Research Involving Human Participants

Category: Academic
Responsibility: Vice President Academic and Research
Revised/Approval Date: May 2, 2014
Approval Body: Senate

Background and Purposes:
Algoma University is committed to promoting research as a fundamental human endeavour deriving from the wish to understand and improve the collective global condition. The University recognizes that the use of Human Participants is indispensable to progress in many areas of research. All research involving Human Participants must be conducted in accordance with the highest ethical standards in ways that protect, and respect the dignity and rights of all Human Participants involved. The trust of the Human Participants and the public in the research process is built upon the consistent application of these ethical standards.

The purpose of this Policy is to create a research environment in which the University's responsibilities towards Human Participants involved in research are discharged in accordance with the highest ethical standards; to promote awareness and understanding of such standards among members or associated members of the University; to articulate clearly the Tri-Council Core Ethical Principles applicable to research in a manner consistent with the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and with international best practices; and to establish an independent research ethics review process.

Related Policy:
Conflict of Interest

Notes:
Defined terms are capitalized in this Policy and can be found in Section 7 at the end of this Policy.

1. Scope

1.1 This Policy applies to:
(a) Research Involving 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.

2. Tri-Council Core Ethical Principles

2.1 Over and above the legal obligations to which all researchers and the University are bound to adhere, a fundamental imperative of Research Involving Human Participants is the respect for human dignity. The University adopts the Tri-Council Core Ethical Principles as principles that will not only guide the conduct of all Research Involving Human Participants but will also guide the Research Ethics Board (REB) when they are reviewing the ethical acceptability of such research.

3. Mandate and Authority of the Research Ethics Board

3.1 The REB is mandated to review and maintain, on behalf of the University, ongoing oversight of the ethical acceptability of all proposed or ongoing Research Involving Human Participants by applying the Tri- Council Core Ethical Principles to such review and oversight.

3.2 The University shall authorize such number of REBs as is determined to be appropriate from time to time by the Vice-President, Academic & Research (VPAR). Algoma University continues to increase its research output both in terms of the awarding of grant monies and increased peer-reviewed publications; however, the number of Faculty involved in human subjects research remains relatively small. As a result, Algoma University currently has one Research Ethics Board to carry out the duties listed in Section 3.1. Reference will be made to a single REB throughout the document.

3.3 The VPAR is responsible for determining the financial and administrative resources that are necessary to enable the REB to fulfill its duties and shall ensure that such resources are provided.

3.4 The VPAR is responsible for:

3.4.1 keeping the REB Chair informed of all ethics requirements of the Tri-Council granting agencies and of all other provincial, national and international laws, regulations, policies, standards (e.g. legal, professional, institutional), and guidelines that are relevant to research ethics review; and

3.4.2 communicating to the REB Chair any changes in such requirements, laws, regulations, policies, standards and guidelines.

3.5 The REB is accountable to the VPAR for its research ethics review processes. However, in conducting their research ethics reviews, the REB must operate in an impartial manner, without interference, and the decisions of the REB with respect to any given Research project are not subject to review by the VPAR or any other person except to the extent that such decisions may be appealed pursuant to the Procedures to this Policy.

4. Ethics Approval

4.1 As there is only one REB of record at Algoma University, every research project conducted by Algoma University staff, faculty and/or students that meets the criteria listed in the Scope (Section 1) of this policy must obtain approval from this REB.

4.2 Any research project external to Algoma University (e.g., from another University) that concerns Algoma University staff, faculty, students and/or premises requires Algoma University REB approval in addition to the necessary REB approvals from that external organization.

4.3 Unless proposed Research Involving Human Participants has first been granted Ethics Approval (with the exception of conducting literature reviews and/or the development (but NOT the distribution) of questionnaires), a researcher must not:

4.3.1 commence or continue to carry out such research;

4.3.2 use University services or facilities, including academic space at affiliated teaching hospitals, for such research; or

4.3.3 accept or use any funds made available to such researcher for such research.

