****

**REVIEW ETHICS BOARD:**

REB REVIEW SUBMISSION

|  |  |
| --- | --- |
| **OFFICE USE ONLY: *Form revised JULY 2018***[ ] Accepted as is [ ] Clearance Pending Revision [ ] Clarification Required [ ] Full Review [ ] Resubmission  [ ]  Withhold Clearance | **Protocol Reference Numbers**:REB#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**NOTE:** When completing form, if question is **NOT APPLICABLE** enter ‘**N/A’** into appropriate field.

**SECTION A: TITLE, CONTACT INFORMATION, TIMELINES, REVIEW TYPE**

**A1. Title of Proposed Research:**

|  |
| --- |
|  |

**A2. Principal Investigator:**

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department:       | Institution/Organization:  |
| Mailing address (if NOT AU):       |
| Phone:        | Institutional E-mail:       |

**A3. Faculty SupervisoR, Co-Investigator, OR Sponsor (Visiting Researcher):**

[ ]  NOT APPLICABLE

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department:       | Institution/Organization:  |
| Mailing address (if NOT AU):       |
| Phone:        | Institutional E-mail:       |

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department:       | Institution/Organization:  |
| Mailing address (if NOT AU):       |
| Phone:        | Institutional E-mail:       |

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department:       | Institution/Organization:  |
| Mailing address (if NOT AU):       |
| Phone:        | Institutional E-mail:       |

**Alternate Contact(S)**: (e.g., Research Coordinator) [ ]  NOT APPLICABLE

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department:       | Institution/Organization:  |
| Mailing address (if NOT AU):       |
| Phone:        | Institutional E-mail:       |

  **A4. Level of AU REB review requested:**  *Research posing only minimal risk* ***may*** *qualify for an EXPEDITED review; see Algoma University REB guide for review criteria.* ***ALL*** *research utilizing a form of* ***deception*** *automatically requires Full Review.*

[ ]  Research qualifies for EXPEDITED review [ ]  Research qualifies for FULL review

Provide a brief (max. 100 words) rationale for level of review, i.e., EXPEDITED or FULL review.

|  |
| --- |
|  |

**A5. Additional REB’s review(S) and/or approval(s):** *(****\**** *Acquire AU REB review PRIOR to seeking clearance from another Institution’s REB)*

Will/Has another REB review(ed) the proposed research? [ ]  NO [ ]  YES

**IF YES,** which institution?

|  |
| --- |
|       |

(*\* Provide a copy of this REB clearance letter along with this application)*

**A6. REB ANNUAL RENEWAL, ONGOING REB REVIEW AND SUBSEQUENT REB REVIEW(S)**

**NOTE:** REB clearance is for ONE year. IF applicable REB clearance can be renewed via the REB Renewal Application.

As proposed research proceeds, is subsequent REB review(s) required? [ ]  NO [ ]  YES

**YES**, please explain why:

|  |
| --- |
|       |

**YES,** please propose a relevant continuing review process:

|  |
| --- |
|       |

**A7. ANY OTHER FORM OF REVIEW:**

Research will undergo other review (e.g., funding/grant application, faculty supervisor, etc.

 [ ]  NO [ ]  YES

Please specify which type of review:

|  |
| --- |
|       |

**SECTION B: SUMMARY OF PROPOSED RESEARCH, LOCATION(S), METHODS, PARTICIPANTS /INFORMANTS, ETC.**

**NOTE:** Once approved by the REB, changes to research protocols require the filing of a **REB APPROVAL AMENDMENT** form. Amended protocols **CANNOT** be implemented until REB approval is received.

