MANITOBA INSTITUTE OF TRADES & TECHNOLOGY

POLICY:		POLICY NUMBER:
Ethical Conduct for Research Involving Human Subjects		**R-5**
		PREVIOUS/REPLACES: **Ethical Conduct for Research Involving Human Subjects**
APPROVED BY: **Executive Council**	EFFECTIVE DATE AS OF: **May 4, 2021**	PRIOR VERSIONS: **December 5, 2018**

1. Policy Statement:

Purpose:

To establish the expectations and principles for the ethical conduct of research involving human subjects at the Manitoba Institute of Trades and Technologies (to be referred to as MITT or Institute).

This policy has been created to ensure awareness of ethical considerations for research involving humans and to ensure that the rights and responsibilities of the Institute, researchers and human subjects are known, and appropriate steps are taken to protect or meet them.

Statement:

MITT believes that the use of human subjects is a necessary and an important component of research in many fields. It expects that any research involving human subjects, when performed at or through the Institute, will be conducted to meet the ethical standards established in the *Tri-Council Policy Statement – Ethical Conduct for Research Involving Humans – 2018* (TCPS2)[1].

MITT mandates that all research involving human subjects performed at or through MITT by MITT researchers, students, employees and volunteers, or non-MITT researchers, institutions or organizations, to be reviewed and approved by the MITT Research Ethics Board (REB) prior to the research being initiated. All such research will be designed and conducted to ensure respect for persons, concern for welfare, and justice.

Principles:

1.1 The REB is authorized to safeguard the rights and well-being of human subjects of research by applying the Principles and guidelines of TCPS2 including reviewing submissions made to the REB, requiring changes in protocols, receiving reports on approved research, and ordering the immediate cessation of research activities in the event of a perceived, potential or actual breach of approved research protocols.

[1] This Policy was developed and is interpreted and implemented by the *Interagency Advisory Panel on Research Ethics*, which was established by Canada's three federal funding agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC), and the Social Sciences and Humanities Research Council (SSHRC). It can be found at https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html.

The Principles listed in this section encapsulate the position of MITT on research involving human subjects and derive from and follow the order of the TCPS2.

1.2 All REB members and researchers shall complete the TCPS2 tutorial[2] and provide a certificate to the REB Administrator prior to submitting any research proposal to the REB, with the exception of students conducting research as part of a Curriculum-Based Research project, who are required to complete research ethics training that is offered as part of their course.

1.3 MITT is committed to protecting the rights, health, safety and well-being of human subjects of research by ensuring the highest standards of ethics are utilized in the design, conduct, analysis and reporting of research involving human subjects. It subscribes to three core principles:

1.3.1 Respect for Persons – all humans have intrinsic value and must be treated with dignity and respect. Participant autonomy shall be considered in the research design and due consideration will be given to factors that could diminish participant autonomy and on respecting the dignity of those with diminished autonomy.

1.3.2 Concern for Welfare – welfare is concerned with the quality of a persons' life and experiences and encompasses factors such as physical, mental and spiritual health; and physical, economic and social circumstances. The impacts of the proposed research on these factors must be considered, along with safeguarding the privacy and the control of personal information, ensuring the treatment of biological materials is in accordance with the consent of the donor, and determining the possible impacts of the research on the welfare of the person's friends, family or other groups.

The research must be designed to eliminate and/or minimize any risks to participants, to maximize any benefits and to provide accurate and accessible information. Assessment of the risks of negative impacts such as stigmatization or discrimination of the proposed research, where applicable, must be done through consultation with groups who may be affected by the research.

1.3.3 Justice – this principle relates to treating people with fairness and equity. Fairness means treating all people with equal respect and concern. Equity means distributing the risks and benefits of participation in the research in such a manner that no section of the population is disproportionately at risk of harm or harmed, by the research nor denied the benefits of the knowledge generated by the research.

1.4 MITT is committed to ensuring that research is reviewed and approved by the REB when required.

1.4.1 Review by and approval of the REB prior is required prior to commencement of research for research activities that:

A) Involve living human participants whose data or responses to research interventions, interactions, stimuli or questions, are relevant to the research question.

B) Involve human biological materials sourced from living or dead individuals, including human embryos, fetuses, fetal tissue, reproductive material and stem cells.

[2] https://ethics.gc.ca/eng/education_tutorial-didacticiel.html .

1.4.2 Research involving the secondary use of data obtained from human subjects in previous projects may require REB review and approval.

1.4.3 Research is exempt from REB review when the:

A) Research relies on publicly available information that is legally accessible and appropriately protected by law.

B) Research comprises observation in public places where there is no reasonable expectation of privacy, there are no staged interventions, no direct interaction with those being observed, and no identification of individuals in the dissemination of results.

