RESPONSIBLE PRACTICE AND ETHICS REVIEW IN RESEARCH

PURPOSE: To establish clear and defined procedures for those wishing to undertake research at Georgian College involving human participants, ensuring 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).

SCOPE: 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 integrity is a commitment to intellectual honesty and personal responsibility for one’s actions. Researchers must follow research practices that characterize the responsible and ethical conduct of research. As an institution accountable to the public, Georgian College fosters an environment that promotes integrity in the conduct of research. The College is guided by its Research Integrity Procedure.

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.

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.
PROCEDURE:

1. STANDARDS AND PROCEDURES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS (Tri-Council Policy Statement):

All Georgian College standards and procedures for research involving human participants shall be in accordance with the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC) (referred to as the “Tri-Council”) policy statement for the ethical conduct of research involving human participants, human remains, cadavers, tissues, biological fluids, embryos or fetuses. (Link to Ethical Conduct for Research Involving Humans.)

2. RESEARCH ACTIVITIES REQUIRING RESEARCH ETHICS BOARD (REB) REVIEW AND APPROVAL:

All research that involves living human participants, human remains, cadavers, tissues, biological fluids, embryos or fetuses requires review and approval by Georgian College’s Research Ethics Board (REB) in accordance with this policy statement, before data collection begins, and as stipulated below. Exemptions from the REB review are outlined in Section 3.

- Research involving human participants recruited from Georgian College
- The use of the College's name in a contract bid or proposal to an outside private or public organization
- College sponsorship of research through professor classroom release time, sabbatical (study leave), or direct funding
- Researchers accessing College facilities, resources, College employees, machines, and other College services or resources, and where the College administers a grant from an outside agency or individual (private or government)
- Data formally collected, through whatever means or methods, from College students, faculty, administration, support staff, or other members of the College community, or from any database containing information about the aforementioned groups
- Research involving human participants planned by Georgian College and Georgian College University Partnership Centre students requires REB review and approval when:
  - The intent of the research is to educate students on research processes used to explore and expand existing theories and conceptual knowledge;
  - Students compare new techniques, practices, programs with standard approaches to determine which is more effective;
  - The results or findings are written in a format that would be acceptable for a research journal or academic conference presentation; or
  - Primary data are collected and organized for analysis and distribution or dissemination.

Researchers requiring REB approval shall complete Georgian College’s Application for Research Approval form and submit the completed form to the Chair of the REB.

3. RESEARCH ACTIVITIES EXEMPT FROM RESEARCH ETHICS BOARD (REB) REVIEW AND APPROVAL:

Research involving human participants exempted from REB review and approval includes:
• Research about a living individual involved in the public area or about an artist, based exclusively on publicly available information
• Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, including:
• Academic departmental administrative research projects approved by the Dean or Director of the department; for example, class data related to marks or attrition;
• 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 College Ontario studies; or
• Primary data collection (such as surveys or focus groups) designed and administered by Organizational Planning and Development for review and renewal of programmes and college 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);
  • 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); or
  • Teach about the design, conduct and process of research and might involve ‘practice’ data collection from or about a few students within their class and the research is considered minimal risk.

4.0 RESEARCH ETHICS BOARD (REB) STRUCTURE

4.1 Purpose

The Research Ethics Board (REB) serves to review the ethical acceptability of all research involving humans conducted within Georgian College’s jurisdiction or under Georgian College’s auspices, that is, by Georgian College faculty, staff or students, regardless of where the research is conducted, in accordance with the Tri-Council Policy Statement.

4.2 Membership

The criteria for REB membership are founded upon the principle that competent research ethics review requires ethics expertise, a multidisciplinary perspective, and REB independence. Guided by these criteria, the Georgian College REB must consist of at least 5 members; including:

• Both men and women
• at least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB
• At least one member who is knowledgeable in ethics
• At least one community member who has no affiliation with the institution
• At least one member is knowledgeable in the relevant law (but that member should not be the institution’s legal counsel or risk manager)
• To ensure the independence of REB decision making, institutional senior administrators shall not serve on the REB.