4.4 Unless Financial Services has received notification that Ethics Approval has been granted to certain Research Involving Human Participants, Financial Services must not, with respect to such Research Involving Human Participants authorize spending on any research accounts.

4.5 If the REB rescinds or terminates an Ethics Approval, the REB may give notice and direction to Financial Services. Upon receipt of such notice and direction from the REB, Financial Services must freeze or close the relevant research account as appropriate.

4.6 A Research project may require a number of different approvals from various officials or committees of the University and other relevant agencies. Ethics Approval and all other required approvals with respect to such Research project must be obtained before the Research project is undertaken. The REB will offer a conditional approval to those organizations that require it; once the organization approves the project, the REB will remove the conditions (i.e., the REB Approval Certificate will be issued with a “P” for Pending which will be removed once approval from the organization has been granted).

5. Ethics Review Agreements with Other Institutions or Organizations

5.1 In order to facilitate collaborative research projects involving researchers, data or participants from more than one institution, and in order to avoid a duplication of efforts with respect to research ethics reviews, the University through its authorized signatories may enter into Ethics Review Agreements.

5.2 An Ethics Review Agreement may be limited to a specific type of Research.

5.3 Prior to entering into an Ethics Review Agreement with another institution, the University shall:

5.3.1 take into account the manner in which the other institution's research ethics board conducts research ethics reviews; and

5.3.2 consult with the Chairs of the REBs.

6. Institutional Conflicts of Interest in Relation to Research

6.1 The University has many diverse objectives. From time to time these objectives may appear to be, or may actually be in conflict with one another. For example, the University has an interest in enhancing its investment returns, fundraising activities and operational efficiencies in order to achieve its mission and to serve the people of northern Ontario, Canada and the world. However, regardless of any other interest it may have, the University has an overriding interest in ensuring that Research activities are undertaken with integrity and in a manner that is consistent with the Tri-Council Core Ethical Principles. To the extent that there is a conflict between this overriding interest and any other interest the University may have, any decisions made by the REB shall be consistent with this overriding interest.

6.2 In addition, academic freedom is one of the University's core values. As a result, no person at the University may interfere with Research unless the Research is contrary to applicable legal requirements or University policies. Furthermore, the University's administrative structure is organized in such a manner as to create separation between Research activities and the financial and other operations of the University. Due to the University's limited ability to interfere with Research and the University's organizational separation, the risk of the University's operational interests influencing or compromising the Tri-Council Core Ethical Principles is minimized.

6.3 In the event that a conflict arises between the Tri-Council Core Ethical Principles and the University's other objectives that cannot be adequately managed by the structural separation described in Section 6.2, the VPAR will be charged with the responsibility of reviewing the matter and reporting to the President of the University, the REB and any external agencies as may be appropriate. Any person who has a concern that such a conflict may exist is encouraged to bring it to the attention of the VPAR. All concerns submitted pursuant to this Section 6.3 will be taken seriously. The anonymity of the person raising a concern cannot be guaranteed given the small number of researchers using the REB. The University will protect personal information of all parties involved as required under the Freedom of Information and Protection of Privacy Act. The University will not tolerate any retaliation, directly or indirectly, against anyone who, in good faith, raises a concern pursuant to this Section 6.3, gives evidence or otherwise participates in a process under this Policy.

7. Definitions

7.1 "Anonymous", when used to describe information, data or materials, means information, data or materials that has never had personal identifiers associated with it (e.g. anonymous surveys) where the nature of the information, data or materials is such that it would be extremely unlikely that the persons having access to the information, data or materials could determine the identities of individuals by combining such information, data or materials with information, data or materials that are publicly available or that would otherwise be expected to be in their possession. For the purposes of this Policy, genetic material shall not be considered Anonymous unless a REB determines otherwise.

7.2 "Tri-Council Core Ethical Principles" means the following principles:

7.2.1 Respect for Persons: This principle requires the recognition of the intrinsic value of human beings and the respect and consideration that they are due, whether they are involved in research directly as subjects, or whether they are involved solely by virtue of their data or Human Biological Materials being used in research. This principle also incorporates the requirement that all Human Participants give their free, informed and ongoing consent as a prerequisite for participation in research.

