Brandon University Research Ethics Committee (BUREC) Procedures

1.0 INTRODUCTION

The *Brandon University Research Ethics Committee (BUREC) Procedures* were created under the guidance of the *Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2)* and the *Brandon University Policy on Research Involving Humans*. Faculty, staff, and students who intend on using human participants in their research should read all policies and procedures before proceeding with an ethics submission. All documents and forms required in the ethics review process are available on the BUREC website.

Given the breadth of research topics and methods reviewed, the *BUREC Procedures* cannot cover all possible circumstances or ethical issues that may arise. Circumstances may occur in which a principle or standard of conduct implied in these materials does not apply or should be applied differently from what is implied or stated. The procedures reflected in this document apply to common research situations. It is the responsibility of the Principal Investigator (PI) to verify with BUREC whether ethics certification is required prior to the commencement of a research project. Failure to obtain the necessary ethics certification for a research project involving human participatory research is a violation of academic integrity and the Tri-Agency Framework: Responsible Conduct of Research. BUREC makes the final determination on exemption from research ethics review.

NOTE: As of April 1, 2026, health-based research project reviews fall under Research Manitoba's Research Improvements Through Harmonization in Manitoba (RITHIM) initiative and are required to go through the Committee for Harmonized Health Impact, Privacy, and Ethics Review (CHIPER) for review and approval. From the Research Manitoba website: *RITHIM is a provincial initiative involving multiple stakeholders with a goal to build a best-in-class provincial program for health research in Manitoba. RITHIM is unique across Canada in that it will harmonize ethics, privacy and health institutional assessment review processes, creating a more efficient process for health research reviews in Manitoba.*

2.0 HUMAN PARTICIPATORY RESEARCH AND THE NEED FOR ETHICS REVIEW

The purpose of ethics review for research involving human participants is to foster and ensure research practices that respect and protect the rights and dignity of participants, promote the integrity of researchers, and uphold the principle of academic freedom. The TCPS2 is based on three core principles (TCPS2 1.1):

1. Respect for Persons: Respect for Persons recognizes the intrinsic value of human beings and the respect and consideration that they are due. It encompasses the treatment of persons involved in research directly as participants and those who are participants because their data or human biological materials are used in research. Respect for Persons incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy. An important mechanism for respecting participants' autonomy in research is the

requirement to seek their free, informed, and ongoing consent.

2. Concern for Welfare: The welfare of a person is the quality of that person's experience of life in all its aspects. Welfare consists of the impact on individuals of factors such as their physical, mental and spiritual health, as well as their physical, economic and social circumstances.
3. Justice: Justice refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it.

Human participatory research conducted under the auspices of Brandon University or within its jurisdiction requires review and approval by BUREC prior to the start of the research. This includes but is not limited to research that:

- is undertaken by faculty, staff, or students; including adjunct professors, visiting professors, visiting professional associates, research associates, and postdoctoral fellows;
- is conducted on or off campus;
- is funded or unfunded;
- is conducted inside or outside of Canada;
- is a pilot or feasibility study;
- involves the secondary use of data gathered in earlier projects; or
- is conducted on University premises using any university resources, equipment or facilities.

Note that research that is conducted in the classroom or a course requirement may require ethics review and approval. See section 2.2 and 2.3.

2.1 The TCPS2 Course on Research Ethics (CORE) Tutorial

The CORE Tutorial is an introduction to the TCPS2 that focuses on the ethics guidance applicable to all research involving human participants, regardless of discipline or methodology. A PI must demonstrate completion of the most current TCPS CORE Tutorial by providing a copy of the Certificate of Completion as an appendix with each new application.

2.2 Research Requiring BUREC Review

The following research requires ethics review and approval by BUREC prior to the start of research (TCPS2 Article 2.1):

a) research involving living human participants, including autoethnographic research; and

b) research that involves 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.

All undertakings that involve the collection of information from human participants, including but not limited to tests, questionnaires, interviews, written communications, and/or representations (such as photographs, audiotapes, videotapes, etc.) of living human participants, normally require approval. This includes the use of secondary information that includes participants' identifiable information.

Undergraduate and Graduate Student Research: Student theses, senior student research projects, and other undertakings where the student takes a significant role in research development, require BUREC review and approval. A Student PI must list their Faculty Supervisor on the application and **the Faculty Supervisor is a resource for the student completing the ethics application, providing guidance, and reviewing and approving the application prior to submission.** Applications may be submitted by either the Student PI or the Faculty Supervisor but both must be copied on all communication to BUREC. Undergraduate and graduate Student PIs must conduct research with a Course Instructor/Faculty Supervisor and within the jurisdiction of an academic program, and not those conducted outside the jurisdiction of an academic program. Furthermore, undergraduate students are limited to conducting research approved as Minimal Risk.

Course Project Research: Course labs, demonstrations, assignments, papers, independent studies courses, and projects, undertaken in a course may require BUREC approval. Course project research is limited to participants, topics, and methods that pose Minimal Risk. Ethics can be applied for collectively by the Course Instructor, if all students will be utilizing the same ethics submission, or individually by the student with the course instructor as the Faculty Supervisor. Instructors should make students aware of ethics requirements and timelines at the beginning of the course to allow sufficient time for completion and review. Student PIs conducting Course Project Research must complete the most current TCPS CORE Tutorial or demonstrate previous completion before commencing the project. The Course Instructor must submit copies of the students' CORE Tutorial certificates with the Annual Progress Report to verify this requirement.