C) Research involves the secondary use of anonymous data or biological materials.

1.4.4 Certain activities do not require REB review, including:

A) Methods such as processes, studies, testing and evaluations used exclusively to improve MITT's educational programs or services and the quality or performance of its normal educational activities or management functions, typically considered to be Institutional Research, unless these methods are not within the mandate of the Institute, the deployment of these methods is not a condition of employment or training for those employing the methods, or the results are intended to be used for research purposes at any time.

B) Creative practice activities (*e.g.* musical performance, theatre), unless there is an intervention with the audience intended to solicit a response that will be analyzed to answer a research question.

1.4.5 Where the researcher is unclear if a REB review is required, it is the responsibility of the researcher to communicate with and obtain a written opinion from the Chair of the REB whether or not a REB review and approval is required.

1.4.6 The REB shall review the ethical implications of the methods and design of the research, taking into account any scholarly or peer reviews that may have been conducted and the relevant disciplinary standards.

1.5 MITT is committed to ensuring that the REB uses the Proportionate Approach in its deliberations, that is that it considers the foreseeable risks to participants along with the potential benefits and ethical implications of the research.

1.5.1 The goals of the REB review are to:

A) Protect participants from being exposed to unnecessary or avoidable risks,

B) Determine that the potential benefits, on the whole, outweigh any foreseeable risks, and

C) Assist research to be conducted in accordance with the core principles of the TCPS2.

1.5.2 Risk assessment is based on two factors (Probability and Magnitude) and results is two outcomes (Minimal Risk and Above Minimal Risk):

A) Probability assesses the likelihood that participants will suffer harm as a result of their participation, and

B) Magnitude assesses the harm, minor or major, that may be experienced by participants including physical, psychological or social harm, or by those in their communities as a result of their participation in the research.

C) Minimal Risk is where the participants can be expected to judge that the probability and magnitude of harm is no greater than what they would expect to encounter in those aspects of their everyday lives that relate to the research.

D) Above Minimal Risk is where the participants can be expected to judge that the probability and/or magnitude of harm is greater than what they would expect to encounter in those aspects of their everyday lives that relate to the research.

1.5.3 Research will be assessed for the probability and magnitude of risk related to physical harm, psychological harm, economic harm and social harm to participants or their communities.

1.5.4 Research will be assessed for benefits including direct benefits to participants, indirect benefits to groups to which participants belong, and advancement and/or application of knowledge.

1.5.5 Although not a primary concern of the REB review process, risks to researchers, including students, will be kept in mind and the REB can refer research that is potentially high-risk for researchers and students to other Institute authorities, such as Health & Safety, for action.

1.6 MITT is committed to ensuring that the consent of individuals to be participants in research follows the principles and process of consent to the greatest extent possible.

1.6.1 The Principles of Consent are:

A) Free/Voluntary – participants shall volunteer to participate without any coercion or pressure to consent or being unduly influenced by incentives that may impair their judgement with regards to the risks and benefits of participation. The decisions of prospective participants to not participate or of participants to withdraw their consent for any reason must be respected. Researchers should never conduct research on subjects who have refused to participate.

B) Informed – researcher must provide full disclosure and ensure prospective participants have an understanding of the purpose of the research, along with identified risks and potential benefits. Participants must be given sufficient time to make a decision and the opportunity to ask questions and seek clarification about the research.

C) On-going – when new information arises about the researcher that may affect participants, researchers must inform them. If participants believe the new information may impact their decision to participate, they must be asked if the wish to continue participation in or withdraw from the study. If consent is given, participants can still withdraw.

D) “Incidental findings”, unanticipated discoveries made in the course of research that are outside the scope of the research, may be encountered. If they are material incidental findings, that is interpreted as having significant welfare implications for the participants, researchers have an obligation to disclose to the participant. However, disclosure should not be taken lightly, and proper consideration must be taken to minimize needless participant anxiety, unnecessary costs or burdensome follow-up. Colleagues and the REB should be consulted if there is unsureness or lack of clarity about the materiality of the incidental findings or how to disclose to the participant.

1.6.2 Recruitment of subjects must be done using accurate and truthful information that does not create a false impression of study conditions and/or foreseeable risks and/or potential benefits. All recruitment material, prior to posting or distribution, shall indicate the study has received REB approval.