Individuals with expertise in areas pertaining to research ethics review may be invited by the REB to serve as a member of the committee. The tenure of an expert’s membership on the REB shall be determined by the Chair of the REB.

4.3 Selection of the Chair and membership committee structure

The Chair will be appointed by the Vice President, Academic. The Chair will 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.

Members of the REB will be appointed by the Vice President, Academic and Chair of the REB. Criteria for member selection 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
• Demonstrated commitment to fostering ethical research practices at Georgian College

Members will be requested to assume a two-year term that is renewable for a maximum of four consecutive years. Departing members will be replaced at the end of their terms, ensuring the representation stated above. This process may be repeated for a former voting member following a one-year break from the committee. The committee will discuss staggered renewal of membership to ensure consistency.

REB 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 applicant in support of his or her proposal). REB members may consult with the Chair at any point in the review process. All REB members shall complete, in a timely manner, the TCPS 2 Tutorial Course on Research Ethics (CORE).

The functions of the Chair are to:

• The REB Chair is responsible for ensuring that the REB review process conforms to the
requirements of this Policy.
- Ensure that ethics reviews are both thorough and prompt
- Maintain the review roster
- Advise REB members on any matters that arise from their review of a proposal
- Use consultative and participative decision making practices
- Encourage ethical research practices

The Chair is expected to actively educate the REB members concerning matters of research ethics as needed. All REB members should actively audit the current literature on research, particularly in the area of research ethics and professional standards. The Chair will organize an orientation seminar for the incoming members of the REB and conduct one educational seminar during his or her term. The procedures and guidelines will be explained, as well as some general instruction on the nature of research ethics and professional standards.

4.4 Proportionate Approach to Ethics Assessment

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 REB (unless they fall under exemptions in Section 3). Proportionate review refers to the practice that the most ethically challenging research must receive the greatest scrutiny. The most extensive REB 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. Full REB Review

2. The REB may delegate research ethics review to an individual or individuals. Delegates shall be selected from among the REB membership with the exception of the ethics review of student course-based research. This can be delegated to the department, faculty or equivalent level as indicated below.

To ensure accountability, regardless of the review level, the REB is responsible for the ethics of all Georgian College research involving human participants. Therefore, all ethics decisions must be reported to the REB, in a timely manner, to ensure that the REB is fully informed on all ethics decisions made on its behalf. The default requirement for research requiring ethics approval is full review by the REB.

4.5 Minimal Risk

The standard for minimal risk is defined as the following: If potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research, then the research can be regarded as within the range of minimal risk. In addition, there is a threshold for undue or excessive offers of benefit. More specifically, an offer of payment in relation to research participation exceeds the normal range of benefits open to the research.
participant; it is increasingly likely to amount to an undue incentive for participation.

Research that may have a negative effect on public figures in politics, business, labour, the arts, or other walks of life, or on organizations should not be blocked through the use of harms-benefits analysis. Those in the public arena can address research that presents them in a negative manner through public debate or through court action for libel.

4.6 Scholarly Review as Part of Ethics Review

The REB will briefly evaluate the merit and the scholarly standards of a research proposal. 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. 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. Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed.

4.7 Full REB Review

4.7.1 Meetings and attendance

The REB is required to meet face-to-face to discuss research proposals and for the collective education of the REB. The schedule will be determined by the Chair. The REB should hold general meetings, retreats and educational workshops to allow members to take advantage of opportunities that improve the functioning of the REB. Regular attendance by REB members is essential to the adequate functioning of the board. Frequent unexplained absences will be treated as a notice of resignation. REB members are required to serve on the board for a minimum of two years.

4.7.2 Record Keeping

Minutes shall be prepared and maintained by the REB for all meetings. Minutes will 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 REB. Correspondence to applicants related to a proposal will be made initially through e-mail, followed by a hard copy.