2.3 Research Exempt from BUREC Review

In accord with the Tri-Council Policy Statement, research does not require ethics review and approval by BUREC prior to the start of research when (TCPS2 Article 2.2-2.6):

a. the information is legally accessible to the public and appropriately protected by law;
b. the information is publicly accessible and there is no reasonable expectation of privacy;
c. the research involves observation of people in public places where interaction or intervention is not staged by the PI, individuals have no reasonable expectation of privacy, and any dissemination of results does not identify specific individuals; or
d. the research relies exclusively on secondary use of anonymous information, or anonymous human biological materials, that does not generate identifiable information.
e. the data collected are for quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within the normal educational requirements when used exclusively for quality management or improvement purpose, unless the data is used for other research or scholarly purposes;
f. it is a skill development activity in undergraduate or graduate courses whereby students/classmates pretend to be study participants, but are not actual participants.
g. the data collected are for the purposes of conducting a needs assessment, provided the data are not also used for other research purposes; or
h. it is a creative practice activity where an artist makes or interprets a work of art or studies how a work of art is generated, unless the research employs creative practice to obtain responses from participants that will be analyzed to answer a research question.

Undergraduate and Graduate Courses

Undergraduate and graduate courses, such as Research Methods, may include class projects and activities designed specifically to develop research skills but not to conduct research as defined in the TPCS2. These projects may be carried out by individual students, small groups, or as a single class project, but are limited to participation by those enrolled in that class. These skill development activities may include the following and do not require BUREC review:

- learning to develop and conduct interviews
- learning to develop and distribute surveys or questionnaires,
- learning to administer standard instruments or equipment, or
- learning to analyze data and write a section for a mock presentation or paper.

If, however, students will be doing research involving human participants who are not in the class (i.e. interviewing family members), research ethics will be required. In this case, the course instructor will submit a Course-Based Research Ethics Application, which will undergo delegated review. All students must complete the TCPS2: CORE-2022 before commencing any research.

To ensure that ethics approvals are in place before the start of the course, ethics applications must be received by July 15 for Fall courses; November 15 for Winter courses; March 15 for Spring/summer courses.

However, if the purpose of asking students is to undertake human participatory research as part of a course and is also intended to advance the instructor's research agenda, then a standard ethics application is required.

All graduate and undergraduate thesis projects involving human participants are considered research and require BUREC review and approval.

Needs Assessment

BUREC has determined that needs assessments constitute a special activity which, while not explicitly identified for exclusion in TCPS2, is consistent with the exclusion criteria identified in the TCPS2 Article 2.5. Organizations engage in a variety of research activities to determine how best to achieve its goals and purposes. Quality improvement and program evaluation are broad labels to describe some of these activities. In its simplest form, these activities are designed to help organizations assess its performance, within its mandate, by examining existing activities.

Some studies are designed to inform the planning of new programs, products, or services. These are more accurately labeled "needs assessments" and are part of program development rather than program review. Formally, a needs assessment may be defined as "a systematic set of procedures undertaken for the purpose of setting priorities and making decisions about program and organizational improvement and allocation of resources. The priorities are based on identified needs" (Witkin and Altschuld 1995, p.4). Needs assessments can take many forms, including opinion polls, feasibility studies, and market surveys. To the extent that needs assessments are part of a planning process to assist organizations in developing new products and services, they can be considered a variant of quality improvement and/or program evaluation. As such, they are exempt from BUREC review, provided the principal purpose of the data collection and analysis is for the internal use of the organization for whom the assessment is undertaken.

If the data collected during a needs assessment will be subsequently used for wider dissemination, then BUREC review and approval are required. Dissemination shall include, but is not limited to, publication in a peer-reviewed journal, conference or public presentation, addition to a publicly available database, and/or posting on a website.

Ethics Exemption Inquiry

A PI seeking confirmation on whether a research project requires ethics certification can submit a BUREC Ethics Exemption Inquiry Form to BUREC for review by the Chair.

3.0 MATTERS OF PARTICULAR CONCERN IN ETHICS REVIEW

Notwithstanding the necessity to address all ethical issues fully, the following key elements of the TCPS2 fall within the core principles and should receive careful attention when preparing an ethics submission:

3.1 Free and Informed Consent

Consent encompasses a process that begins with the initial contact of participants (e.g., recruitment) and carries through to the end of participants' involvement in the project, (TCPS2, Article 3.3). Free and informed consent must be given by each participant and must be maintained throughout the research study. Evidence of consent shall be contained either in a signed consent form or in documentation by the PI of another appropriate means of consent (TCPS2, Article 3.12). A consent form provided from the PI and signed by the participant is a common means of demonstrating consent; however, there are other means of providing consent that are equally ethically acceptable. Where a signed consent form is not used, the procedures used to seek and confirm consent must be documented. Whether or not a consent form is signed, it may be advisable to leave a written statement of the information conveyed in the consent process with the participant. The requirement to leave said written statement with the participant is a matter of judgment by BUREC and is dependent on the degree of risk and the general nature of the research participation.