**B1. Research START and END dates (Year/Month/Day): *(\**** *Start Date is* ***AFTER*** *REB clearance)*

|  |  |
| --- | --- |
| Estimated start date for research:       | Estimated start date for data collection:       |
| Estimated research completion date:       |  |
| Estimated date for feedback to participants/informants *(\* if applicable):*       |

**B2. RATIONALE FOR PROPOSED RESEARCH**

Briefly describe purpose/rationale of proposed research, including hypotheses or research question(s). Include all information an educated layperson would require to understand the purpose/rationale.

|  |
| --- |
|  |

**B3. IDENTIFYING KEYWORDS:** *(\* Provide 5 to 7 key words/terms to identify proposed research).*

|  |
| --- |
|       |

**B4. RESEARCH LOCATION OR PARTICIPATING GROUP:**

**NOTE: I**f **location or participating group** dictates specific type of clearance/consent, include all clearance/consent forms including drafts. If the additional form(s) of clearance are required, researcher(s) is responsible for acquiring this.

*(\* Please indicate all locations or groups that apply)*

[ ]  Algoma University

[ ]  On Reserve or Territory - (*specify site)*

[ ]  Band Council - (*specify site)*

[ ]  Institution (e.g., Hospital) - (*specify site)*

[ ]  Community agency - (*specify site)*

[ ]  School board - (*specify site])*

[ ]  Community within the Algoma District - (*specify site)*

[ ]  Other - (*specify site)*

[ ]  International - (*specify site)*

**B5. RESEARCH EXPERIENCE**

Please provide a brief description of investigator, co-investigator and/or research team, research experience **with each type of research employed.**

|  |
| --- |
|       |

IF PRIOR to start-date of research, researchers, team members, etc. require training or skills acquisition, how what is the process for this? [ ]  NOT APPLICABLE

|  |
| --- |
|       |

**B6.** **RESEARCH METHODS:** *(\* Indicate* ***ALL*** *the research methods that apply)*

[ ]  Action Research [ ]  Ethnography [ ]  Observation [ ]  Survey

[ ]  Documentary/Filmmaking [ ]  Focus Group [ ]  Experimental lab study

[ ]  Interview(s) [ ]  Oral/Life history [ ]  Collecting of Human Tissues

[ ]  Experimental behavioral study

[ ]  Online Research **(\* IF YES:** complete REB ONLINE RESEARCH checklist)

[ ]  Collection of Cultural Products

[ ]  Use of Cultural Protocols (e.g., tobacco, wild rice, semaa, etc.)

[ ]  Other

Please provide a step-by-step outline for EACH research method employed. Include settings, types of information involved, materials produced & data analysis approach. By specific re: procedures that participants/informants will undertake. ATTACH ALL study instruments as Appendices.

Method #1:

|  |
| --- |
|       |

Method #2 (if applicable):

|  |
| --- |
|       |

Method #3 (if applicable):

|  |
| --- |
|       |

**B7.** **PARTICIPANT OBSERVATION:**

Will participant observation be employed in this study? [ ]  NO [ ]  YES

If **YES,** please describe the space of observation, explaining how the researcher will gain entry to area/space, how observation(s) will take place (e.g., living in a community, visiting on a bi-weekly basis, attending organized functions, etc.) If permission is required for observation(s) attach letter(s) of permission from organization, community, Band Council, etc.

|  |
| --- |
|       |

**B8. AUDIO/VISUAL RECORDINGS:**

Does proposed research require employ any of the following: [ ]  NO [ ]  YES

(\* **IF** **YES**, indicate **ALL** that apply)

(\* **ALSO**, participants/informants must complete the Audio/Photograph/ Video Consent form)

[ ]  Audio Recording [ ]  Taking Photographs [ ]  Video Recording

Describe the rationale this method(s).

|  |
| --- |
|       |

**B9. USE OF DECEPTION:** *(\* Researchers employing deception must complete SECTION E: E13 & E14)*

Will deception be used in this study? [ ]  NO [ ]  YES

If **YES,** please describe and justify the need for deception:

|  |
| --- |
|       |

**B10. RESEARCH PARTICIPANTS/INFORMANTS**

Describe the participants/informants to be recruited. Describe any inclusion and/or exclusion criteria. Include any the types of personal information to be collected, e.g., age range, special characteristics, etc. Describe from whom the information is obtained and what is included (*include permission letters if applicable*).