7.2.2 Concern for Welfare: This principle requires that the welfare of Human Participants in research be protected and promoted, and the recognition that the welfare of a person is the quality of that person's total experience of life, which consists of the impact caused, among other things, by factors such as his or her physical, mental and spiritual health, as well as his or her physical, economic and social circumstances.

7.2.3 Justice: This principle requires that all Human Participants in research be treated fairly and equitably so that individuals or groups are not inappropriately included in or excluded from participation in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender, age, developmental stage, reproductive capacity, capacity to consent, or presumed vulnerability. Instead, the question of participation should be based on inclusion and exclusion criteria that are required in order to carry out the research project. Also, the principle of justice requires that researchers consider ways to ensure the equitable distribution of any benefits of participation in research (e.g. amelioration of a health condition for an individual as a result of experimental therapy; the establishment of health care or beneficial services in a community which has been involved in research).

For further information, reference may be made to the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

7.3 "Ethics Approval" means the research ethics approval granted by a REB in accordance with this Policy.

7.4 “Ethics Review Agreement” means an agreement between the University and another research institution or organization that authorizes an alternative model or models for ethics review of Research Involving Human Participants. Such agreements may or may not be reciprocal in nature.

7.5 “Human Biological Materials” means human tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids, embryos, fetuses, fetal tissues, reproductive materials and stem cells.

7.6 “Human Participants” means individuals whose data, or responses to interventions, stimuli or questions by a researcher are gathered or utilized for the purposes of a Research project.

7.7 “REB” means a research ethics board authorized by the University.

7.8 “Research” means any disciplined inquiry or systematic investigation (including pilot studies) intended to extend knowledge or to establish facts or principles that is:

7.8.1 conducted by members or associated members of the University acting in their University capacity, including but not limited to faculty, emeritus faculty, staff, sessional instructors, clinical professors, administrators, students, visiting or adjunct scholars, fellows, paid or unpaid associates and any other person associated with research at the University;

7.8.2 conducted with the authorization of the University using resources (including but not limited to space that is under the administration of the University and academic space at affiliated teaching hospitals) that have been provided by the University but that are not generally available to the public; or

7.8.3 in need of research ethics review by the University pursuant to the terms of an affiliation agreement with another agency;

but does not include:

7.8.4 quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes. For greater certainty, where data is collected for purposes set out in the preceding sentence but later proposed to be used for research purposes, such use may be considered Secondary Use of information not originally intended for research, which would require research ethics review in accordance with this Policy.

7.9 “Research Ethics Appeal Committee” means the committee which the VPAR may from time to time create for the purpose of hearing appeals of decisions made by the REB.

7.10 “Research Involving Human Participants” means Research involving

7.10.1 Human Participants; or

7.10.2 Human Biological Materials;

but does not include:

7.10.3 Research that relies exclusively on publicly available information when such information: (i) is made accessible to the public through legislation and regulation, and is therefore appropriately protected by law, or (ii) is disseminated in the public domain (e.g. through print or electronic publications), may contain identifiable information, and for which there is no reasonable expectation of privacy;

7.10.4 Research involving the observation of individuals or groups in public places so long as: (i) the research does not involve any intervention staged by the researcher or any direct interaction between the researchers and the individuals or groups; (ii) the individuals or groups being observed have no reasonable expectation of privacy; and (iii) the dissemination of research results from such observation does not allow identification of specific individuals; and

7.10.5 Research that relies exclusively on Secondary Use of Anonymous information or Anonymous materials, so long as the process of data linkage or recording or dissemination of the Research results does not generate information about an identifiable individual.

7.11 “VPAR” means Vice-President, Academic & Research assigned by the President to be responsible for this Policy and any associated Procedures.

7.12 “Secondary Use” means the use in Research of information or Human Biological Materials originally collected for a purpose other than the purpose of the current Research.