The PI shall provide prospective participants, or authorized third parties, with full disclosure of the information necessary to make an informed decision to participate in a research project (TCPS2, Article 3.2). At the commencement of any process of consent, the PI (or their qualified representatives) shall provide prospective participants with the information set out in the following list, as appropriate to the particular research project. Not all listed elements are required for all research. However, additional information may be required in particular types of research or under particular circumstances. If a PI does not include some of the listed disclosure requirements, they should explain to BUREC why the requirements do not apply to the project. It is the responsibility of BUREC to consider whether all elements listed, or additional elements included, are necessary to the consent process of the research project (TCPS2, Article 3.2).

3.2 Broad Consent for the Storage of Data and Human Biological Materials for Future Unspecified Research

Broad consent is defined as consent for future unspecified research (subject to applicable law)

and applies to the storage of secondary use of participants' data and human biological materials collected for research purposes. Broad consent always includes specific restrictions (e.g., consent may be restricted to a particular field of study, to a specific disease, or may prevent use by private industry). It is used in the context of future research using data and human biological materials with no direct contact or intervention with participants at that time. Broad consent is a separate process from seeking free and informed consent for the original study/project. When seeking consent for a specific research project at the same time as seeking consent for storage of data and human biological materials for future unspecified research, prospective participants must be provided with an option to consent to each separately, either through separate consent forms or separate sections on the same form. (TCPS2, Chapter 3, E).

Where data or human biological materials are being stored for use in future unspecified research, the PI, relevant authority of the repository, and future researchers share the responsibility of ensuring that the terms of participant consent are respected and that participant privacy, confidentiality, and welfare are protected throughout the life of the research project (TCPS2 Article 3.2).

To seek broad consent for the storage and future unspecified use of data and human biological materials, the PI shall provide prospective participants, or authorized third parties, with applicable information as outlined in *Section 3.1 – Free and Informed Consent* (above), as well as the following, as appropriate to the particular research project (TCPS2, Article 3.13):

a) the type, identifiability, and amount of data and human biological materials being collected and stored for re-use, and for what potential purpose;
b) the voluntariness of the participant's consent, including any limitations on the feasibility of withdrawal;
c) a general description of the nature and types of future research that may be conducted, including whether the research might be conducted outside of Canada (if known);
d) the risks and potential benefits of storage of data and human biological materials, and of their use in future unspecified research, including areas of uncertainty where risks cannot be estimated;
e) access to a general description of the repository and its governance;
f) a statement regarding participants' preference to being recontacted for additional future research;
g) whether the data or human biological materials could be shared with researchers who are not subject to the TCPS2;
h) whether the research will (if known) or might include whole genome sequencing or similar technologies that may pose a substantial risk of re-identification of the participant or reidentification of material incidental findings (when appropriate);
i) whether linkage of data gathered in the research or derived from human biological materials with other data about participants – either contained in public or person records – is anticipated; and
j) separate options for consenting to participate in a specific research project and for consenting to the storage of data and human biological materials for future unspecified research.

3.3 Departures from General Principles of Consent – Temporary Concealment and/or

Partial Disclosure

If there is a plan to temporarily conceal the purpose of a research project or any other aspects of the research from the participants, or if the research involves partial disclosure, this must be discussed fully in the application. In some types of studies, the purposes initially are only partially disclosed to avoid over-sensitizing participants to particular issues, but the undisclosed information would not be likely to affect informed consent. If this is the case, describe the way in which disclosure is incomplete, provide a rationale, and provide assurance that the information left undisclosed would not reasonably be expected to influence informed consent. If there is concealment or partial disclosure about matters that reasonably might be expected to influence informed consent, the proposal may be a higher level of risk. In such cases, potential risks must be discussed and how they will be minimized; describing how the reasons for the concealment or incomplete disclosure will be explained, and how any negative feelings or loss of trust/respect that has been created will be dispelled. In addition, where feasible, the PI must offer an opportunity to withdraw consent for the use of the data after debriefing. In all cases, an explanation of how participants will be debriefed on the undisclosed information must be included. Where there is a moderate or greater risk of harm to participants, or where participants cannot later be debriefed, BUREC may not approve the research. (TCPS2 Article 3.7A and 3.7B)

3.4 Privacy and Confidentiality

Participants have the right to expect that their identities will be kept private and their personal information kept confidential. Even when the PI has reason to believe that participants will agree to being identified publicly, the PI must still ask for consent. The application must specify whether the PI will protect privacy, anonymity, and/or confidentiality, and if so, how it will be done. This should also be referred to in the informed consent material. If there are risks attached to the accidental revelation of participants' identities or private information, describe these, explain how they will be minimized, and take them into account in assessing the risk level of the research. Should the risk of revelation of information present a greater risk than participants encounter in their everyday lives, the proposal will be considered under the Full Review process.

