabeth Erwin, Ron McDonald, Greg McGregor, Nancy Noldy-

MacLean, Kathryn Peet, William Harvey

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Date

**Approved By:** Brian Tamblyn June 8, 2012

College President Date

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**Revised:** 06.08.12

#### AD-014 Responsible Practice and Ethics Review in Research

Version	Version Date (MM/DD/YYYY)	Review Date (MM/DD/YYYY)	Description of Changes
04	05/01/2020	05/07/2022	Old policy 2-119 updated to clarify language and procedures, and bring policy in line with TCPS2 (2018).



## **Appendix A**

Memorandum of Agreement for the Research Ethics Appeal Board (REAB)





## MEMORANDUM OF AGREEMENT

#### BETWEEN

#### NIAGARA COLLEGE AND GEORGIAN COLLEGE

This memorandum of agreement constitutes the understanding of Georgian College and Niagara College to continue to have their individual college Research Ethics Boards (REB) act in the role of Research Ethics Appeal Boards (REAB) to the other institution, in the event of an appeal of a decision of the REB.

Whereas a researcher may desire to appeal a college Research Ethics Board (REB) decision,

and

Whereas the researcher is permitted to do so in accordance with each college's appeal process, and

Whereas such an appeal needs be addressed by a Research Ethics Appeal Board (REAB),

This agreement between Niagara College and Georgian College confirms that:

 A Niagara College Research Ethics Board decision may be appealed and reviewed by the Georgian College Research Ethics Board;

and likewise ...

 A Georgian College Research Ethics Board decision may be appealed and reviewed by the Niagara College Research Ethics Board.

Researchers have the right to appeal their REB's review decision in accordance with their respective college's appeal process. Such appeals may only be initiated by the research applicant, made in writing and must follow the procedures outlined in Georgian College's procedures on Responsible Practice and Ethics Review in Research and Niagara College's practice on Research Involving Human Participants.

Georgian College and Niagara College are each responsible for maintaining their own Research Ethics Board (REB) in accordance with the TCPS. Each institution's REB is responsible for ensuring that the rights of human subjects participating in research are respected and that such research is conducted ethically. The Chair of the REB is responsible for calling and chairing regular meetings of the REB and other meetings as required.

Each institution is also responsible for establishing a Research Ethics Appeal Board to hear any appeals arising from negative decisions of its Research Ethics Board. Members of the institution's REAB cannot also be members of the REB. Therefore, in order to comply with the requirement that REBs and REABs be independent of each other within an institution and not share membership, Georgian College and Niagara College agree to permit their individual REBs to act as the REAB for the other institution. No member of the REB at Georgian College can be a member of the REB at Niagara College and vice versa.

In the event that an appeal review is requested by a research applicant of one of the institutions, Georgian College and Niagara College agree to the following:

The research applicant will be instructed on the review procedure and the contact information for the Chair of the REAB.

The research applicant will submit all required materials (the original proposal, the letter of rejection from the REB, and a letter requesting the review and citing the grounds for appeal) in writing to the Chair of the REAB within the allotted time of ten (10) working days. The Chair of that REAB will notify the Chair of the researcher college's REB that it has received an appeal request from the research applicant. The Chair of the other institution's REB then notifies the REB members that they must now act as the REAB for the research applicant requesting an appeal. The REAB will ensure the appeal review is conducted as follows:

- 1. The REB, now operating as a REAB, will communicate through its Chair with the applicant requesting the appeal.
- 2. In considering an appeal, the REAB will deliberate on the expressed grounds for appeal in accordance to the ethical principles and standards outlined in the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018 and future revisions (TCPS).
- 3. The REAB will make every attempt to reach consensus in its decision making.
- 4. All decisions must be made in writing with reasons for the decision and communicated within 30 days to the research applicant by the Chair of the REAB and copied to the Chair of the REB of other institution. All files involving the REAB will be

maintained by the Offices of Research by both institutions. The decision of the REAB is final.

This Memorandum Agreement (MOA) shall be effective as of the date of the last signature below. It will remain in effect for ten (10) years and shall be renewable at the end of that period. This agreement may, however, be terminated earlier by either institution if the agreement proves not to be mutually beneficial. A copy of the fully executed MOA will be kept on file at the Research Ethics Board offices of both institutions.

Signed in agreement:

Andrea Bodnar & Tatiana Young

Co-Chairs, Niagara College Research Ethics

Board

Dr. Eleanor Gittens

Chair, Georgian College Research Ethics

**Board** 

Dr. Marc Nantel

Vice-President, Research, Innovation &

-Strategic Initiatives, Niagara-on-the-Lake

Niagara College

Kevin Weaver

Vice President, Academic

Georgian College