7.13 “University” means Algoma University.

PROCEDURES

Revised/Approval Date: May 2, 2014

1. Researcher Responsibilities

1.1 A researcher who plans to conduct Research Involving Human Participants is required to:

1.1.1 be familiar with all University policies relating to research, including without limitation this Policy (Research Involving Human Participants), these Procedures, and the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

1.1.2 if the research project constitutes Research Involving Human Participants, submit a proposal for such research project to the REB for review and approval of its ethical acceptability prior to the start of recruitment of Human Participants, access to data, or collection of Human Biological Materials, and include in such proposal such details as are reasonably required by the REB in order to enable the REB to discharge its duties as set out in Section 3.1, including certificates of module training for each individual listed as Principal Investigator(s), Co-investigator(s), Research Coordinator(s) and/or Supervisor(s);

1.1.3 if there is any doubt as to whether such research project constitutes Research Involving Human Participants, consult the REB to obtain a determination as to whether such research project requires research ethics review;

1.1.4 conduct all REB-approved Research Involving Human Participants in accordance with:

1.1.4.1 any determinations respecting such research made by the REB that has continuing oversight of such research and comply with and maintain in good standing any Ethics Approval issued by such REB for as long as is required by such REB;

1.1.4.2 the Tri-Council Core Ethical Principles;

1.1.4.3 the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

1.1.4.4 the University's policies and procedures governing security and privacy, and all other applicable policies and procedures of the University; and

1.1.4.5 other relevant legal obligations (including provincial, national and international laws and regulations), policies, standards (including professional and institutional standards) and guidelines, where applicable to a particular area of research or to the funding of such research;

1.1.5 promptly report to the REB the occurrence of any unanticipated issue or event during the course of the implementation of the approved research project that may result in an increased level of risk to Human Participants involved in the research project, or that has other ethical implications that may affect the welfare of such Human Participants;

1.1.6 promptly submit to the REB any proposed changes to the research project and notify such REB when the research project concludes; and

1.1.7 ensure that any proposed changes to an approved research project are approved by the REB prior to implementation of the changes, except when such changes are required to be made in order to eliminate immediate hazards to Human Participants involved in such research project or to implement minor logistical changes.

1.1.8 Noncompliance which can include, but is not limited to, failure to obtain prior REB approval before starting a research project, inadequate supervision of the research, failure to report adverse events or protocol changes to the REB, failure to provide ongoing reports, or significant deviation from the approved protocol. All instances of noncompliance with policies or procedures for research involving human subjects should be brought to the attention of the VPAR, in writing, for review and resolution.

1.1.9 Actions taken by the Chair or VPAR, as appropriate, may include but are not limited to the following: education measures, terminating or suspending REB approval of the active studies, restrictions on the ability to serve as an investigator on research projects involving human subjects or freezing of research funds. Any action taken by the Chair or VPAR will be reported promptly, in writing, to the principal investigator.

2. Composition of REB

2.1 Appointments to the REB will be elected by Algoma University Senate at the Senate meeting in June. All members are required to complete the TCPS ethics training certificate and will be required to be familiar with all University policies relating to research, including without limitation this Policy (Research Involving Human Participants) , these Procedures, and the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

2.2 Any REB constituted by the Senate under Section 4 of this policy (Research Involving Human Participants) will consist of at least 7 members, including both men and women, of whom:

a. at least 3 members shall have broad expertise in the methods or in the areas of research that are covered by the REB; one member being elected from each Division;

b. at least one member shall be knowledgeable in ethics;

c. at least one member shall be knowledgeable in research in First Nations Communities and fully cognizant of Chapter 9 requirements of the TCPSII;

d. at least one member shall be knowledgeable in law; and

e. at least one member shall have no affiliation with the University, but shall be recruited from the community served by the University. This member will be recommended by the Committee and approved by Senate prior to serving on the REB.

f. that departments involved in human subjects research (including course work and / or student theses projects), nominate delegated reviewers that would provide subject matter expertise to the REB.