1.6.3 Information shall be provided prospective participants in language they can understand, including:

A) They are being invited to participate in a study/research project and an assurance that this invitation abides by the Principles of Consent (1.6.1),

B) The purpose of the research, identities of researchers and funders or sponsors, anticipated duration and nature of participation and what they will be expected to do,

C) Foreseeable risks and potential benefits to participation,

D) The possibility of commercialization of research findings along with any actual, potential or perceived conflicts of interest of researchers, their institutions or sponsors,

E) How the research results will be disseminated and whether participants will be directly identified or not,

F) The identity and contact information of a designated representative who is qualified to explain scientific or scholarly facets of the study to participants,

G) The identity and contact information of the appropriate person(s) independent of the research team whom participants can contact to discuss possible ethical issues in the research,

H) The information to be collected about participants and the rationale; who will have access to the identifying information; how confidentiality of the data will be protected; the anticipated use of the data; and who may have a duty to disclose collected information, and to whom such disclosures could be made,

I) Payments such as incentives for participation, reimbursement of participation-related expenses and compensation for injury,

J) That by consenting, participants have not waived any rights to legal recourse in the event of research-related harm,

K) That in clinical trials, information on stopping rules and when participants may be removed from the trial by researchers.

1.6.4 If researchers wish to exclude any of the information in 1.6.3, they must provide a rationale to the REB and the REB will make the final determination on whether the information should be included.

1.6.5 The REB can require additional information to be included in the informed consent process.

1.6.6 No research on a participant shall be conducted prior to the participant, or authorized third party, having provided their consent.

1.6.7 Critical inquiry, that is the analysis of social structure or activities, political policies or other social phenomena, does not require permission to conduct the research from the organization being studied. Participants must be informed of any foreseeable risks posed by their participation.

1.6.8 REBs should not prohibit research that may be controversial, unpopular or looked upon with disfavour by communities, governments or organizations either nationally or internationally.

1.6.9 MITT recognizes alteration to consent requirements may be justifiable from time to time.

A) Alteration requests must be approved by the REB and meet all of the following criteria:

a. The research involves no more than minimal risk to participants.

b. The alteration is unlikely to affect the welfare of participants,

c. Carrying out the research and addressing the research question is impossible or impractical, due to the research design, if the consent of participants is required prior to their participation.

d. The precise nature and extent of the proposed alteration is clearly defined,

e. A plan to provide a debriefing, whenever possible, practical and appropriate, which offers participants the opportunity to refuse consent and/or request withdraw of data and/or human biological materials.

B) Alterations to consent requirements may be requested for research involving partial disclosure or deception, studies where seeking prior consent could prejudice the data collected or potentially cause undue harm to participants, use of participants in vulnerable circumstances, and population and public health research.

C) The TCPS2 addresses the issue of “Consent for Research in Individual Medical Emergencies” and indicates that research can be conducted on participants without their prior consent only if, subject to all applicable legal and regulatory requirements, it deals with the emergency needs of the individuals involved, and then only in accordance with criteria the REB has established in advance of such research. If this becomes a field of research for MITT researchers or external researchers studying MITT, this section will have to be amplified in order to understand and comply with TCPS2 guidelines.

1.6.10 MITT is committed to ensuring that the decision-making capacity of potential participants is thoroughly assessed and considered as part of the consent process.

A) "Capacity" refers to the ability of potential participants to understand relevant information presented to them about the project and grasp any potential consequences of their participation or non-participation. Individuals may lack decision-making capacity temporarily or permanently.

B) The capacity to consent may change as a result of the complexity of the choice being considered, the circumstances in which the decision is to be made, and changes in the potential or actual participants condition.

C) For individuals who lack the capacity to consent at a given moment in the consent process, the REB shall as a minimum ensure that:

a. To the greatest extent possible, researchers involve these individuals in the decision-making process.

b. Consent is sought and maintained from authorized third parties with due consideration for the best interests of the individual,

c. The authorized third party is not the researcher or member of the research team,

d. The researcher demonstrates that the research question cannot be addressed without the participation of the identified group;

e. The research, whether minimal risk or above minimal risk, will be of direct benefit to the participant; or the research will provide benefits to other persons in the same group that is the focus of the research, while exposing the participant only to minimal risk and minimal burden with protections in place to safeguard the welfare of the participant throughout the participation in the research.

f. If consent to participate in research was granted by a third party and a participant regains or acquires the capacity to make an autonomous informed decision, the researcher shall immediately seek the consent of the participant as a condition of the participant remaining in the study.

g. When authorized third parties provide consent for individuals to participate in research and the individuals have some capacity to understand the significance of the research, the researcher shall determine the wishes such individuals with respect to their participation and shall not include them in the research if they dissent.

D) When individuals sign research directives that indicate their preference concerning their future participation in research in the event they lose the capacity to consent, researchers and authorized third parties should be guided by these directives during the consent process.

