



Procedure

Procedure Name	Research Involving Human Subjects		
Procedure #	RI 10.01	Parent Policy	RI 10.0: Research Involving Human Subjects
Policy Owner	VP Academic, Neil Fassina	Effective Date	December 16, 2015
Procedure Owner	AVP Research & Innovation, Chris Dambrowitz	Review Date	December 2018
Approved by	AVP Research & Innovation	Approval Date	December 16, 2015

1.0 Purpose/ Background

NAIT is responsible to establish clear procedures for approving research that involves human subjects. This requires that NAIT establish and actively support a Research Ethics Board (REB).

This procedure pertains to the organizational authority under which the REB is established and empowered; defines the purpose of the REB; states the authority of the REB; and outlines research and activities requiring REB review; and summaries the review process.

2.0 General Principles

2.1 Statement of Organizational Authority

- 2.1.1 The organization has authorized the REB to review research involving human participants conducted under the auspices of the organization;
- 2.1.2 The REB is established and empowered under the authority of the organization. The organization requires that all research involving human participants be reviewed and approved by an REB prior to initiation of any research related activities.

2.2 Purpose of the REB

- 2.2.1 The REB's purpose is to protect the rights and welfare of human participants taking part in research conducted at NAIT.
- 2.2.2 The committee shall act to:
 - 2.2.2.1 Work with researchers to identify and resolve ethical issues in their research.
 - 2.2.2.2 Protect the interests of research participants, maximize the benefits of the research and minimize harms.
 - 2.2.2.3 Approve, reject, propose modifications, suspend or terminate research activity that involves human participants, under the jurisdiction of NAIT and the purview of the TCPS2 or relevant regulations and guidelines.

- 2.2.2.4 Provide decisions that are based on the TCPS2 policy and other regulation and guidelines
- 2.2.3 The REB reviews and oversees the research to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection;
- 2.2.4 These include, but are not limited to, the Food and Drugs Act and applicable Regulations, the International Conference on Harmonization Good Clinical Practice Guidelines, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Research ethics oversight of biomedical clinical trials (CAN/CGSB-191.1-2013) and where applicable, US Federal Regulations.

2.3 REB Authority

- 2.3.1 The REB is established to review all research involving human participants within its established jurisdiction;
- 2.3.2 The REB has the authority to ensure that all research conducted under its oversight is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research participants.
- 2.3.3 Specifically the REB has the authority to:
 - 2.3.3.1 establish the ethics review processes, and provide research ethics oversight to ensure the ethical conduct of the research,
 - 2.3.3.2 approve, require modifications to, or disapprove, any research activity that falls within its jurisdiction,
 - 2.3.3.3 ensure that the researcher has policies and procedures to protect the rights, safety and welfare of research participants,
 - 2.3.3.4 request, receive and share any information involving the research that the REB considers necessary to fulfil its mandate, while maintaining confidentiality and respecting privacy,
 - 2.3.3.5 conduct continuing ethical review to protect the rights and welfare and privacy of research participants,
 - 2.3.3.6 suspend or terminate the ethics approval for the research,
 - 2.3.3.7 place restrictions on the research,
 - 2.3.3.8 take any actions considered reasonably necessary, and consistent with policies and procedures, to ensure the protection of the rights, safety, and well-being of participants in research conducted under the REB’s jurisdiction.

3.0 Definitions

Term	Definition
Applied Research	Applied research is a systematic investigation and discovery of knowledge that results in an immediate and identifiable impact on the potential commercial, environmental, or social value of a technology.
Participant	A Participant is an individual whose data or responses to interventions, stimuli, or questions by a Researcher are relevant

	to answering a research question; also referred to as “human participant” and in other policies/guidance as “subject” or “research subject.”
Researcher	Includes all members of the Institute who participate in applied research activities. Members of the Institute may include academic and non-academic staff, administrators, students, visiting or adjunct scholars, paid and unpaid research assistants, and any other person in a similar position.
Research Ethics Board (REB)	The Research Ethics Board is a body of Researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an organization to review the ethical acceptability of all research involving humans conducted within the organization’s jurisdiction or under its auspices.

4.0 Procedures

4.1 Research that Requires REB Review

4.1.1 The following requires ethics review and approval by an REB before the research commences:

- (a) Research involving living human participants,
- (b) Research involving 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.

4.2 Research Exempt from REB Review

4.2.1 Research that relies exclusively on publicly available information does not require REB review 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;

4.2.2 REB review is not required for research involving the observation of people in public places where:

- (a) It does not involve any intervention staged by the Researcher, or direct interaction with the individuals or groups,
- (b) Individuals or groups targeted for observation have no reasonable expectation of privacy, and
- (c) Any dissemination of research results does not allow identification of specific individuals;

4.2.3 REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information;

4.2.4 The opinion of the REB should be sought whenever there is any doubt about the applicability of the guidelines and regulations.

4.3 Activities Not Requiring REB Review

- 4.3.1 Activities outside the scope of research subject to REB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an REB;
- 4.3.2 Quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this SOP, and do not fall within the scope of REB review;
- 4.3.3 Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.

4.4 Auspices of the REB

All research projects involving human subjects conducted at, or under the auspices of NAIT require ethics review and approval by the REB prior to starting. This requirement of prior ethics review and approval applies to:

- 4.4.1 All research involving human subjects conducted by the Institute's staff, including academic staff, administrative and support staff, students, persons with adjunct appointments, visiting instructors, visiting professional associates, and research associates;
- 4.4.2 All research carried out on Institute premises regardless of whether using NAIT facilities, equipment, financial or material resources, or whether involving any members of the NAIT community;
- 4.4.3 All research from outside NAIT who intend to use NAIT employees or students as participants, or other individuals recruited by NAIT as participants, in their research activities.

4.5 REB review

- 4.5.1 REBs should adopt a proportionate approach to ethics assessment based on the general principle that the more invasive or harmful the proposed and ongoing research, the greater should be the care in assessing the research. Full Board review by an REB should be the default requirement for all research involving human participants unless the REB decides to authorize delegated review based primarily on the harms that are expected to arise from the research. While all research must be reviewed adequately, requirements for proportionate review allow the REB to provide a higher level of scrutiny, and correspondingly more protection, for the most ethically challenging research.
- 4.5.2 In practice, the proportionate review implies different levels of REB review for different research projects. The two levels typical used by REBs are Full Board review or delegated review by one or more experienced REB members, as determined by the REB Chair or designee.

5.0 Exceptions to the Procedure

5.1 Exceptions to this procedure must be documented and formally approved by the Policy Lead.

Procedure exceptions must include:

- The nature of the exception
- A reasonable explanation for why the procedure exception is required
- Confirmation that the exception aligns with the general principles
- Any risks created by the procedure exception and how they will be managed.

6.0 Related Documentation

RI 10.0 Research Involving Human Subjects Policy

Document History

<i>Date</i>	<i>Action/ Change</i>
December 2015	Procedure Updated
Feb/05/2007	Original Approval