3.5 Vulnerable Persons

Ethical conduct precludes the exploitation of individuals who, due to legal or other limitations, lack the capacity to provide informed consent. However, research involving such people may provide benefits to them or to the group that they represent. Thus, those who lack the capacity to decide on their own behalf must neither be unfairly excluded from the potential benefits of research participation, nor may their lack of decision-making capacity be used to include them in research inappropriately. This may include the development of consent materials that are appropriate to the cognitive and communication abilities of prospective participants to give the opportunity to assent or dissent from participating in the research. If vulnerable persons are the participants in human participatory research, the consent procedures must comply with all legal requirements that might apply. Consent must be obtained from an authorized representative who is capable of advocating independently for the vulnerable person. The PI must demonstrate that the study poses no more than minimal risks to participants without offering them any direct benefits. Special care must be taken to ensure that there is no coercion, constraint or undue

influence to participate. It must be indicated in the proposal how these requirements will be met. Many individuals who lack legal capacity to make decisions may still be able to express their wishes in a meaningful way, even if such expression may not fulfill all the requirements for consent. Prospective participants may be capable of verbally or physically assenting to, or dissenting from, participation in research. The participation of vulnerable persons may place the proposal in the higher risk category. Thus, a Full Review may be required, and additional review time may be required to address any ethical issues raised.

3.6 Minors

The TCPS2 does not specify an age of consent for minors. In practice, the PI plays a key role, sometimes in collaboration with the parents, in determining whether the minor is capable of consent. Seeking consent from minors is not based on their age, but on whether they have the capacity to understand the significance of the research and the implications of the risk and benefits to themselves (TCPS2 Section 3.C.). BUREC shall review an application with a level of scrutiny appropriate to ensure that potential risks and harms for the minor participant are considered. BUREC will also consider the research topic, methodology, and the PI's experience to determine the capacity of the minor participant before approving an application that proposes no third-party authorization.

Factors to consider in deciding to seek consent from minors as participants include, but are not limited to, the nature of the research, the research setting, the level of risk the research may pose to participants, provincial legislation and other applicable legal and regulatory requirements related to legal age of consent, and the characteristics of the intended research participants - who may differ in many aspects including their capacity to make their own decisions.

Minors who lack the capacity to consent may still be able to express their wishes in a meaningful way (assent or dissent), even if such expression may not be sufficient to fulfill the requirements for consent. PIs must respect the decision of children who are capable of verbally or physically assenting to, or dissenting from, participation in research, even if the authorized third party has consented on their behalf (see Article 3.10). Information provided to children must be comprehensible for their age and development level. Particular care must be taken to prevent real or apparent coercion, constraint or undue influence to the participant.

A Brandon University student participating in a PI's research project or in a class research project is considered an adult who meets the age of consent. Parental consent is not required, and therefore, University students shall be included as potential participants in research projects, where applicable.

3.7 Captive or Dependent Populations

If the participants are drawn from captive or dependent populations (e.g., in prisons, universities, schools, hospitals, psychiatric facilities, treatment programs, etc.), special care must be taken to ensure that consent is given freely, and that no actual or perceived coercion, constraint, or undue influence or inducement to participate is present. Often, because the member(s) of the research team has good intentions, they may fail to note some way in which potential participants might feel subtle pressure to participate. For example, a token payment of five or ten dollars for

research participation might represent a large inducement to someone who has no other means of obtaining extra money. Even if a study is being conducted by a member(s) of the research team who has no connection to a participant's doctor or therapist, the participant might nonetheless feel that refusal to participate might compromise his/her treatment or therapy. The onus is on the member(s) of the research team to identify potential problems of free and informed consent and/or actual or perceived coercion, to devise safeguards to prevent or minimize such problems, and to explain these matters fully in the proposal.

3.8 Research Involving First Nations, Inuit, and Métis Peoples

Where the PI is conducting Indigenous-based research or conducting research within an established Indigenous community as defined and outlined in the TCPS2, Chapter 9, the PI shall seek engagement with and approval from the relevant community.

PIs should read Chapter 9 of the TCPS2 in its entirety, and any discipline-specific ethics guidelines that may apply to the study. PIs should become informed about formal rules and oral customs that may apply in accordance with a particular First Nations, Inuit, or Métis (FNIM) authority, and should engage in the development of a relationship/partnership with the applicable FNIM communities. With their application to BUREC, the PI must demonstrate what engagement occurred or will occur, and is expected to provide a formal research agreement from the community.

While Chapter 9 is designed to guide research involving particular communities, its discussion of respectful relationships, collaboration, and engagement between researchers and participants may also be an important source of guidance for research involving other distinct communities. The need to respect a community's cultural traditions, customs, and codes of practice may extend beyond FNIM communities, (TCPS2 Interpretation, Research Involving FNIM Peoples of Canada).

3.9 Fairness and Equity in Research Participation

The PIs should be inclusive when selecting participants for their research studies. Participants shall not be excluded based on attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age. Where such exclusion occurs, the PI must demonstrate a justifiable reason to BUREC.

3.10 Conflict of Interest (COI)

A COI 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 interest. These interests include, but are not limited to, business, commercial or financial interests pertaining to an institution and/or the individual, their family members, friends, or their former, current or prospective professional associates. A conflict of interest may involve the institution, PI, or BUREC member. Any real, potential or perceived conflict of interest must be disclosed. This includes dual roles in which the PI/research team and their associated obligations (e.g., acting as both a PI and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, student or employer) may create conflicts, undue influences, power imbalances or coercion that could affect

relationships with others and affect decision-making procedures (e.g., consent of participants).

When acting in dual or multiple roles, the PI shall disclose the nature of the conflict to BUREC, outlining how this conflict will be mitigated, as well as to the participant in the consent process. For more information, please refer to the Brandon University Conflict of Interest in Research Policy.