4.7.3 Decision Making

To apply for a research ethics review, the applicant will complete the required forms and submit them to the Chair of the committee. Under most circumstances applications will be reviewed within 30 days from receipt of application.

Unless otherwise directed by the Chair of the REB, each applicant shall provide proof that he or she has completed the TCPS 2 Tutorial Course on Research Ethics (CORE).
Quorum for the REB shall be three members and must include the REB Chair and a community member. The quorum should also possess experience in research, and knowledgeable in ethics, and knowledgeable in law if the application includes biomedical research.

The committee will 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 will be made by majority vote. The decision of the REB will be made in writing and signed by the Chair. Decisions may be to approve an application, request modification, or deny the application.

REB review shall be based upon fully detailed research proposals. 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 researchers to participate in discussions about their proposals. Researchers may not be present when the REB makes decisions. When the 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. Researchers will be given the opportunity to reapply if there is a negative decision. The committee will work with the applicant, within reason, to modify the research methodology to ensure that the research is in compliance with the Tri-Council standards.

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 REB 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 REB may refer these concerns to the Vice-President, Academic or designate at the VP level.

If the length of research is to be extended, the researcher must request an extension in writing to the Chair. For ongoing research see 4.7.6

A conflict of interest may arise when activities or situations place an individual or institution in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. These interests include, but are not limited to, business, commercial or financial interests pertaining to the institution and/or the individual, their family members, friends, or their former, current or prospective professional associates. The REB shall refer to and be guided by Georgian College’s Research Integrity Procedure regarding conflicts of interest.

4.7.4 Reconsideration

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

4.7.5 Appeals

If the researchers and REB cannot reach agreement through discussion and reconsideration,
the REB from Niagara College will review the decision. The formal Memorandum of Understanding is attached in Appendix A.

4.7.6 Review procedures for ongoing research

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 REB review, the researcher shall propose to the REB 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 REB. The REB shall be promptly notified when the project concludes.

4.7.7 Review of Multi-centred Research

Principles of institutional accountability require the College’s REB to be responsible for the ethical acceptability of research undertaken within Georgian College. Therefore, Georgian College requires all research proposals reviewed by the REB of another institution to also be reviewed by the College’s REB.

4.7.8 Review of Research in Other Jurisdictions or Countries

Research to be performed outside the jurisdiction or country of the institution that employs the researcher shall undergo prospective ethics review both (a) by the REB within the researcher’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.

4.8 Delegated REB review

The REB Chair, or a REB committee member designated by the Chair, will review each REB submission to assess whether the proposed research will pose no greater than minimal risk to research participants. If, in the sole opinion of the REB Chair or designate, the research poses no more than minimal risk and raises no other substantive ethical concerns, the REB Chair or designate may refer the proposal to delegated REB review.

Multi-centred research that has been approved by a REB of another institution and that conforms to the Tri-Council Policy Statement for the conduct for research involving humans is eligible for delegated REB review. It is the responsibility of the researcher seeking Georgian College ethics approval to provide documentation confirming that the other approving REB abides by the Tri-Council policy.

If, on the basis of the initial review, it is determined that the ethics submission may be of minimal risk, its ethical acceptability will be assessed by two REB members who will each provide a written assessment. The REB members will determine whether there are additional risk factors that constitute greater than minimal risk and evaluate compliance with ethical standards. If both REB members determine that the risk is greater than minimal risk, the ethics submission will be referred to the full REB review. If the two REB members disagree, and if such disagreement cannot be resolved through discussion between the two REB members and the REB Chair, the Ethics submission will be referred to the full REB review. Findings must be reported.
back to the full REB at the next meeting for their information as the REB remains responsible for the ethics of all research involving human participants at Georgian College.

