Brandon University Research Ethics Committee (BUREC) Policies and Procedures

1.0 INTRODUCTION

The *Brandon University Research Ethics Committee (BUREC) Policies and 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 from the Research Office website at: http://www.brandonu.ca/burec.

Ethics applications and other required documents and forms are to be submitted electronically to the Research Office at burec@brandonu.ca.

Given the breadth of possible research topics and methods to be reviewed, the *BUREC Policies and Procedures* cannot exhaustively 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 is inappropriate, or should be applied differently from what is implied or stated. The policies and procedures reflected in this document have been selected to apply to frequently encountered research situations. It is the responsibility of the researcher to verify with BUREC whether ethics certification is required, prior to 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 responsible conduct of research. BUREC makes the final determination on exemption from research ethics review.

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 definitions:

- Research - an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.
- Participant - an individual whose data, biological materials, or responses to interventions, stimuli, or questions by a researcher are relevant to answering the research question(s).

Human participatory research conducted under the auspices of Brandon University or within our jurisdiction requires review and approval by BUREC prior to the start of the research. This includes research that:

a) is undertaken by faculty, staff, or students; including adjunct professors, visiting professors, visiting professional associates, research associates, and postdoctoral fellows;

b) is conducted on or off campus;

c) is funded or unfunded;

d) is conducted inside or outside of Canada;

e) is conducted in the classroom or a course requirement;

f) is a pilot or feasibility study;

g) involves the secondary use of data gathered in earlier projects; or

h) is conducted on University premises using any university resources, equipment or facilities.

2.1 Research Requiring BUREC Review

The following research requires ethics review and approval by BUREC prior to the start of research:

a) research involving living human participants; 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.

Effective January 1, 2023, the Principal Investigator must complete the most current TCPS CORE Tutorial and provide a certificate of completion as an appendix with each new application submitted to BUREC.

Undergraduate and Graduate Student Research: Student theses, senior student research projects, and other undertakings where the student takes a significant role in the research development, require BUREC review and approval. A student researcher must list their research supervisor on the application and the supervisor should be a resource for the student when completing the ethics application, providing guidance and reviewing the application prior to submission. Applications can be submitted by either the student researcher or the supervisor; however, the supervisor must be copied on all communication to BUREC from the student researcher. Brandon University only endorses undergraduate and graduate student principal investigators conducting research with a course advisor and within the jurisdiction of an academic program. BUREC will only consider such applications 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 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 their research 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 researchers conducting research under "Course Project Research" must complete the most current TCPS CORE Tutorial or demonstrate previous completion before commencing the project. The course instructor must submit with the Annual Progress Report copies of the students' CORE Tutorial certificates to verify this requirement.

2.2 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:

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 the observation of people in public places where interaction or intervention is not staged by the researcher, 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.

See TCPS2 articles 2.2, 2.3, and 2.4 for further details.

2.3 Other Activities Exempt from BUREC Review

The Tri-Council Policy Statement recognizes that some activities may use the techniques and methods of research while not constituting research as defined above. Such activities do not require ethics review and approval when:

a) the data collected is for quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within the normal educational requirements when used exclusively for assessment, management or improvement purpose, unless the data is used for other research or scholarly purposes (see TCPS2 article 2.5);

b) it is a skill development activity in undergraduate or graduate courses whereby students/classmates pretend to be study participants, but are not actual participants.

c) the data collected are for the purposes of conducting a needs assessment, provided the data are not also used for other research purposes; or

d) 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 (see TPCS2 article 2.6).

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.

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

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 article 2.5. Organizations engage in a variety of research activities to determine how best to achieve their goals and purposes. Quality improvement and program evaluation are broad labels to describe some of these activities. In simplest form, these activities are designed to help organizations assess their performance, within their mandate, by examining existing activities. However, some studies are designed to help plan 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 collection is also to be used or will subsequently be used for wider dissemination, then BUREC review and approval is 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.

3.0 MATTERS OF PARTICULAR CONCERN IN ETHICS REVIEW

"A fundamental premise of this Policy is that research can benefit human society. In order to maximize the benefits of research, researchers must have academic freedom… With academic freedom comes responsibility, including the responsibility to ensure that research involving humans meets high scientific and ethical standards that respect and protect the participants. Thus, researchers' commitment to the advancement of knowledge also implies duties of honest and thoughtful inquiry, rigorous analysis, commitment to the dissemination of research results, and adherence to the use of professional standards." (TCPS2 – Ethics Framework)

The TCPS2 is based on three core principles (TCPS2 Article 1.1):

- Respect for Persons – "Respect for Persons recognizes the intrinsic value of human beings and the respect and consideration that they are due. This requirement reflects the commitment that participation in research… should be a matter of choice and that, to be meaningful, the choice must be informed."
- 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."
- 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."