1.6.11 MITT mandates that the consent of all individuals agreeing to participate in research is documented. Recognizing that the provision of consent may take different forms in different cultures and contexts, documentation may include, but not be limited to, signed consent forms, video or audio recordings of consent, oral consent, verbal agreement, a handshake, or records maintained in field notes. For consents not recorded in writing, the procedures used to seek consent must be documented.

1.7 MITT is committed to ensuring that the principle of justice is manifested in research design and execution and evidenced by fairness and equity in the engagement, selection and treatment of participants.

1.7.1 Researchers should be inclusive in the selection of participants, taking into account the scope and objectives of their study. Individuals shall not be excluded on the basis of culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion related to the research question.

A) Women shall not be inappropriately excluded from participating in research solely on the basis of their gender, sex or reproductive capacity or because they are pregnant or breastfeeding.

B) Children shall not be inappropriately excluded from participating in research solely on the basis of their age or developmental stage.

C) Elderly shall not be inappropriately excluded from participating in research solely on the basis of their age.

D) Individuals who lack the ability to consent at a given moment in the consent process shall not be inappropriately excluded from participation in research. Researchers and REBs shall ensure that the participation is designed and executed in accordance with Principle 1.6.10C).

E) Individuals of groups who are vulnerable in the context of research due to their circumstances should not be inappropriately included or automatically excluded from participation in research on the basis of their circumstances.

1.7.2 Researchers should consider ways to ensure there is an equitable distribution of research results and benefits. This could include making research results such as publications, reports and products available to host institutions or organizations which are best suited to act as repositories of these results and disseminators of the results within the participating communities.

1.8 MITT is committed to ensuring that the privacy of participants and the confidentiality of participant information is protected in accordance with TCPS2 guidelines.

1.8.1 Researchers have an ethical duty to and shall safeguard information entrusted them and not misuse or wrongfully disclose it. MITT shall support its researchers in maintaining promises of confidentiality.

A) Researchers are required to maintain their promise of confidentiality to participants to the extent permitted by ethical principles and/or law.

1.8.2 Researchers shall describe the steps they are taking to meet confidentiality obligations and explain any foreseeable disclosure requirements:

A) In their applications submitted to the REB, and

B) During the consent process when recruiting individuals to be participants.

1.8.3 Researchers shall describe the measures proposed to safeguard the information for its full life cycle, including its collection, use, dissemination, retention and/or disposal.

A) The REB shall determine the adequacy of the proposed measures by assessing factors such as:

a. The type of information to be collected,

b. The purpose for which the information will be used and any secondary use of identifiable information,

c. Limits on the use, disclosure and retention of information,

d. Risks to participants in the event of a breach of data security, including the re-identification of individuals,

e. Appropriate safeguards for the full life cycle of the information,

f. Any recording of observations that may allow for the identification on individual participants,

g. Any anticipated uses of personal information from the research, and

h. Any anticipated linkage of data collected in the research with other public or personal data about participants.

1.8.4 MITT shall establish appropriate physical, administrative and technical institutional security safeguards to protect data over the life cycle of the information.

1.8.5 Secondary use of identifiable information in circumstances where researchers have not obtained consent from participants for such use shall only be permissible when researchers have satisfied the REB that:

A) Identifiable information is essential to the research,

B) Use of the identifiable information without the participant's consent is unlikely to adversely affect the welfare of the participant,

C) Appropriate measures will be taken by the researchers to protect the privacy of individuals and safeguard any identifiable information,

D) The researchers will comply with any known preferences previously expressed by individual participant about any use of their information,

E) It is impossible or impractical to seek consent from individuals to whom the information relates, and

F) The researchers have obtained any other necessary permissions for secondary use of information for research purposes.

1.8.6 When research relies exclusively on the secondary use of non-identifiable data, researchers are not required to seek participant consent but are required to seek REB review.

1.8.7 When the REB has approved the use of secondary identifiable data without the requirement to seek consent, researchers proposing to contact individuals for additional information shall seek REB approval of the plan for making contact prior to making contact.

1.8.8 Prior to engaging in data linkage with information that is not exclusively publicly available information, researchers shall obtain REB approval by describing the data that will be linked and the likelihood that identifiable information will be created through the linkage.

A) If identifiable information is or likely to be produced, researchers shall satisfy the REB that:

a. The data linkage is essential to the research, and

b. Appropriate security measures will be implemented to safeguard information.

1.9 MITT is committed to ensuring that a REB is established, functioning and adequately resourced to fulfill its duties as enumerated in this policy.

1.9.1 The REB is independent in its decision-making and is established by and accountable to the President and CEO of MITT.