For submissions which have been determined to meet the minimal risk criterion and which meet relevant standards of ethical acceptability, the REB Chair may approve the project on behalf of the REB or may grant approval conditional on certain changes being made to comply with relevant standards of ethical acceptability. Approval may then be granted once conditions are met.

All decisions will be corresponded to the applicant in a timely manner.

4.9 Course Instructor level review of student projects carried out within formal course requirements

As per Section 3 of this document, the following student activities are exempt from REB ethics review. 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);
- 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); or
- Teach about the design, conduct and process of research and might involve ‘practice’ data collection from or about a few students within their class and the research is considered minimal risk.

For student activities that do not fall within the criteria provided above the course instructor, upon approval by the REB, may oversee the conduct of his or her individual students’ research if the research projects:

- Objective is to provide students exposure to research methods in their field of study
- Pose 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 and persons who are not legally competent to consent
- Does not involve any personal, sensitive or incriminating topics or questions which could place participants at risk
- Does not manipulate behaviour of participants beyond the range of “normal” classroom activity or daily life
- Does not involve physically invasive contact with the research participants
- Does not involve deception
- Is not part of the faculty member’s own research program. Such research should be reviewed by the regular institutional REB procedures.
A Course Instructor seeking permission to oversee the conduct of his or her individual students’ research must complete Georgian College’s “Request for Ethical Approval of Course-Based Student Research Projects” form and submit the completed form to the full REB for approval. Course instructor REB approval to oversee course-based projects shall be maintained for three years. The approval is conditional upon there being no changes to the course curriculum pertaining to the student research projects. If changes to the course curriculum occur and the changes affect the nature of the student research projects, then the course instructor shall re-apply for approval to oversee student research projects. New course applications must be re-submitted to the REB after three years. The REB is ultimately responsible for the ethics of all research involving human participants at Georgian College.

The Course Instructor shall have his or her students complete a “Student Application to Involve Human Participants in Research” form for each separate research project being undertaken in the class. The Course Instructor will review and approve each application, ensuring that proposals are complete and in compliance with all applicable ethics review requirements. Once a decision has been made the original form for each project is to be maintained by the instructor for three years. Each course instructor will submit to the REB a list of research project proposals along with a brief description of each proposal for all research to be conducted by their students under the course instructor permission agreement. The list of proposals shall be submitted to the REB prior to the commencement of the research. At the end of the course the course instructor shall submit to the REB Chair a list of completed research projects along with a brief summary of each research project. Course Instructors shall ensure that all students completing research complete the TCPS 2 Tutorial Course on Research Ethics (CORE).

If a student research project does not meet the requirements for course instructor level delegated review, the course instructor shall refer the proposal to the Research Ethics Board for review. Failure to comply with this requirement shall result in revocation of the REB’s delegation of ethics review responsibilities to the course instructor.

Georgian College students planning to complete research at other institutions or agencies (such as schools, hospitals, government agencies, etc.) shall be made aware that the research may require full REB review and that permission to access premises or to obtain private information from another institution may be required and must be obtained if required by the other institution.

GUIDELINES:

Note: The guidelines presented in this section were chosen from the Tri-Council policy statement for the ethical conduct of research involving human participants. For further information regarding the guidelines please refer to the Tri-Council statement website (Tri-Council Policy Statement).

5.0 RESEARCH ETHICS – FREE AND INFORMED CONSENT

Prospective participants, or authorized third parties, must be given the opportunity to give free and informed consent about participation in a research study, and once their free and informed consent has been given it is maintained throughout their participation in the research. In considering the voluntariness of consent, researchers should be cognizant of situations where undue influence, coercion or the offer of incentives may undermine the voluntariness of a participant’s consent to participate in research.
Evidence of free and informed consent by the participant or authorized third party should ordinarily be obtained in writing. Where written consent is culturally unacceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.