4.0 TYPES OF REVIEW

The type of review and the ongoing review procedures must be proportionate to the level of risk posed by the proposed undertaking. The PI has a responsibility to minimize any possible risks and to ensure that these risks do not outweigh the benefits expected from research. The PI should select the appropriate review upon careful consideration of level of risk and the potential benefits of the proposed project. Proposals will be subject to one or more of the types of review described below:

4.1 Full Review

Full Review is the default review process (TCPS2 Article 6.12.1). All proposals will be reviewed by BUREC at the monthly scheduled, face-to-face meetings of the full ethics committee.

A Full Review is required if the research involves a level of risk higher than the standard of everyday life, and/or is moderately invasive. Categorization of risk level depends on the possibility of the occurrence of harm, and the level of foreseeable risk posed to participants by their involvement in research, which is assessed by considering the magnitude or seriousness of the harm and the likelihood that it will occur, whether to the participants or to third parties. For Moderate and High Risk research, it must be demonstrated that all possible steps have been taken to minimize harm, and that the potential benefits of the research outweigh the potential harms.

4.2 Delegated Review

Projects involving Minimal Risk research may be eligible for Delegated Review, provided that the PI requests such review (TCSP2 Article 6.12) and the BUREC Chair concurs with the rationale for categorizing the level of risk as minimal. The TCPS2 defines Minimal Risk as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research (TCPS2, p.25).

If the Chair concurs, the submission will be reviewed by the Chair and normally two BUREC Members. Should the Chair or any of the reviewers decide that a Full Review is necessary, they will review the reasons for consideration and come to a final decision about the level of the review. The Chair may seek out additional BUREC reviewers at their discretion.

Delegated Review approvals shall be reported at the next BUREC meeting.

Please note that a Delegated Review is available for Minimal Risk proposals and is not meant to

accommodate a PI's time constraints or an expedited review process.

4.3 Multi-Site and Multi-Jurisdiction Research Review

Multi-jurisdictional research is defined as research involving multiple institutions and/or multiple research ethics boards (REBs). (TCPS2, Chapter 8) and may include, but is not limited to:

a) a research project conducted by a PI/team of researchers s affiliated with different institutions;
b) several research projects independently conducted by PIs affiliated with different institutions, with data combined at some point to form one overall research project;
c) a research project conducted by a PI/team of researchers affiliated with one institution, but that involves collecting data or recruiting participants at different institutions;
d) a research project conducted by a PI/team of researchers who has multiple institutional affiliations (e.g., two universities, a university and a college, or a university and a hospital);
e) a research project conducted by a PI/team of researchers at one institution that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g., statisticians, lab or x-ray technicians, social workers and school teachers); or
f) a research project that a PI/team of researchers , working under the auspices of a Canadian research institution, conducts in another province, territory, or country.

Brandon University will accept the ethics approval granted by the REB of the primary institution, typically the institution of the PI, subject to the following:

- the project is Minimal Risk;
- the project was approved by a TCPS2 compliant REB;

Moderate/High Risk submissions shall undergo Full Review by BUREC.

The ethics application, as approved by the primary institution, certificate of approval, contact information for the PI and the primary institution's REB shall be submitted to BUREC electronically. The application shall be reviewed by the Chair of BUREC to ensure local characteristics, values, customs, and issues are addressed, as applicable.

If questions are raised for clarification or revisions are requested, the PI shall be notified. Should there be procedural inconsistencies or substantive disagreements between BUREC and the primary institution's REB, the appropriate representative from the primary institution's REB and the Chair of BUREC shall engage directly in effort to find a resolution. If deemed acceptable, a Multi-Site Research Letter of Acknowledgement will be issued to the PI and the primary institution's REB. Ethical oversight and post approval monitoring shall remain with the primary institution, including continuing ethics review or the review of amendments. The PI is responsible for bringing any project-specific deviations, unanticipated challenges, material incidental findings, or new project information related to the research project to the attention of the primary institution's REB. When the Final Report for a research project is filed with the primary institution's REB, a copy shall be submitted to BUREC in order to close the file.

A new Faculty Member hired by Brandon University who holds ethics certification from another

institution, that falls under the TCPS2, can undergo BUREC review through the Mult-Site Research Review process. Upon approval, a BUREC ethics certificate will be issued and the project will fall under the oversight of BUREC.

4.4 Secondary Use of Data for Research Review

Secondary use of data 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 data sets 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 (TCPS2 Chapter 5.D.).

There are three categories of Secondary Use data that require application to BUREC:

1. **Identifiable:** Data that contain identifiable information.
2. **Coded:** Data that have direct identifiers removed and replaced with a code. New consent procedures may be required if the PI accessing the data set also has access to the code that re-identifies individuals to whom the information relates.
3. **Non-identifiable:** Data do not identify an individual, for all practical purposes, when used alone or combined with other available information.

BUREC approval is not required for the secondary use of data that is anonymous, with no process for data linkage, and dissemination of results will not generate identifiable information. Anonymous is defined as data that never had identifiers attached to them. Data Linkage is defined as the merging or analysis of two or more separate data sets (e.g., health information and education information about the same individuals) for research purposes.

5.0 REVIEW PROCEDURES

It is the responsibility of the PI to allow sufficient time for review in advance of the anticipated project start date and in consideration of BUREC meeting dates and turnaround times. BUREC suggests starting the review process at least three (3) months in advance of the project start date. The length of the review process timeline may be affected by the following:

- **Submission Completeness:** A submission shall normally be submitted as **one PDF** starting with the application, followed by the appendices in order. A submission that lacks the required items or does not provide sufficient detail for review will be returned to the PI for completion and resubmission.