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 (e.g., recruitment) and carries through to the end of participants' involvements in the project, (TCPS2, Article 3.3 - Application). 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 researcher of another appropriate means of consent (TCPS2, Article 3.12). Written consent in a signed statement from 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.

Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project (TCPS2, Article 3.2). At the commencement of any process of consent, researchers (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 the listed elements are required for all research. However, additional information may be required in particular types of research or under particular circumstances. If a researcher does not include some of the listed disclosure requirements, they should explain to BUREC why these requirements do not apply to that particular project. It is the responsibility of BUREC to consider whether all elements listed, or additional elements, are necessary to the consent process of the research project:

a) information that the individual is being invited to participate in a research project;

b) a statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;

c) a plain language description of all reasonably foreseeable risks and potential benefits, both to the participant and in general, that may arise from research participation;

d) an assurance that prospective participants:

- are under no obligation to participate and are free to withdraw at any time without prejudice to pre-existing entitlements;
- will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdrawn from participation; and
- will be given information on their right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;

e) information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;

f) the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly.

g) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;

h) the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;

i) an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants; a description of how confidentiality will be protected (Article 5.2); a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;

j) information about any payments, including incentives for participation, reimbursement for participation-related expenses, and compensation for injury;

k) statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research related harm; and

l) in clinical trials, information on stopping rules and when researchers may remove participants from trial.

Additional notes on informed consent:

- In situations where a parent or legal guardian has provided consent, the participant must also agree to participate via an assent process.
- Where recruitment is separate from the consent process, researchers are expected to provide a description of the initial contact process and supporting scripts.
- See TCPS2, Chapter 3, for complete details on the consent process.

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 researcher, the 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 and confidentiality, as well as participant welfare are protected throughout the life of the research project. For more information, refer to Article 3.2 and Application of the TCPS2.

To seek broad consent for the storage and future unspecified use of data and human biological materials, researchers 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 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 researcher 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 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.

See TCPS2 article 3.7A and 3.7B for more details.

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 researcher has reason to believe that participants will agree to being identified publicly, the researcher must ask whether participants consent to this. The application must specify whether the researcher 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 persons who legally or otherwise lack decision-making 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 inappropriately include them in research. 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 able to advocate independently for the vulnerable person. The researcher must demonstrate that the study will not pose more than minimal risks to participants without the potential for direct benefits to them. Special care must be taken to ensure that there is no coercion, constraint or undue influence to participate. It must be clearly 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, Full Review may be required, and additional review time may be required to address any ethical issues raised.

3.6 Children:

The TCPS2 does not specify an age of consent for children. The decision to seek consent from children instead of an authorized third party will be considered on a case-by-case basis. In practice, the researcher plays a key role, sometimes in association with the parents, in determining whether the child is able to consent. Seeking consent from children 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 – as defined in TCPS2 Section 3.C. – Decision-Making Capacity. 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 researcher's experience to determine the capacity of the minor participant before approving an application that proposes no third-party authorization.

Factors to consider in making the decision to seek consent from children 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.

Children who lack 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. Researchers 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.

3.7 Captive or Dependent Populations:

If the participants are drawn from captive or dependent populations (e.g., in prisons, 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 researcher 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 researcher 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 researcher 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 research is likely to affect the welfare of an Indigenous community, or communities, to which the participants belong, the researcher shall seek engagement with the relevant community. The conditions under which community engagement is required include, but are not limited to:

a) Research conducted on First Nations, Inuit or Métis lands;

b) Recruitment criteria that include Indigenous identity as a factor for the entire study or for a subgroup in the study;

c) Research that seeks input from participants regarding a community's cultural heritage, artefacts, traditional knowledge or unique characteristics;

d) Research in which Indigenous identity or membership in an Indigenous community is used as a variable for the purposes of analysis of the research data: and

e) Interpretation of research results that will refer to Indigenous communities, peoples, language, history or culture.