A) The REB is granted the mandate to review the ethical acceptability of research involving human subjects on behalf of MITT. This mandate includes:

a. The ability to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects.

b. Review and approve research proposed and conducted under the auspices or within the jurisdiction of MITT, including research by MITT affiliated researchers and students or research on MITT by external researchers from other institutions and organizations.

B) The REB shall consist of a minimum of five and a maximum of eleven members, including men and women, none of whom shall be MITT senior administrators, where at least:

a. Two members have expertise in the disciplines, fields and methodologies covered by the REB,

b. One member is knowledgeable in ethics,

c. One member is knowledgeable in the relevant law (but not MITT's legal counsel or risk manager). This is mandatory for biomedical research and optional, but advisable, for other disciplines, and

d. One member of the community with no affiliation with MITT. One community member shall be appointed for every four or more MITT members.

C) Procedures for appointing members, maintaining membership, renewing members, replacing members and removing members are established by MITT outside of this policy.

D) Each member shall be appointed in only one area of expertise.

E) Members shall be appointed for a two- or three-year term to ensure balance, continuity, diversity of opinion and dissemination of knowledge gained while a REB member throughout MITT.

F) MITT may appoint substitute members meeting the criteria above to replace regular members who are unable to perform their duties due to illness or unforeseen circumstances.

G) MITT, at its discretion, may appoint research ethics administration staff as non-voting members of the REB where they have the requisite experience, expertise and knowledge.

H) The REB may consult *ad hoc* advisors with specific knowledge and expertise that is lacking within its members, in order to provide a competent review of a proposal.

I) MITT recognizes that the REB Chair plays an integral role in the success of the REB and is responsible for ensuring that the REB review process is conducted in accordance with this policy.

a. The Chair shall provide annual status reports to the President and CEO summarizing the activities, decisions and operations of the REB.

J) The MITT REB shall meet regularly to discharge their responsibilities and to provide educational opportunities to enhance REB knowledge and operations. Review meetings shall be held not less than eight times per calendar year nor with no more than two months between meetings. Meetings shall be face-to-face where possible.

K) A quorum shall consist of at least five members meeting the requirements in Principle 1.9.1B) and able to competently provide adequate research ethics reviews for the proposals under consideration.

L) REB Review Meeting and Proposal Submission dates shall be posted on the Institute's REB website at least two months in advance of the scheduled meeting date.

1.10 MITT mandates all proposals for REB review are submitted and reviewed in accordance with the following high-level process. A detailed review procedure is available to provide more in-depth guidance to researchers.

1.10.1 All research involving the use of human subjects must be submitted using the REB Proposal Template for review and approval prior to the commencement of any recruitment of research participants, access to data, or collection of human biological materials.

1.10.2 The REB shall assess the foreseeable level of risk that the proposed research poses to participants and determine the appropriate level of research ethics review, delegated or full REB.

A) As a default, all research using human subjects shall be subject to a full REB review, that is a review conducted by all REB members.

B) The REB, at its discretion and where the research poses minimal risk to participants, may proceed with a delegate review in which the ethics review is delegated to an individual or individuals who are voting members of the REB. Delegates may call on other members or refer the proposal back to the full REB if they believe full REB review is needed. In the case of a negative decision by a delegate or delegates, the proposal shall be referred to the full REB for review and endorsement of the decision prior to the decision being communicated to the

researcher.

C) Student course-based research activities, intended solely for pedagogical purposes and not conducted as part of an instructor or staff member's research project, can be delegated to non-REB members at the department or school level. These delegated reviewers must have the experience, knowledge and expertise comparable to those expected of REB members.

1.10.3 The REB shall accommodate reasonable requests from researchers to be present during the review of their research proposals. However, researchers shall not be present during the decision-making process.

1.10.4 The REB shall provide reasons to the researcher for considering a negative decision and provide the research with an opportunity to respond prior to making a final decision.

1.10.5 When possible, REB members should seek to reach consensus where a majority of members approve a research proposal and a minority consider it unethical.

1.11 MITT mandates that there shall be a continuing research ethics review for research projects involving human subjects. The frequency of such reviews can be proposed by the researcher or established by the REB on a project-by-project basis.

1.11.1 Multi-year project protocols are approved for a maximum of one year and can be renewed on the submission of an annual status report prior to the anniversary date of the original approval. The status of data collection should be clearly specified and any changes to the previously approved proposal identified. If no substantive changes have been made, the REB Chair can issue a one-year extension. Substantive changes may require re-submission of the revised proposal to the REB for review and approval.

1.11.2 Projects lasting less than one year shall submit an end-of-study report.

1.11.3 Researchers shall provide prompt notification to the REB on the completion of their project.

1.11.4 Researchers reporting to the REB any unanticipated issue or event that could increase the risk for, or has elicited negative reactions from, participants or has other ethical implications that may affect participant welfare.