- **Ethical Complexities:** A submission involving ethical issues that necessitate further consideration by BUREC may require time for consultation, revision, and/or Committee discussion at more than one scheduled meeting.

5.1 Type of Review Required

There are two types of BUREC review, Full and Delegated, and each has a different review process and approval timeframe.

a) **Full Review**

For Moderate/High Risk research, the PI submits a complete application with all required attachments electronically to BUREC by the posted deadline, for review at the next scheduled BUREC meeting. BUREC requires sufficient time to read submissions prior to the meeting, therefore, proposals received between the submission deadline and the meeting date will be reviewed at the next regularly scheduled BUREC meeting. The review process will produce one of the following three outcomes:

1. ethically acceptable as is,
2. return to the PI for further information and/or revision, or
3. unacceptable, the PI is to revise and submit a new application.

Where minor revisions are required by BUREC, the PI and the BUREC Chair, acting on behalf of BUREC, will work together to finalize the submission requirements. When more substantial revisions are requested by BUREC, the revised application may require final review and approval by the full Committee at the next scheduled meeting for which the deadline has not passed. Once approved, BUREC shall issue an ethics certificate indicating approval for the research. Any changes made to a submission during the review process will be documented and kept on file.

b) **Delegated Review**

For Minimal Risk research, the PI submits a complete application with all required attachments electronically to BUREC anytime for review by the BUREC Chair and one BUREC Member. If the reviewers decide that the submission is greater than Minimal Risk, the procedure moves to Full Review (Section 5.1.a.) and the submission will be considered at the next scheduled BUREC meeting for which the deadline has not passed. The review process will produce one of the following four outcomes:

1. ethically acceptable as is,
2. return to PI for further information and/or revision,
3. recommended for Full Review, or
4. unacceptable, PI to revise and submit a new application.

Where minor revisions are required by BUREC, the PI and the BUREC Chair will work together to finalize the submission requirements. Once approved, BUREC shall issue an ethics certificate indicating approval for the research. Any changes made to a submission during the review process will be documented and kept on file.

5.1 Pending Approval

A submission must be either approved or withdrawn within six (6) months of the initial BUREC review date, after which time a new ethics submission is required.

5.2 Ethics Certification

Once BUREC has approved the ethics submission, a BUREC Ethics Certificate will be released to the PI. Ethics approval is granted for a maximum of (5) years with the requirements of an annual Progress Report and a Final Report, and any other applicable continuing research ethics

requirements (see Section 6.0). Projects continuing beyond five years will require the submission of a Renewal Application.

No human participatory research shall begin until the PI has received a signed ethics certificate from BUREC. This includes the recruitment of participants and any data collection.

6.0 CONTINUING RESEARCH ETHICS REVIEW

Continuing research ethics review is a requirement of the TCPS2 and includes the ongoing monitoring of an approved ethics submission over the term of the formal ethics approval, i.e., from the start date to the end date stated in the ethics certificate. At minimum, continuing ethics research review shall consist of an annual Progress Report for multi-year projects and a Final Report at the end of all projects. At the time of review, BUREC will determine if more frequent ongoing review is required in accordance with a proportionate approach to review and level of risk.

Failure to fulfill the reporting and continuing research ethics review requirements is considered an act of non-compliance and will result in:

- the suspension of active ethics certifications until the matter is resolved;
- no new applications reviewed until the matter is resolved;
- the refusal to review and approve any new research ethics submissions until the matter is resolved; and/or
- other outcomes as outlined in the *BUREC Non-Compliance Policy and Procedures*.

BUREC strongly recommends that the PI set reminders in their calendars to meet the mandatory reporting requirements and to remain in compliance with BUREC policies.

Types of reporting and continuing research ethics review include, but are not limited to:

6.1 Progress Report

A Progress Report is to be submitted to BUREC by the anniversary of the approval date. The Faculty Supervisor is responsible for ensuring that their student Principal Investigator submits an annual Progress Report as outlined above. The report is due on the anniversary date of approval, found on the ethics certificate.

6.2 Final Report

A Final Report is to be submitted to BUREC upon completion or termination of an approved ethics submission and when ethics approval is no longer required. Reports are to be submitted no later than the end date of the certification. Student PIs must remember to submit their reports prior to leaving/graduating from the University. The Faculty Supervisor is responsible for ensuring that Student PI submits a Final Report as outlined above. The report is due on the anniversary date of approval, found on the ethics certificate.

6.3 Unanticipated Issue or Event Report

An Unanticipated Issue or Event Report shall be **SUBMITTED WITHOUT DELAY** to BUREC. An unanticipated issue or event is something that occurs during the conduct of research **that may increase the level of risk to participants or have other ethical implications that may affect participants' welfare** and were not anticipated by the PI in the research proposal

submitted for research ethics review. For more information please refer to the *BUREC Standard Operating Procedures: Reporting Unanticipated Issues and Events*.