2.3 Members of the REB shall normally serve in one capacity only for each of the membership categories listed in Section 2.2.

2.4 Terms of appointment of individual members shall be established at the time such appointments are made and should be staggered to allow for continuity of the research ethics review process. Individual members are to serve two year terms (i.e., July 1 to following June 30 is considered a one year term).

2.5 An REB member shall disclose to the REB in question the nature of any real, potential or perceived conflict of interest such member may have with respect to any Research project being reviewed by such REB. If the REB member chooses to recuse himself or herself from all discussion or decisions regarding such Research project or group of Research projects, such recusal shall be recorded in the minutes of the REB proceedings. If the REB member does not recuse himself or herself, the conflict of interest disclosure shall be recorded in the minutes of the REB proceedings and the REB Chair and remaining REB members shall reach agreement on an appropriate course of action by majority vote. If the REB Chair is the individual disclosing a real, potential or perceived conflict of interest, the Associate Chair shall perform the duties of REB Chair during all discussion or decisions regarding such conflict of interest, or if the Associate Chair is conflicted, unable to act, or not present, such non-conflicted REB member as may be selected by the majority of the non-conflicted REB members, shall perform the duties of REB Chair during all discussion or decisions regarding such conflict of interest.

2.6 When there is less than full attendance, decisions requiring full review will be adopted only if the members attending the meeting possess the range of background and expertise stipulated in Section 2.2. Therefore, quorum will be at least 50 percent of the REB voting members, including the representation set out in article 2.2.

2.7 Through the office of the VPAR, secretarial and clerical support is provided to the REB; this support is independent of senior administration and solely reflects the procedures of this policy and the decisions of the REB.

3. REB Chair

3.1 The REB members will elect a Chair for the REB and may also appoint one or more Associate Chair(s).

3.2 The Chair of the REB is responsible for ensuring that the research ethics review process adhered to by their REB conforms to the requirements of the Tri-Council Core Ethical Principles and all other relevant requirements, laws, regulations, policies, standards and guidelines that are relevant to research ethics review.

3.3 The role of the REB Chair is to:

3.3.1 provide leadership for the REB;

3.3.2 facilitate the research ethics review process, based on University policies and procedures and the most current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans;

3.3.3 oversee decisions of the REB for consistency;

3.3.4 ensure that REB decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible by the Chair or his or her designate; and

3.3.5 ensure appropriate quorum requirements are met for each Research project being reviewed.

4. Responsibilities of the REB

4.1 The REB is responsible to the VPAR and Senate. The REB shall conduct initial reviews of the ethical acceptability of all proposed Research Involving Human Participants (exempt, expedited and full) and continuing reviews of all previously approved Research Involving Human Participants of which they have ongoing oversight, and may, where applicable, approve, reject, propose modifications to, terminate or suspend such research.

4.2 In discharging their responsibilities described in Section 4.1 above, the REB shall:

4.2.1 have regular meetings and shall normally meet face to face;

4.2.2 function impartially, provide a fair hearing to the researchers involved, and provide reasoned opinions and decisions;

4.2.3 make the final determination as to the nature and frequency of continuing research ethics review of approved research projects;

4.2.4 communicate to researchers in writing all approvals and refusals of, all proposed modifications to, and any requirements they may impose on proposed or ongoing Research Involving Human Participants; and

4.2.5 prepare and maintain comprehensive records, including all documentation related to the research projects submitted to REB for review, attendance at all REB meetings, and accurate minutes reflecting REB decisions, as well as any dissents and the reasons for them. Where the REB denies approval for a Research project, the minutes shall clearly document the reasons for this decision. Providing reasons for REB decisions is optional when approval is granted.

5. Reconsideration of REB Decisions

5.1 A researcher may request reconsideration of a decision made by the REB. The REB will reconsider its decision upon receipt of a written request, and the researcher may submit additional information and/or attend the REB meeting in person to present information.