The REB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB is satisfied, and documents that all of the following apply:

- the research involves no more than minimal risk to the participants;
- the lack of the participant’s consent is unlikely to adversely affect the welfare of the participant;
- it is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required;
- whenever possible and appropriate, after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information in accordance with Articles 3.2 and 3.4, at which point they will have the opportunity to refuse consent in accordance with Article 3.1; and
- the research does not involve a therapeutic intervention, or other clinical or diagnostic interventions.

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

5.1 Voluntariness

The element of voluntariness has important implications. Consent must be freely given and may be withdrawn at any time. Undue influence may take the form of inducement, deprivation or the exercise of control, or authority over prospective participants.

Voluntariness is especially relevant in research involving restricted or dependent participants, and is absent if consent is secured by the order of authorities or as a result of coercion or manipulation. The influence of power relationships on voluntary choice should be judged according to the particular context of prospective participants. For example, the voluntariness of prisoners, members of organizations with authoritarian structures (such as the military, police, some religious groups or street gangs), or of employees or students may be restricted because their institutional context implies undue pressure. Care should be exercised in developing relationships between researchers and authorities, so as not to compromise either the free and informed consent or the privacy and confidentiality of participants.

Conversely, situations may arise in which an organization, such as a corporation, a government, a political party or a criminal organization that may have been approached about a research project, may wish to prevent the research; however, individuals over whom the organization has some authority may be willing to participate. Researchers and REBs should not prevent such research, but should ensure that potential participants are fully informed of the views of the organization's authorities and the possible consequences of participation, and pay special attention to confidentiality.
REBs should also pay particular attention to the elements of trust and dependency, for example, within doctor-patient or professor-student relationships, as these can constitute undue influence on the patient to participate in research projects, especially those involving residents in long-term care facilities or psychiatric institutions.

Researchers should avoid being put in a position of becoming informants for authorities or leaders of organizations. The offer of benefits in some contexts may amount to undue inducement, and thus negate the voluntary aspect of the consent of participants who may perceive such offers as a way to gain favour or improve their situation.

5.2 Naturalistic Observation

REB review is normally required for research involving naturalistic observation. Observational research is of two kinds: “non-participant” where the researcher observes, but is not a participant in, the action (also known as “naturalistic observation”); and “participant” where the researcher engages in, and observes, the action. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility.

A matter that is publicly accessible may, nevertheless, be considered private in a prospective participant’s culture. There may be a reasonable expectation of privacy by some groups, or for some activities. For example, individuals involved in religious services or practices, or chat rooms on the Internet, may assume that participants and observers will accord the proceedings some degree of privacy. Observing sacred ceremonies without approval from the appropriate individuals or groups (e.g., Elders or traditional knowledge holders in Aboriginal research) and without engaging them about the subsequent use or interpretation of the data may have unintended negative implications (see Articles 9.5, 9.6 and 9.8). Considerations of the nature of the research, its aims and its potential to invade sensitive interests may help researchers improve the design and conduct of such research.

Observational studies in public places where there is no expectation of privacy are exempt from REB review.

In research involving observation in natural environments or virtual settings where people have a reasonable or limited expectation of privacy, the researcher shall explain the need for an exception to the general requirement for consent. The REB may approve research without requiring that the researcher obtain consent from individuals being observed on the basis of the justification provided by the researcher and appropriate privacy protection.

5.3 Informing Potential Participants

Researchers shall provide, to prospective participants or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the free and informed consent process, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the free and informed consent process, researchers or their qualified designated representatives shall provide prospective participants with the following:

- Information that the individual is being invited to participate in a research project;
• A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;
• A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;
• An assurance that prospective participants are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate, and;
• The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

Under the normal process of obtaining written consent, the prospective participant should be given a copy of the consent form and any relevant written information. The consent of the participants shall not be conditional upon, or include any statement to the effect that, by consenting, participants waive any legal rights.