6.4 Amendment to an Approved Ethics Submission

An Amendment Application is required when there are proposed changes to an approved submission that may have ethical implications for the participants, including their right to free and informed consent. The impact of the change and level of risk to participants should be taken into consideration. Proposed changes include, but are not limited to:

- the consent form
- the tasks or interventions involved in the research
- measures to protect privacy and confidentiality
- research team members
- recruitment methods or materials
- location of research
- length of study and participant involvement
- participant inclusion/exclusion criteria
- conflicts of interest
- compensation type or amount
- the data management plan

An application to amend an approved ethics submission must be submitted to BUREC for review and approval, prior to the implementation of changes. The BUREC Chair reviews and approves all Amendment Applications unless:

- the project was originally moderate/high risk, in which case the application goes through Full Review;
- there are substantive changes that warrant a new review; or,
- there is an increase in the level of risk, which results in the initiation of a Full Review.

Changes shall be reported to BUREC in a timely manner.

6.5 Renewal of an Approved Ethics Application

A BUREC-approved project that continues beyond the maximum five-year certification window will require a Renewal Application. Applications must be submitted prior to the certificate expiration. Approved renewals are valid for one (1) year and can be applied for on an annual basis, as needed. Renewal Applications are subject to current policies and procedures, and revisions may be required to ensure compliance. The BUREC Chair is given the discretion to decide whether a Renewal Application is approved or requires further BUREC review.

6.6 Material Incidental Findings Report

An "Incidental Finding" is a discovery about research participants or prospective participants that is made during the course of research but is outside the objectives of the research study. Incidental Findings are considered to be Material Incidental Findings if they are reasonably determined to have significant welfare implications for the participant or prospective participant. (TCPS2, Article 3.3). A PI is responsible for disclosing any Material Incidental Findings discovered during the course of research.

The PI must first determine whether Material Incidental Findings **are reasonably**

foreseeable. If they are, a Management Plan must be included with the ethics application that describes:

- the potential Material Incidental Findings
- the process used to determine the materiality of the findings
- how the participants will be informed of the possibility of findings in the consent process
- how the PI will disclose findings to participants, where applicable

To determine whether Incidental Findings are material, expertise relevant to the findings is required. If the PIs does not have such expertise and is unsure how to interpret the findings or is uncertain whether findings are material, they should seek expertise relevant to the findings and/or refer to professional practices and standards.
If Material Incidental Findings **are not reasonably foreseeable**, in the event of an unexpected discovery of incidental findings, the PI shall report the discovery to BUREC and include a Management Plan for BUREC approval, prior to implementation. (See TPCS2 Article 3.4.).

7.0 PRINCIPAL INVESTIGATOR (PI)

7.1 PI and Research Team Responsibilities

All members of the University community (faculty, staff, and students) and those within our jurisdiction who conduct research or teaching activities involving human participants have the responsibility to:

a) familiarize themselves with the TCPS2 and the BUREC Policies and Procedures, as well as any relevant disciplinary ethics guidelines, and to abide by these;

b) demonstrate completion of the most current TCPS CORE Tutorial by attaching a certificate of completion as an appendix to the BUREC application (PI only).

c) receive ethics approval prior to undertaking any project involving human participants;

d) ensure that proposals submitted for review are complete and describe all aspects of the project relevant to ethics review;

e) disclose in the application any real, potential, or perceived conflicts of interest regarding their relationship with potential participants, co-investigators, collaborators, organizations, etc. and/or the potential uses of the research findings;

f) conduct their research in accordance with the contents of their approved proposals;

g) submit an Amendment to Approved Ethics Submissions to BUREC for review and approval, prior to the implementation of any changes;

h) comply with all undertakings, reporting procedures, and monitoring procedures that form the conditions of project approval;

i) obtain signed Confidentiality Agreements from all individuals involved with collecting and/or with access to the data, where applicable. This should be addressed in the application;

j) submit Unanticipated Issue/Event Report form **WITHOUT DELAY** to BUREC;

k) submit annual Progress Reports to BUREC for all approved ethics submissions.

Certain projects may require more frequent progress reports and/or ongoing monitoring which will be outlined in the approval documentation;

l) submit Final Reports to BUREC in a timely manner upon completion or termination for all approved ethics submissions and when ethics approval is no longer required;

m) submit a Renewal Application for any approved ethics submission lasting longer than five (5) years from the date of approval; and

n) submit a Material Incidental Findings Report to BUREC via BUREC in a timely manner when a discovery about research participants or prospective participants is made in the course of research, but is outside the objectives of the research study.

7.2 Application Preparation

Before preparing an application, PIs should thoroughly read the BUREC Procedures and familiarize themselves with the TCPS2 which can be found on the BUREC website. Additionally, all required forms and templates can be downloaded for completion for electronic submission. A submission shall normally be submitted as **one PDF** starting with the application, followed by the appendices in order. The following items are to assist PIs in preparing and submitting their ethics applications:

a) ALL applicable sections of the BUREC Application form must be completed or labeled "n/a".

b) The PI must identify and justify the level of risk posed to participants and propose the type of review the project should receive.

c) All information must be provided that is pertinent to the assessment of the level of risk, harms/benefits of participating in the research, and the possible need for ongoing review.

d) The PI must disclose in the submission any potential conflicts of interest that may arise.

e) Copies of all research instruments should be attached, for example, questionnaires, surveys, interviews, etc. Where the research is qualitative and involves emergent design, the PI must provide BUREC with all available information to allow for a proportionate approach to ethics review, for example, a draft set of sample questions, thematic categories, or other guides and outlines. Note that final versions should be submitted to BUREC as soon as they become available.