Researchers should read Chapter 9 of the TCPS2 in its entirety, and any discipline-specific ethics guidelines that may apply to the study. Researchers should become informed about formal rules or oral customs that may apply in accordance with a particular First Nations, Inuit, or Métis authority, and should engage in the development of a relationship/partnership with the applicable First Nations, Inuit, and/or Métis communities. With their application to BUREC, the researcher must demonstrate what engagement has been done or will be done, and is encouraged to provide the formal research agreement.

3.9 Fairness and Equity in Research Participation:

Researchers 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 researcher must demonstrate a valid reason to BUREC.

3.10 Conflict of Interest:

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 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, researcher, or BUREC member. Any real, potential or perceived conflict of interest must be disclosed. This includes dual roles in which the researcher(s) and their associated obligations (e.g., acting as both a researcher 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 researcher 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 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 researcher has a responsibility to minimize any possible risks and to ensure that these risks do not outweigh the benefits expected from research. The researcher 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. 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 probability that it will occur, whether to the participants or to third parties. For higher 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 may be eligible for Delegated Review, provided that the researcher requests such review 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, p22).

If the Chair concurs, the submission will be reviewed by the Chair and two BUREC members. Should any of the reviewers decide that Full Review is necessary, they can provide reasons to the Chair for reconsideration. The Chair, in consultations with the delegates shall come to a final decision.

Should a Delegated Review result in an approval, this will be reported at the next BUREC meeting.

Please note that Delegated Review is available for minimal risk proposals and is not available to accommodate a researcher's time constraints.

4.3 Multi-Site and Multi-Jurisdiction Research Review and Transferring Ethics Certification:

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

a) a research project conducted by a team of researchers affiliated with different institutions;
b) several research projects independently conducted by researchers affiliated with different institutions, with data combined at some point to form one overall research project;
c) a research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting participants at different institutions;
d) a research project conducted by a researcher 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 researcher 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 researcher(s) working under the auspices of a Canadian research institution conduct 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 Principal Investigator, subject to the following:

- the project is minimal risk;
- the project was approved by a TCPS2 compliant REB;
- The Principal Investigator is in good-standing with the primary institution;
- A copy of the ethics application approved by the primary institution's REB is submitted to BUREC for a review to ensure local characteristics, values, customs, and issues are addressed, as applicable.

The ethics application, as approved by the primary institution, as well as contact information for the Principal Investigator and the primary institution's REB shall be submitted to BUREC electronically. The application shall be reviewed by the Chair of BUREC or designate. If deemed acceptable, a Letter of Acknowledgement will be issued to the primary institution's REB and the Principal Investigator, and ethical oversight shall remain with the primary institution. In the event that questions are raised for clarification or revisions are requested, the primary institution's REB and the Principal Investigator shall be notified. Should there be procedural inconsistencies or substantive disagreements between the REBs, the appropriate representative from the primary institution REB and the Chair of BUREC shall engage directly in effort to find a resolution.

Higher risk ethics submissions shall undergo Full Review by BUREC. The ethics application, as approved by the primary institution, as well as contact information for the Principal Investigator and the primary institution's REB shall be submitted to BUREC electronically by the applicable submission deadline. The application shall be reviewed by the BUREC at their next scheduled meeting. Questions raised for clarification, revisions requested, or conditions for approval shall be communicated to the Principal Investigator and the primary institution REB. Should there be procedural inconsistencies or substantive disagreements between the REBs, the appropriate representative from the primary institution and the Chair of BUREC shall engage directly in effort to find a resolution. A BUREC Certificate is issued for approved projects and ongoing ethical review requirements as per BUREC Policy must be adhered to for compliance.

When a researcher is hired by Brandon University with research projects having ethics certification from another institution, certification from Brandon University is also required. Minimal risk applications will be reviewed and approved by the Chair of BUREC and a Brandon University Research Ethics Certificate will be issued. Moderate/high risk projects shall undergo Full Review by BUREC, and upon approval, a Brandon University Research Ethics Certificate will be issued. Ethical oversight will be assumed by the BUREC and the ethics certificate shall be subject to BU and BUREC policies and procedures.

5.0 TIME FRAME AND REVIEW PROCEDURES

It is the responsibility of the researcher to allow sufficient time for review in advance of the anticipated project start date in consideration of BUREC meeting dates and turnaround. Time frame considerations include the following:

5.1 Submission Completeness:

A submission that lacks required items or does not provide sufficient detail for review will be returned to the researcher for completion and resubmission.