Research participants, whether inside or outside Canada, may have cultural values different from those of the researcher. Researchers must clearly explain the nature and goals of the research and other essential information, in a manner appropriate for the prospective participants' cultural settings. With some cross-cultural research projects, it may not be possible to offer an adequate translation of the researcher's understanding to prospective participants. REBs should proceed cautiously in such cases and require stringent protection for the interests of participants, such as appointing an individual to act in an independent advocacy role. On the other hand, REBs should not assume an unnecessarily protective role which suggests that those who do not share the culture of the researchers, particularly those in foreign countries, are incapable of making rational decisions in their own interest.

In some types of research, and for some groups or individuals, written signed consent may be perceived as an attempt to legalize or formalize the consent process and therefore may be interpreted by the participant as a lack of trust on the part of the researcher. In these cases, oral consent, a verbal agreement or a handshake may be required, rather than signing a consent form. In some cultures, the giving and receiving of gifts symbolizes the establishment of a relationship comparable to consent.

Where consent is not documented in a signed consent form, researchers may use a range of consent procedures, including oral consent, field notes and other strategies, for documenting the consent process. Consent may also be demonstrated solely by the actions of the participant (e.g., through the return of a completed questionnaire). Where there are valid reasons for not recording consent in writing, the procedures used to seek consent must be documented (see Article 10.2).

5.4 Capacity

Capacity refers to the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate. This ability may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the point in time at which consent is sought. The
determination of capacity to participate in research, then, is not a static determination. It is a process that may change over time, depending on the particular point in time, whether a participant (or prospective participant) sufficiently understands the nature of a particular research project, and the risks, consequences and potential benefits associated with it.

For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:

- the researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;
- the researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;
- the authorized third party is not the researcher or any other member of the research team;
- the researcher demonstrates that the research is being carried out for the participant’s direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant’s welfare will be protected throughout the participation in research; and
- when authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant’s consent as a condition of continuing participation.

Where free and informed consent has been obtained from an authorized third party and in those circumstances where the individual is legally defined to lack capacity, understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential participant’s dissent will preclude his or her participation.

5.5 Research in Emergency Health Situations

The conduct of research in emergency health situations must follow details outlined in that TCPS Article 3.8 found at TCPS-2 Chapter 3

6.0 RESEARCH ETHICS – PRIVACY AND CONFIDENTIALITY

6.1 Accessing Private Information Surveys, Questionnaires and the Collection of Data

Researchers shall secure REB approval for obtaining identifiable personal information about participants. Approval for such research shall include such considerations as:

- The type of data to be collected;
- The purpose for which the data will be used;
- Limits on the use, disclosure and retention of the data;
- Appropriate safeguards for security and confidentiality;
• Any modes of observation (e.g., photographs or videos) or access to information (e.g., sound recordings) in the research that allow identification of particular participants;
• Any anticipated secondary uses of identifiable data from the research;
• Any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records; and
• Provisions for confidentiality of data resulting from the research.

6.2 Secondary Use of Data

Secondary use refers to the use in research of information originally collected for a purpose other than the current research purpose. Common examples are social science or health survey datasets that are collected for specific research or statistical purposes, but then re-used to answer other research questions. Information initially collected for program evaluation may be useful for subsequent research. Other examples include health care records, school records, biological specimens, vital statistics registries or unemployment records, all of which are originally created or collected for therapeutic, educational or administrative purposes, but which may be sought later for use in research. Chapter 5 of the TCPS-2 provides further guidance on research involving secondary use of previously collected biological materials. If identifying information is involved, REB approval shall be sought for secondary uses of data. Researchers may gain access to identifying information if they have demonstrated to the satisfaction of the REB that:

• Identifying information is essential to the research;
• They will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to participants; and
• Individuals to whom the data refer have not objected to secondary use.

Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:

• identifiable information is essential to the research;
• the use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
• the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
• the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
• it is impossible or impracticable to seek consent from individuals to whom the information relates; and
• the researchers have obtained any other necessary permission for secondary use of information for research purposes.

If a researcher satisfies all the conditions in Article 5.5(a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates.