f) If participants are to be photographed, audio taped, videotaped, or otherwise recorded, a detailed description of the parameters within which recording will occur must be provided.

g) The application must include a participant consent form template for signature, or an explicit method of otherwise obtaining and documenting informed consent. Where a PI considers a consent form impossible, not appropriate, or unnecessary, they must demonstrate to BUREC why and how consent will be sought(See TCPS2, Chapter 3).

h) For human participatory research conducted within or in association with other institutions/organizations, a letter of permission or appropriate approval from a person with institutional/organizational authority must be provided to BUREC, either with the proposal or before the project begins.

i) An incomplete BUREC application will be returned to the PI for completion and resubmission.

j) A PI may reach out to BUREC with any questions they have on the application process.

k) The application must specify a mechanism for providing a summary of the study's results to interested participants, where practical and appropriate.

l) If sensitive information is to be recorded in a manner that might identify individual participants, the proposal must describe the provisions that will be made for storing such information securely.

9.0 BUREC APPEALS

A PI may request that BUREC reconsider a decision made regarding their ethics submission. They must do so in writing to the Chair of BUREC, detailing the reasons for their request. Reconsiderations will normally occur at the next regularly scheduled BUREC meeting. Reasons for the reconsideration should be provided and the specific applicable sections of the TCPS2 and *BUREC Procedures* should be referenced.

Where BUREC upholds its original decision, the PI may appeal. Appeals will be heard at The University of Winnipeg by the Senate Committee on Ethics in Human Research and Scholarship, under the conditions of a joint appeal agreement between Brandon University and The University of Winnipeg. Appeal decisions of The University of Winnipeg Senate Committee on Ethics in Human Research and Scholarship are final. A request for appeal should be submitted to BUREC within 30 days of BUREC's reconsideration decision.

10.0 COMPLIANCE

Brandon University requires that all faculty members, staff, and students adhere to the *BUREC Policies and Procedures*. The University considers non-compliance and the inappropriate treatment of human participants to be a serious offence, subject to penalties, including, but not limited to, suspension of ethics certifications, withdrawal of privileges to conduct research involving humans, and/or disciplinary action. All acts of ethics non- compliance will be reviewed on a case-by-case basis by BUREC and may involve the Vice-President (Research & Graduate Studies) for further investigation as per the *Brandon University Policy on Academic Integrity and the Responsible Conduct of Research, Scholarship, and Creative Work*. Any actions taken will take into account the severity of non-compliance. For more information, please refer to the *BUREC Non-Compliance Policy and Procedures*.

11.0 PUBLICLY DECLARED EMERGENCY

BUREC Review during a Publicly Declared Emergency

A publicly declared emergency is defined by the TCPS2 as: *"an emergency situation that, due to the extraordinary risks it presents, has been proclaimed as such by an authorized public official (in accordance with legislation and/or public policy). (TCSP2, p. 85, D.)"*. Publicly declared emergencies are unique and rare situations and BUREC will exercise due diligence in respecting ethical principles, procedures, and the law in effect in order to preserve the core principles of the TCPS2. During publicly declared emergencies only essential research will be considered. This includes:

- the initial review process of new research projects arising from the emergency (e.g., research involving interviews with first responders and victims to understand human response during a disaster, such as a tornado, flood, communicable disease outbreak, environmental disaster, catastrophic civil disorder, bio- hazardous release, and humanitarian emergency);
- the continuing ethics review of research undertaken prior to the occurrence of the emergency; and
- the ethics review process for changes to approved research because new information has become available and requires immediate action during the emergency.

BUREC recognizes two categories of emergency:

1. A Publicly Declared Emergency that has not affected Brandon University and its normal function; and
2. A Publicly Declared Emergency that has affected Brandon University and its normal function.

Publicly Declared Emergency that has not Affected Brandon University
Research to be conducted at a time when an emergency has been publicly declared and that emergency has not affected Brandon University, will be initiated through BUREC during regular business hours. The Chair of BUREC may consult with the Vice-President (Research & Graduate Studies) to determine the type of review and quorum necessary to review and approve the application, e.g., face-to-face meeting or electronic review of the application with the full BUREC or a delegated committee of BUREC.

Publicly Declared Emergency that has Affected Brandon University:
Research to be conducted at a time when an emergency has been publicly declared and that emergency has had a direct impact on Brandon University (e.g. destruction of campus buildings due to a tornado), will be initiated via contact with the Vice-President (Research & Graduate Studies) as per the Brandon University Emergency Procedures Manual . The Vice-President (Research & Graduate Studies) will make contact with the Chair of BUREC or designate, to determine the procedures for the review and approval of the ethics application.

BUREC will ensure adherence to a rule of reasonable, fair and principled design. For both categories of emergency, review will be dealt with on an emergency-by-emergency basis with full understanding that procedures may be modified to include attention to such things as timing, locale, expertise, form and scope of review, quorum, availability of BUREC Members, appointment of substitute BUREC Members, ad hoc committees, and communications.

Emergency procedures will end as soon as possible after public officials have declared the emergency over. Once regular BUREC policies and procedures are reinstated, a post-response evaluation will be conducted by BUREC in order to review the emergency process and improve or revise it, if necessary.

Revised September 2025