5.2 Ethical Complexities:

A submission involving ethical issues that necessitates further consideration by BUREC may require time for consultation, revision, and/or committee discussion at more than one scheduled meeting.

5.3 Type of Review Required:

The level of review (Full or Delegated) will affect the review time frame. **Provided that no additional time is needed because of submission incompleteness or ethical complexities**, the guidelines for review timing are as follows:

a) Full Review:

The researcher must submit the complete application electronically to the Research Office 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 not be reviewed until the subsequent scheduled BUREC meeting. The researcher will normally be notified of the outcome of the BUREC review within five (5) working days. In cases of Full Review, the review process will produce one of the following three outcomes:

- ethically acceptable as is;
- return to researcher for further information and/or revision; or
- unacceptable, researcher to revise and resubmit.

Where minor ethics submission changes are required by BUREC, the researcher 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; which shall be done at the next scheduled meeting for which the deadline has not passed. Once approved, the Chair shall issue a certificate indicating ethics approval for the research. Any changes to a submission will be documented and kept on file.

b) Delegated Review:

The researcher submits the complete application electronically to the Research Office anytime for review by the BUREC Chair and two BUREC members. The researcher will ideally be notified within fifteen (15) working days from the date of acknowledged receipt of the application. If the reviewers decide that Full Review is required, the procedure reverts to Full Review, as described above, and the submission will be considered at the next scheduled BUREC meeting for which the deadline has not passed. In cases of Delegated Review, the review process will produce one of the following four outcomes:

- ethically acceptable as is;
- return to researcher for further information and/or revision;
- recommended for Full Review; or
- unacceptable, researcher to revise and resubmit.

Where minor ethics submission changes are required by the Delegated Reviewers, the researcher 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 all appointed Delegated Reviewers or the full Committee. Once approved, the Chair shall issue a certificate indicating ethics approval for the research. Any changes to a submission will be documented and kept on file.

5.4 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.

5.5 Ethics Certification:

Once BUREC has approved the ethics submission, a BU Research Ethics Certificate will be released to the researcher. Ethics approval is granted for a maximum of (5) years with the continuing research ethics review requirement of an Annual Progress Report (see Section 6.0). Projects continuing beyond five years will require a renewal application in each year the project is continuing, and must be submitted prior to the certificate expiration. Renewal applications are subject to current policy/procedures, and revisions may be required to ensure compliance. The BUREC Chair, or designate, is given the discretion to decide whether a renewal application is approved or requires further BUREC review.

No human participatory research shall begin until the researcher has received a signed ethics certificate from BUREC.

6.0 CONTINUING RESEARCH ETHICS REVIEW

Continuing research ethics review is a requirement of the TCPS2 and an approved ethics submission is subject to ongoing monitoring throughout the life of the project. At minimum, continuing ethics research review shall consist of an Annual 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 continual research ethics review is required in accordance with a proportionate approach to review and level of risk. **Failure to fulfill the continuing research ethics review requirements is considered an act of non-compliance and may result in the suspension of active ethics**

certifications; refusal to review and approve any new research ethics submissions; and/or others as outlined in BUREC Non-Compliance Policy and Procedures. Types of continuing research ethics review include, but are not limited to:

6.1 Annual Reports:

Annual Reports are to be submitted to BUREC within one month of the anniversary of the approval date. The faculty supervisor is responsible for ensuring that student Principal Investigators submit Annual Progress Reports as outlined above. The Annual Progress Report form is available from the Research Office website.

6.2 Final Reports:

Final Reports are 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 within one month of completion/termination. Students must remember to submit their reports prior to leaving the University. The faculty supervisor is responsible for ensuring that student Principal Investigators submit a Final Report as outlined above. The Final Report Form is available from the Research Office website.

6.3 Unanticipated Issue/Event Reports:

Unanticipated Issue/Event Reports are to be submitted **WITHOUT DELAY** to BUREC. An unanticipated issue or event is an issue 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 researcher 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. The Unanticipated Issues and Events Report form is available from the Research Office website.

6.4 Amendment to a Previously Approved Ethics Submission:

Amendments to an Approved Ethics Submission are submitted to BUREC for review and approval, prior to implementation. The BUREC Chair will determine whether additional review is required, and if so, what type. Amendment to an Approved Ethics Submission form is available from the Research Office website. The BUREC Chair reviews and approves all amendments to an approved research submission unless there are substantive changes that warrant a new review or there is an increase in the level of risk, which would result in the initiation of a Full Review.