6. Appeal of REB Decisions

6.1 If, after the completion of the relevant REB's reconsideration, a researcher is still not satisfied with the decision made by a REB, such researcher may make a written request to the VPAR to appeal such decision.

6.2 The VPAR shall appoint individuals to a Research Ethics Appeal Committee which shall hear such appeal.

6.3 The composition of the Research Ethics Appeal Committee, as well as its terms of membership and quorum requirements, must satisfy the REB requirements in Section 2 of these Procedures.

6.4 No person can serve as a member of the Research Ethics Appeal Committee with respect to a review of a decision made by a REB if such person was a member of the REB that made or reconsidered such decision.

6.5 The Research Ethics Appeal Committee shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented decisions and reasons for such decisions.

6.6 Both the appealing researcher and a representative of the REB whose decision is being appealed shall be granted the opportunity to address the Research Ethics Appeal Committee, but neither shall be present when the Research Ethics Appeal Committee deliberates and makes a decision.

6.7 When reviewing decisions made by a REB with respect to a Research project, the Research Ethics Appeal Committee may approve, reject or request modifications to such Research project.

6.8 The decision made by the Research Ethics Appeal Committee on behalf of the University shall be final and should be communicated in writing to the relevant researcher and to the REB whose decision was appealed.

7. Research Involving Aboriginal Peoples

7.1 Where research is to be conducted within an Aboriginal community, or where the research involves a sample of persons who are members of an Aboriginal community (or communities), Chapter 9 of the TCPSII that deals with Aboriginal peoples must be adhered to in full. The researcher (investigator and supervisor) is responsible for being fully aware of the scope of that policy and must abide by the guidelines presented therein.

7.2 The REB of Algoma requires that researchers complete and submit the checklist provided in Appendix A which pertains to engaging in research that involves Aboriginal Peoples. This checklist does not replace the Algoma University Application Form for Ethical Review Research Involving Human Subjects Research.

8. Complaints, Concerns and Recommendations

(This section is directly related to Appendix B and is under the jurisdiction of the Chief Research Officer of the University).

8.1 Research subjects, researchers, staff members, REB members and any other individuals who have concerns, complaints or recommendations related to human subjects research are required to complete the form found in Appendix B (Reporting Form for Research Concerns or Complaints). The completed form must be submitted to the VPAR. All written inquiries will be taken seriously and dealt with in a confidential and timely manner.

8.2 If research misconduct is suspected, the VPAR shall initiate the necessary reporting process. The REB will be notified of any investigation in process to allow the REB to take any safety measures that may be necessary to protect the welfare of the research subjects. All complaints and actions taken, with confidentiality maintained shall be reported in the REB Annual Report.

8.3 All founded complaints or cases of research misconduct, including the researcher's nominative information, must be reported to the relevant authorities as required by the applicable regulations, policies, code or collective agreement to which the researcher is subject. This includes the Academic Dean, Divisional Chair of the Department, the REB, and where relevant, the board of Governors and to other persons who have a legitimate knowledge to know.

8.4 All REB records, including investigator proposals and nominative information, shall be made available to authorized individuals for the purposes of auditing, monitoring and investigation of complaints or research misconduct.

Acknowledgement: Algoma University wishes to acknowledge that sections of this policy have been adapted from the documentation developed by the TCPSII other institutions and is grateful the materials have been made widely available.

APPENDIX A

Research Ethics Form for Projects That Involve Aboriginal Peoples

(As listed in Section 7.0 of the Algoma University Research Ethics Policy)

1. Will the research be conducted on territory that is under the authority of a First Nation, Métis or Inuit government (this includes mail or telephone surveys within such territories)?
   Yes ☐ No ☐
   If yes, please provide contact information where consent of a formal leader might be verified.

Contact Name:
Contact Information:

2. Has the researcher engaged in consultations with the community concerning the viability of the research?
   Yes ☐ No ☐
   If yes, please describe the nature and context of those consultations below:

3. What manner of research partnerships/community involvement will be formed in the process of collecting this data? Please describe these:

4. Does the research involve the appropriation and/or commercialization of Aboriginal cultural heritage?
   Yes ☐ No ☐
   If so, please describe:

5. Has the researcher consulted with the community as to the nature of safeguards that should be employed to protect Indigenous cultural knowledge that may be shared in the context of the data collection?
   Yes ☐ No ☐
   If yes, please include a description of those means.