6.3 Data Linkage

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

Advances in our abilities to link databases create both new research opportunities and new threats to privacy. These techniques may provide avenues for addressing previously unanswerable questions and for generating better social and health-related information. The values underlying the ethical obligation to respect privacy oblige researchers and REBs to exercise caution in the creation and use of data of this kind. REBs should also be aware of relevant statutory frameworks, and the criteria required by government for authorization of use of data in governmental data banks.

Researchers who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information as discussed in Article 2.2. The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage. Where data linkage involves, or is likely to produce identifiable information, researchers shall satisfy the REB that:

- the data linkage is essential to the research; and
- appropriate security measures will be implemented to safeguard information.

7.0 RESEARCH ETHICS – CONFLICT OF INTEREST

7.1 Conflicts of Interest Involving Researchers

A conflict of interest may arise when activities or situations place an individual or institution in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. These interests include, but are not limited to, business, commercial or financial interests pertaining to the institution and/or the individual, their family members, friends, or their former, current or prospective professional associates.

The REB shall refer to and be guided by Georgian College’s Research Integrity Procedure regarding conflicts of interest.

The REB should assess the likelihood that the researcher's judgment may be influenced, or appear to be influenced, by private or personal interests, and assess the seriousness of any harm that is likely to result from such influence or from the mere appearance of undue influence. Competing interests may arise from family relationships, financial partnerships or other economic interests.

The appearance of a conflict may in some cases be as damaging as a real conflict. Two approaches can be suggested for assessing the potential implications of apparent or real conflicts of interest. One might ask whether an outside observer would question the ability of the individual to make a proper decision despite possible considerations of private or personal interests; alternatively, one might ask whether the public would believe that the trust relationship between the relevant parties could reasonably be maintained if they had accurate information on the potential sources of conflict of interest.

When a significant real or apparent conflict of interest is brought to its attention, the REB should require the researcher to disclose this conflict to the prospective participants during the free and informed consent process.
7.2 Conflicts of Interest by REB Members

To maintain the independence and integrity of ethics review, it is of the highest importance that members of the REB avoid real or apparent conflicts of interest. For example, REB members are in a clear conflict of interest when their own research projects are under review by their REB or when they have been in direct academic conflict or collaboration with the researcher whose proposal is under review. To manage such conflicts, REB members must withdraw from the committee when such projects are under consideration.

7.3 Institutional Conflicts of Interest

The REB must act independently from the parent organization. Therefore, institutions must respect the autonomy of the REB and ensure that the REB has the appropriate financial and administrative independence to fulfill its primary duties. Situations may arise where the parent organization has a strong interest in seeing a project approved before all ethical questions are resolved. As the body mandated to maintain high ethical standards, however, the public trust and integrity of the research process require that the REB maintain an arms-length relationship with the parent organization and avoid and manage real or apparent conflicts of interest.

8.0 RESEARCH INVOLVING ABORIGINAL PEOPLES

For a fuller discussion and resources please visit TCPS-2 Chapter 9 (RESEARCH INVOLVING THE FIRST NATIONS, INUIT AND MÉTIS PEOPLES OF CANADA)

8.1 Requirement of Community Engagement in Aboriginal Research

Where the research is likely to affect the welfare of an Aboriginal community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community. The conditions under which engagement is required include, but are not limited to:

- research conducted on First Nations, Inuit or Métis lands;
- recruitment criteria that include Aboriginal identity as a factor for the entire study or for a subgroup in the study;
- research that seeks input from participants regarding a community’s cultural heritage, artifacts, traditional knowledge or unique characteristics;
- research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data; and
- interpretation of research results that will refer to Aboriginal communities, peoples, language, history or culture.

8.2 Nature and Extent of Community Engagement

The nature and extent of community engagement in a project shall be determined jointly by the researcher and the relevant community, and shall be appropriate to community characteristics and the nature of the
Responsible Practice and Ethics Review in Research

Administration

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