6.5 Material Incidental Findings Report:

An "incidental finding" is a discovery about research participants or prospective participants that is made in the course of research, but is outside the objectives of the research study. To determine whether an incidental finding is material, expertise relevant to the finding is required. If researchers do not have such expertise, and are unsure of how to interpret the findings or are uncertain whether findings are material, they should seek expertise relevant to the finding and/or refer to professional practices and standards. Incidental findings would be considered material if they have all three of the following key determinants: analytical validity; potential significance; and actionability. The researcher must first determine whether material incidental findings are reasonably foreseeable. If they are so, a management plan must be included with the original application. If material incidental finds are not reasonably foreseeable and/or in the event of an unexpected discovery of incidental findings, the researcher shall report the findings to

the BUREC, and develop a management plan for REB approval prior to implementation. For more information, refer to the *How to Address Material Incidental Findings – Guidance in Applying TPCS2 (2018) Article 3.4.*

7.0 RESEARCHER

7.1 Researcher 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 an application to BUREC (Principal Investigator only).

c) not undertake any project involving human participants that requires review without obtaining the necessary approval;

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

e) disclose in their proposals any real, potential or perceived conflicts of interest regarding their relationship with potential participants or regarding the potential uses of the research findings;

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

g) submit Amendment to Approved Ethics Submissions to BUREC for review and approval, prior to implementation;

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 and Event Reports WITHOUT DELAY to BUREC via the Research Office;

k) submit Annual Progress Reports to BUREC via the Research Office for all approved ethics submissions. Certain projects may require more frequent progress reports and/or ongoing monitoring;

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

m) submit a new ethics 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 the Research Office 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 Proposal Preparation:

Before preparing a proposal, researchers should thoroughly read the BUREC Policies and Procedures and familiarize themselves with the TCPS2 which can be found on the Research Office website. Additionally,

all required forms and templates can be downloaded for completion for electronic submission. The following items are to assist researchers in preparing and submitting their ethics applications:

a) All applicable sections of the BUREC Application must be completed or labeled "n/a";

b) The researcher 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 are 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 researcher must disclose in the submission any potential conflicts of interest that may arise in their relationships with participants and/or in the potential uses of the findings;

e) Copies of all research instruments should be attached, for example, questionnaires, surveys, and interviews. Where the research is qualitative and involves emergent design, the researcher 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. Please 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 proposal must include a participant written consent form, or an explicit method of otherwise obtaining and documenting informed consent. Where a researcher considers a consent form impossible, inadvisable, or unnecessary, they must demonstrate to BUREC how this will be done. See TCPS2, Chapter 3, for complete details on the consent process;

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

i) An incomplete proposal received by BUREC will be returned for resubmission when complete;

j) Researcher may consult with the Research Office and/or the BUREC Chair, if they are uncertain what information is required or how the proposal preparation guidelines apply to their project.

k) The proposal 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.

8.0 BRANDON UNIVERSITY RESEARCH ETHICS COMMITTEE (BUREC)

8.1 BUREC Responsibilities:

It is the responsibility of BUREC to:

a) establish and maintain policies and procedures for the ethical conduct of human participatory research. These must include the TCPS2, the BUREC Policies and Procedures, and should also include accepted disciplinary guidelines relevant to the nature of the project.

b) nominate a Chair who has the necessary knowledge of and experience with TCPS2, all applicable University policies and procedures, and the administrative responsibilities of BUREC;

c) approve, propose modifications, or terminate any proposed or ongoing ethics research conducted by members of, or within, Brandon University under the guidance of the TCPS2 and BUREC's policies and procedures;

d) ensure that appropriate mechanisms exist to inform researchers of these Policies and Procedures;

e) provide consultation to researchers on human ethics matters;

f) provide periodic opportunities for education on human participants' ethics to its own members and to members of the University's research and scholarly community;

g) disclose any real, potential or perceived conflicts of interest regarding any relationship to researchers (and team members) who have submitted ethics applications;

h) regularly review these Policies and Procedures, and recommend any necessary policy changes for Senate approval;

i) in the event of an ethics appeal at The University of Winnipeg, will serve as an appeal body, under the terms of a joint appeal agreement between Brandon University and The University of Winnipeg; and

j) in situations of non-compliance, issue the appropriate course of action and penalty.