1.11.5 Researchers submitting to the REB in a timely manner any changes to their procedures that affect interactions with participants, and any substantive changes to their originally approved research, for REB review and determination of ethical acceptability of those changes.

1.12 MITT mandates that the REB prepare, maintain and make available accurate and comprehensive records of meeting minutes reflecting attendance and REB decisions, projects submitted for review and their associated documents, and reasons for negative decisions.

1.12.1 The REB shall notify researchers in writing of the decision made on their proposals and the reasons for the decision. Decisions shall be:

A) Approved as submitted;

B) Approved with suggestions for minor changes;

C) Approved with conditions (that must be met before final approval is granted);

D) Deferred, pending receipt of additional information or major revisions;

E) Not approved.

For approvals and deferred decisions researchers may accept proposed modifications, offer counter-proposal or provide the required information or revisions. This iterative process can continue until agreement on an ethically acceptable form of the proposal is reached. Ideally, the REWB should specify criteria that need to be met to enable the Chair to review and grant approval on behalf of the REB.

1.12.2 In the event of a negative decision or a researcher does not agree with the decision of the REB,

A) Researchers have the right to request prompt reconsideration of decisions affecting research and REBs have an obligation to provide such reconsideration, and

B) If the REB and researcher cannot reach agreement through reconsideration, the researcher can appeal the REB decision once the REB has issued the decision. Appeals may only be granted on procedural grounds or when there is significant disagreement in interpretation of TCPS2. The appeal can be refused if the reason for the negative decision is non-compliance with the substance of the TCPS2.

a. MITT shall establish an appeal committee with members reflecting the range and expertise of the REB, but not members of the REB whose decision is under appeal. The appeal committee could comprise MITT employees or a REB from another institution with which MITT has a cooperative relationship.

b. The appeal committee has the authority to review the original decision and approve, reject or request modifications to the research proposal. Its decision on behalf of MITT is final.

1.13 TCPS2 contains a section on “Research Ethics Review during Publicly Declared Emergencies” (Chapter 6, Section D) that is not relevant to the type of research engaged in at MITT. If MITT anticipates or plans to participate in this type of research, this policy will be updated as appropriate to account for this activity.

1.14 MITT is committed to ensuring that actual, potential or perceived conflicts of interest in research using human subjects are identified, reported and addressed.

1.14.1 MITT’s Conflict of Interest policy is applicable to research.

1.14.2 As a large institution with a variety of activities, there is a high probability that there will be conflicts of interest at times between two substantial institutional obligations. MITT shall report any actual, potential or perceived conflicts of interest it may have that may affect research to the REB. The REB shall determine if any given conflict of interest should be disclosed to prospective participants as part of the consent process.

1.14.3 REB members shall disclose to the REB any actual, potential or perceived conflicts of interest that they may have in reviewing a research proposal. When necessary, those REB members may be requested to withdraw from the deliberations and decision-making on the research project in question.

1.14.4 REB members may be compensated or provide with honoraria for the work with the REB. Care should be taken to ensure that REB members not be put in a conflict of interest in view of the provision of compensation or honoraria.

1.14.5 Researchers shall disclose in research proposals they submit to the REB any actual, potential or perceived individual or institutional conflicts of interest of which they have awareness and that may affect their research. The REB shall discuss the situation with the researcher and then determine the appropriate measures to be taken to manage the conflict of interest.

1.15 MITT is committed to ensuring that multijurisdictional research involving human subjects that is conducted at MITT by internal or external researchers or by MITT researchers at other institutions is carried out in accordance with this policy.

1.15.1 Any research proposed by external researchers that utilizes MITT's students, staff or resources shall be submitted to MITT's REB for review, feedback and approval.

1.15.2 Any research proposed by MITT to be conducted in any part at non-MITT affiliated Canadian or international sites shall require submission to, review by, and approval from MITT's REB.

A) Such research may also require REB review and approval from the host site. It is the responsibility of the researcher to determine and adhere to the REB standards and procedures of the other institutions and organizations.

B) Researchers shall inform the MITT REB of the rules and ethics review requirements for research involving human subjects at those sites, and the names and contact information for the relevant REB.

C) Research ethics approval from the host site does not exempt a researcher from submitting the research proposal to the MITT REB for review and approval.

D) Research involving human subjects outside of Canada shall, as a minimum, be conducted to the standards of MITT for ethical acceptability. Prospective participants shall be afforded no less protection and respect than what this policy requires.