6. Has the researcher sought community advice to guide them concerning the nature of research ethics in the community of interest (e.g., does the community adhere to the guidelines outlined in OCAP: Ownership, Control, Access and Possession at http://cahr.uvic.ca/nearbc/documents/2009/FNC-OCAP.pdf)?
   Yes ☐ No ☐

7. Have the researcher(s) and the community formulated a research agreement for the purposes of this project? Yes ☐ No ☐
   If yes, please attach that agreement to your submission.

8. What means will be put in place to allow access to the research by members of the community of interest? Please describe (briefly) below:

9. What benefits will this research offer to the community of interest?

10. Please describe the mechanism the researcher will put in place to ensure that information derived from the research data can be reviewed by community members, verified as to accuracy and applicability, and that will provide for consent to permit its usage to be reaffirmed (if desired by the community) before publication (or other usage) of the results?

Appendix B

RESEARCH ETHICS BOARD
REPORTING FORM FOR RESEARCH CONCERNS OR COMPLAINTS

DATE:_____

Instructions for submitting this form:
You may choose to use this form to report a concern or complaint. You can send us this form in one of two ways:

By email:
vpar@algomau.ca

By mail:
Research Ethics Board
c/o Vice President Academic and Research
Algoma University
1520 Queen Street East
Sault Ste. Marie, Ontario
P6A 2G4

There is an additional way you can choose to report a concern or complaint:

- You can also send a letter to the above address to report your concern or complaint. If you send a letter, you may find it helpful to use the questions in this form as a guide for the content of your letter.

Important Note: All research concerns and complaints are taken very seriously. Sections A and B must be completed for the complaint to be addressed. The information you provide on this form will be kept confidential. However, we may need to share this information with others in order to follow-up with your concern or complaint.

A. Your Name		
Name(s):		
May we reveal that you are the source of this concern or complaint to the study's Principal Investigator and other study staff?	☐ **Yes** ☐ **No**	

B. Personal Contact Information			
Phone :		Email Address:	
Alternate Phone :		Other Contact Info:	
Unless you authorize us to do so, your personal contact information will not be released to anyone outside the REB.			
Are you making this report for someone else?	☐ **Yes** → ☐ **No**	If yes, please explain:	

C. Study Information			
1. Please tell us about the study for which you have a concern or complaint:			
Study Name or Description:			
Name of Study Investigator(s):		Study Phone Number:	

2. Please tell us about the research concern or complaint you are reporting:

3. Please tell us how would like to see your concern or complaint resolved:			
4. Have you discussed this concern or complaint with the Principal Investigator or other study staff?	☐ **Yes →** ☐ **No**	*If yes, please let us know who you contacted:*	
5. Are you or were you a participant in this study?	☐ **Yes →** ☐ **No**	If yes, please answer questions a to d below:	
a. When did you start participating in the study? (Please guess even if you can't remember):		Date:	
b. Are you still participating in the study?	☐ **Yes** ☐ **No**		
c. Do you have a consent form for this study?	☐ **Yes →** ☐ **No**	If yes, please attach a copy of the consent form or other written information that you have.	
d. Do you have any other written information about this study?	☐ **Yes →** ☐ **No**		

If you have additional comments or need additional space, please attach additional sheets.

Office Use Only
Intake/Initial Processing CASE # _____ Received By: Date Received: _____ Date Entered to Tracking Log: _____ Date REB File Requested: _____ Resolution Date (Document Resolution in Tracking Log): _____ Referred to: _____ Date of Referral: _____
Study Information Principal Investigator(s): _____ PI Phone#: _____ Department Contact _____ Contact Phone #: _____ Title of Study: _____ REB Approval #: _____ Date(s) of Approval: _____