8.2 BUREC Chair Responsibilities:

In addition to such other responsibilities as may be delegated to the BUREC Chair, they are responsible for:

a) having sound knowledge of and experience with the TCPS2, all applicable University policies and procedures, and any other relevant human ethics information;

b) reviewing all proposals received by the BUREC, whether for Full or Delegated Review;

c) signing ethics certificates, once the application is approved;

d) appointing an Acting Chair from the BUREC membership, when away from the university;

e) making initial decisions regarding an application's eligibility for Delegated Review;

f) reviewing and approving minimal risk amendments to previously approved ethics submissions on behalf of BUREC;

g) conducting any aspects of ongoing review delegated to the Chair by BUREC;

h) communicating with researchers as required concerning their ethics applications and consulting with BUREC when required;

i) ensuring that BUREC meets at reasonable, scheduled, publicized times;

j) appointing ad hoc BUREC members as required;

k) participating in BUREC and University ethics-educational undertakings; and

l) ensuring that any concerns arising with BUREC policies and procedures are noted and brought forward for discussion at the BUREC policy review meeting.

8.3 BUREC Composition:

All BUREC members are to be appointed by the Senate Research Committee. BUREC membership shall include:

- Chair, to be nominated by and from members of BUREC for a one-year renewable term;
- One assistant professor, associate professor, full professor or P.A. (II, III, or IV) from the Faculty of Education;
- One assistant professor, associate professor, full professor or P.A. (II, III, or IV) representative from the Faculty of Health Studies;
- One assistant professor, associate professor, full professor or P.A. (II, III, or IV) representative from the Faculty of Arts;
- One assistant professor, associate professor, full professor or P.A. (II, III, or IV) representative from Faculty of Science;
- One representative from the Library and may also include one representative from Student Services P.A. (II, III or IV);
- One Brandon University representative, normally a faculty member, experienced in Indigenous research;
- One community representative who has no affiliation with Brandon University; and
- One member who is knowledgeable in relevant law, who is not the institution's legal council or risk manager.

As per the TCPS2, the following additional requirements shall be satisfied among members, who reflect gender diversity:

- two (2) members have expertise in relevant research disciplines, fields and methodologies covered by BUREC;
- one member is knowledgeable in ethics;

8.4 BUREC Administrative Matters:

a) Meeting quorum shall be 50% plus one of the membership. When there is less than full attendance, decisions shall be adopted only when the members in attendance at that meeting have the specific experience, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.

b) BUREC members shall come to meetings prepared with comments, having thoroughly read the agenda package.

c) BUREC members who have three or more meeting absences in a year, for which regrets and the reasons therefore are not conveyed, will automatically be considered to have resigned from the committee.

d) BUREC members who are unable to attend a meeting are encouraged to submit written comments concerning proposals to be reviewed at that meeting.

e) Minutes of BUREC deliberations shall be kept. For proposal reviews, the minutes shall document clearly the decisions, any dissents and the reasons for them. Although proposal deliberation minutes are generally confidential, such minutes (or relevant portions of them) shall be accessible to all BUREC members, authorized administrative assistants, the Vice-President (Research and Graduate Studies), and the appeal body.

f) It is expected that the University continue to provide BUREC with sufficient administrative assistance to ensure that adequate record-keeping is maintained, and that proposals are processed administratively in a fashion adequate to the needs of BUREC's work.

9.0 BUREC APPEALS

A researcher 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 Policy and Procedures* should be referenced. A request for appeal should be submitted within 30 days of BUREC's decision.

Decisions of BUREC may be appealed and such requests 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 the Research Office 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 and 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 PUBLICALLY DECLARED EMERGENCY

BUREC Review during Publicly Declared Emergencies:

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.

Procedures:

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 the Office of Research Services during regular business hours. The Chair of BUREC may consult with the Vice-President (Research and 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 board or a delegated committee.

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 to the Vice-President (Research and Graduate Studies) as per the Brandon University Emergency Procedures Manual (https://www.brandonu.ca/vp-finance/files/EmergencyProceduresManual.pdf). The Vice-President (Research and 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 the 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 the BUREC in order to review the emergency process and improve or revise it, if necessary.

References:

- *"Skills Development" exemption adopted and adapted from University of Waterloo.*

Revisions Approved by BUREC – August 2023
Revisions Approved by Senate Research Committee – October 2023
Revisions Approved by Senate – November 21, 2023 (Updated December 19, 2023)