1.16 MITT is committed to ensuring that research involving human subjects with Indigenous persons or communities, which includes First Nations, Inuit and Métis, shall be conducted in a manner that respects the Indigenous land, knowledge and traditions. Much of the section is abstracted directly from Chapter 9 of the TCPS2. Although it may appear repetitive to other principles in this policy, the principles enumerated in this Principle have been placed within the context of Indigenous peoples, places and communities.

1.16.1 MITT research shall seek engagement with Indigenous communities where research is proposed and is likely to affect the welfare of the community, or communities, to which prospective participants belong. The conditions under which 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, artifacts, traditional knowledge or unique characteristics;

D) Research in which Indigenous identity or membership in an Indigenous community is used as a variable for the purpose of analysis of the research data; and

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

1.16.2 Researchers shall determine jointly with the relevant community the nature and extent of community engagement in a research project and ensure it is appropriate to community characteristics and the nature of the research.

1.16.3 Where a proposed research project is to be conducted on lands under the jurisdiction of a First Nations, Inuit or Métis authority, researchers shall seek the engagement of formal leaders of the community, except as provided under Principles 1.16.5, 1.16.6, 1.16.7.

A) In addition to research ethics review and approval by MITT's REB, review by any responsible community body recognized by the First Nations, Inuit or Métis authority (see Principles 1.15 and 1.16.10) is required prior to recruiting and securing consent of individuals.

1.16.4 Indigenous organizations, including First Nations, Inuit and Métis representative bodies, and service organizations and communities of interest, shall be recognized by researchers and REBs as communities for the purposes of community engagement and collaboration in research undertakings. Where appropriate, these groups may also be recognized through representation of their members on ethical review and oversight of projects.

1.16.5 In instances where agreement to conduct proposed research is not secured from formal leadership for research on First Nations, Inuit or Métis lands, researchers should engage communities process and document measures taken to obtain endorsement from other authorities to enable the REB to review the proposal with due consideration of community authority structures.

1.16.6 In engaging territorial or organizational communities, researchers should ensure, to the extent possible, that they take into consideration the views of all relevant sectors – including individuals and subgroups who may not have a voice in the formal leadership. Groups or individuals whose circumstances make them vulnerable may need or desire special measures to ensure their safety in the context of a specific research project. Those who have been excluded from participation in the past may need special measures to ensure their inclusion in research.

1.16.7 Research involving Indigenous peoples that critically examines the conduct of public institutions, First Nations, Inuit and Métis governments, institutions or organizations or persons exercising authority over First Nations, Inuit or Métis individuals may be conducted ethically, notwithstanding the usual requirement of engaging community leaders.

1.16.8 Researchers have an obligation to become informed about, and to respect, the relevant customs and codes of research practice that apply in the particular community or communities affected by their research. Inconsistencies between community custom and this Policy should be identified and addressed in advance of initiating the research, or as they arise.

1.16.9 When proposing research expected to involve First Nations, Inuit or Métis participants, researchers shall advise MITT's REB how they have engaged, or intend to engage, the relevant community. Alternatively, researchers may seek REB approval for an exception to the requirement for community engagement, on the basis of an acceptable rationale.

1.16.10 Where a community has formally engaged with an MITT researcher or research team through a designated representative, the terms and undertakings of both the researcher and the community should be set out in a research agreement before participants are recruited.

1.16.11 As part of the community engagement process, researchers and communities should consider applying a collaborative and participatory approach as appropriate to the nature of the research, and the level of ongoing engagement desired by the community.

1.16.12 MITT researchers should ensure as much as possible that, where the form of community engagement and the nature of the research facilitate it, the research is relevant to the communities needs, benefits the community participants as well as extends the boundaries of knowledge.

1.16.13 Researchers should endeavour to ensure that research projects support capacity building that enhance the skills of community personnel in research methods, project management, and ethical review and oversight.

1.16.14 Researchers should engage the community in identifying Elders or other recognized knowledge holders to participate in the design and execution of research, and the interpretation of findings in the context of cultural norms and traditional knowledge. Community advice should also be sought to determine appropriate recognition for the unique advisory role fulfilled by these persons.

1.16.15 Researchers and community partners shall address privacy and confidentiality for communities and individuals early on in the community engagement process. The extent to which limited or full disclosure of personal information related to the research is to be disclosed to community partners shall be addressed in research agreements where these exist. Researchers shall not disclose personal information to community partners without the participant's consent.

1.16.16 Researchers should afford community representatives engaged in collaborative research an opportunity to participate in the interpretation of the data and the review of research findings before the completion of the final report, and before finalizing all relevant publications resulting from the research.

1.16.17 In accordance with MITT's Intellectual Property policy, for collaborative research projects, intellectual property rights should be discussed by researchers, communities and institutions. The assignment of rights, or the grant of licences and interests in material that may flow from the research, should be specified in a research agreement (as appropriate) before the research is conducted.

