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NAIT *Procedure*

IR 10.2

Research Involving Human Subjects

Implementation Date: May 2007

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1.0 Purpose

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). The REB will review all research protocols that involve humans as the source of either quantitative or qualitative data. The REB will approve proposed research in accordance with the Canadian Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans. The procedures specify the requirements of researchers in their interactions with the REB.

2.0 Definitions

- **Research Ethics Board (REB)**

3.0 Procedures

3.1 Responsibilities of Researchers

Whenever research involving human subjects is to be performed under the auspices of NAIT or by any Institute researcher, the researcher is responsible for meeting the following requirements:

3.1.1 Ensuring that the research being conducted is scientifically valid and/or appropriate in a scholarly sense, and that the benefits to knowledge that will result from the research warrant the investment of time, effort and risks to be incurred by the number of

human subjects for which the research is planned. Scientifically invalid research or research that is more intrusive or requires more subjects to experience the research procedures than those warranted by the research design is unethical. The researcher shall carefully monitor and assure the validity of the research submitted to the REB.

3.1.2 Reading and becoming thoroughly familiar with applicable ethical guidelines.

3.1.3 Determining if their proposed research requires ethics review. If there is any uncertainty about whether the research requires ethics review and approval, the researcher shall consult the Chair of the REB for advice and decision.

3.1.4 Notifying the REB of the proposed research by submitting a completed Human Subject Research Ethics Protocol accompanied by any supplementary materials necessary for full ethics review, and providing any additional information requested by the REB in a timely fashion.

3.1.5 Not involving human subjects in the proposed research until the REB has informed him/her of approval in writing for the use of human subjects in the research.

3.1.6 Abiding by all decisions of the REB, including following all modifications required for REB approval and not undertaking the research if it has not been approved.

3.1.7 Obtaining free and informed consent from all subjects as outlined in all procedures and policy documents related to this guideline.

3.1.8 Maintaining the confidentiality of data obtained from subjects in the manner required by the REB and relevant organizations.

3.1.9 Promptly reporting to the Chair of the REB any injuries to human subjects, any unanticipated problems which involve risks or unusual costs to the subjects, or other adverse events resulting from the research. Initial reports may be verbal; subsequent reports shall be in the manner required by the REB.

3.1.10 Promptly reporting to the Chair of the REB any proposed changes in the research which would result in a significantly different involvement of human subjects and obtaining the approval of the REB prior to the changes being made, except where necessary to eliminate apparent and immediate hazards to subjects.

3.1.11 Promptly reporting to the Chair of the REB any proposed involvement of human subjects in research which previously had no plans, or only indefinite plans, for subject involvement and

obtaining the approval of the REB prior to the involvement of any subjects.

3.1.12 Promptly reporting to the Chair of the REB any serious or continuing non-compliance with the requirements of this policy or of the procedures stipulated by an REB by any individual associated with the research.

3.2 Free and Informed Consent of Subjects

3.2.1 The researcher is responsible for obtaining free and informed consent from all prospective subjects, or authorized third parties, prior to commencing research activities. Free and informed consent must be maintained throughout participation in the research. Free and informed consent must be given voluntarily, without manipulation, undue influence or coercion.

3.2.2 Evidence of free and informed consent in the form of a signed document by the subject or authorized third party should be obtained in writing and stored in a secure repository.

3.2.3 The REB may approve a consent procedure that differs from that outlined in 3.2.1 and 3.2.2 if the REB finds that:

- The research involves no more than minimal risk to the subjects;
- The alteration or waiver of the consent procedure is unlikely to adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the alteration or waiver of the consent procedure;
- Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and
- The alteration or waiver of consent does not involve a therapeutic intervention.

3.2.4 Participants in naturalistic observation studies normally do not give informed consent because they are unaware they are being observed. The REB can approve such projects as long as the research records protect the identities of the subjects, as well as their dignity. If the research environment is staged, however, special care must be taken to ensure the privacy, well being, safety, and dignity of the subjects.

3.2.5 Researchers shall provide prospective subjects or authorized third parties with:

- Information that the individual is being invited to participate in a research project;
- A statement of the research purpose, identity of the researcher, the expected duration and nature of participation and a description of the research procedures;

- A description of the reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related treatment;
- If a randomized trial protocol is employed, a statement of the likelihood that the subject will be selected to the experimental sample;
- An assurance that prospective subjects are free not to participate and have the right to withdraw at any time without prejudice to pre-existing entitlements; and
- The possibility of commercialization of the research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

3.2.6 Research Subjects Who are Not Legally Competent

3.2.6.1 Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:

- The research question can only be addressed using individuals within the identified group(s);
- Free and informed consent will be sought from their authorized representative(s); and
- The research does not expose them to more than minimal risks without the potential for direct benefits for them.

3.2.6.2 For research involving legally incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:

- The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the subjects best interests will be protected;
- The authorized third party may not be the researcher or any other member of the research team. The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent;
- When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.

3.2.6.3 When free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the

nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation.

3.2.7 Research in Emergency Health Situations

3.2.7.1 Research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of the research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or of his or her authorized third party only if ALL of the following apply:

- A serious threat to the prospective subject requires immediate intervention; and
- Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and
- Either the risk of harm is not greater than that involved in standard efficacious care, or it is not clearly justified by the direct benefits to the subject; and
- The prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research; and
- Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
- No relevant prior directive by the subject is known to exist.

3.2.7.2 When a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

Related Policy:
IR 10 Research Involving Human Subjects

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