1.16.18 As part of community engagement, researchers shall address and specify in the research agreement the rights and proprietary interests of individuals and communities, to the extent such exist, in human biological materials and associated data to be collected, stored and used in the course of the research.

1.16.19 Secondary use of data and human biological material identifiable as originating from an Indigenous community or peoples is subject to REB review. Researchers shall engage the community from which the data or human biological materials and associated identifiable information originate, prior to initiating secondary use where:

A) Secondary use has not been addressed in a research agreement and has not been

B) Authorized by the participants in their original individual consent; or

C) There is no research agreement; and

D) The data are not publicly available or legally accessible.

Individual consent for the secondary use of identifiable information is required unless the REB agrees that either Principles 1.8.5 or 1.8.6, or Articles 12.3A or 12.4 may apply.

1.16.20 Where research relies only on publicly available information, or on legally accessible information as defined in Article 2.2, community engagement is not required. Where the information can be identified as originating from a specific community or a segment of the Indigenous community at large, seeking culturally informed advice may assist in identifying risks and potential benefits for the source community.

1.16.21 REB review is required where the researcher seeks data linkage of two or more anonymous datasets or data associated with human biological materials and there is a reasonable prospect that this could generate information identifiable as originating from a specific Indigenous community or a segment of the Indigenous community at large.

1.17 MITT is committed to ensuring that qualitative research, which is particular applicable to social sciences and humanities research, is conducted in accordance with this policy.

1.17.1 Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, or access to data.

1.17.2 Researchers shall explain in their research design the proposed procedures for seeking consent and the strategies they plan to use for documenting consent.

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

1.17.4 In some research contexts, the researcher may plan to disclose the identity of participants. In such projects, researchers shall discuss with prospective participants or participants whether they wish to have their identity disclosed in publications or other means of dissemination. Where participants consent to have their identity disclosed, researchers shall record each participant's consent.

1.17.5 In studies using emergent design in data collection, where data analysis and collection can evolve over the course of a research project in response to what is learned in earlier parts of the study, researchers shall provide the REB with all the available information to assist in the review and approval of the general procedure for data collection.

Researchers shall consult with the REB when, during the conduct of the research, changes to the data collection procedures may present ethical implications and associated risks to the participants.

1.18 TCPS2 contains a chapter on "Clinical Trials" (Chapter 11) that is not relevant to the type of research engaged in at MITT. If MITT anticipates or plans to participate in clinical trials, this policy will be updated as appropriate to account for this activity.

1.19 TCPS2 contains a chapter on "Human Biological Materials Including Materials Related to Human Reproduction" (Chapter 12) that is not relevant to the type of research engaged in at MITT. If MITT anticipates or plans to participate in this type of research, this policy will be updated as appropriate to account for this activity.

1.20 TCPS2 contains a chapter on "Human Genetic Research" (Chapter 13) that is not relevant to the type of research engaged in at MITT. If MITT anticipates or plans to participate in this type of research, this policy will be updated as appropriate to account for this activity.

2. Scope:

This Policy applies to all:

2.1. MITT employees who engage in research activities as part of their duties and responsibilities, whether as administrators, clients or as researchers,

2.2. All students of MITT who engage in research delivered through curriculum,

2.3. All volunteers of MITT who engage in research through their activities,

2.4. All clients of MITT when engaging in research projects in collaboration with MITT, and

2.5. Any researcher, institution or organization not legally affiliated with MITT who desires to use MITT students or employees as human subjects in their research or the Institute's name and resources to conduct research involving human subjects.

Non-compliance with this policy in any form by any researcher, internal or external, conducting research using human subjects, is a serious offense and subject to severe penalties, including but not limited to the loss of privileges to conduct research using human subjects and/or disciplinary action.

This Policy does not apply to MITT students, staff, contractors or other persons who are conducting Institutional Research on behalf of the Institute, which is directed to gathering information on the Institute regarding its normal course of operations for the purpose of administering, evaluating, improving or reporting on Institute programs, services, processes and procedures.

3. Procedure:

To be determined after the policy has been endorsed.

4. Administration:

The Vice-President Academic is responsible for ensuring that this policy is adhered to.

5. Review:

This policy will be reviewed every five years by Executive Council.

6. References:

Research

1. Administration of Research
2. Integrity in Research and Scholarship
3. Intellectual Property
4. Research and Innovation

General

1. Conflict of Interest
2. Privacy and Access to Information
3. Privacy Guidelines

Supporting Information

1. Panel on Research Ethics https://ethics.gc.ca/eng/home.html

7. Definitions:

See Applied Research Policy Definitions (R-6)