|  |
| --- |
|       |

**B11. METHODS OF RECRUITING PARTICIPANTS/INFORMANTS**

Describe how and from where, research participants/informants will be recruited. Indicate if there is a different recruitment method for each research method used. ATTACH copies of recruitment tools such as posters, advertisements, web postings, flyers, etc.

|  |
| --- |
|       |

**B12. COMPENSATION/INCENTIVE(s) FOR PARTICIPANTS/INFORMANTS**

Will participants/Informants receive compensation for their participation? *(\* Check* ***ALL*** *that apply)*

[ ]  NO (\* GO to SECTION C)

[ ]  Financial [ ]  In-Kind [ ]  Draw Prize [ ]  Other:

**B13.** Provide details and justification for the compensation/incentive that are offered:

|  |
| --- |
|       |

**B14.** Provide details re: source of funding, goods, services, etc. used for the compensation/incentive:

|  |
| --- |
|       |

**B15.** In cases of participants/informants withdrawing from the research, how will compensation/incentive be dealt with? I.e., received regardless; has to be returned?

|  |
| --- |
|       |

**SECTION C: FUNDING, CONFLICTS OF INTEREST, RESEARCH RELATIONSHIPS**

**C1. FUNDING STATUS OF PROPOSED RESEARCH:** *(\* Provide ALL funding application or grant numbers associated with research)*

Research FUNDING: [ ]  NO (\* GO to **C4**) [ ]  YES

|  |  |
| --- | --- |
| Funding Applied For [ ]  | Agency:       |
| Title of proposed funded research IF different from name submitted to REB.       |
|
| Submission dates:       |
| Funding Received [ ]  | Agency:       |
| Title of proposed research associated with funding (\* If differs from name submitted to REB.)       |
|  |
| Funding date:       |

**C2. IF awaiting funding,** should REB clearance be tied to release-date of funds? [ ]  NO [ ]  YES

**IF YES,** RESEARCH FUNDED**,** list ANY additional protocols related to proposed research by title & RIS#.

|  |
| --- |
|       |

**C3. CONTRACTS**

Is there ANY contract or agreement associated with the research? [ ]  NO [ ]  YES

*(\** ***IF YES,*** *include copy of the contract/agreement with this submission)*

**C4.** **BENEFITS:** *(****\* ‘BENEFIT’*** *does NOT include benefits common to conducting research such as travel costs, conferences fees, etc.)*

Will the researcher(s), co-investigators, research team members, etc. and/or their partners or immediate family members, receive any personal NON-FINANCIAL BENEFIT (e.g., intellectual property rights, rights of employment, consultancies, receive equipment, etc.) because of this study? [ ]  NO [ ]  YES

IF **YES**, please describe benefits.

|  |
| --- |
|       |

**C5. FINANCIAL BENEFITS TO RESEARCHERS**

As a result of this research WILL researcher(s), co-investigators, research team members, etc. FINANCIALLY BENEFIT because of this study? [ ]  NO [ ]  YES

**IF YES,** explain.

|  |
| --- |
|       |

**C6. PRE-EXISTING RELATIONSHIPS**

Describe ANY pre-existing relationship between the researcher(s), co-investigators, research team, etc. and those individuals OR groups participating in research (e.g. instructor-student; manager-employee; minister-congregant, Band membership, etc.) that MAY give the appearance of, OR present a conflict of interest.

|  |
| --- |
|       |

**C8. RESTRICTIONS ON ACCESS TO AND/OR DISCLOSURE OF INFORMATION**

Describe and explain ANY restrictions regarding access to, OR the disclosure of, information (during or at end of the study) placed on the investigator(s), e.g., restrictions imposed by funders, sponsors, advisory/steering committees, Band Councils, etc.)

|  |
| --- |
|       |

**SECTION D: DESCRIPTION OF ANY RISKS & BENEFITS OF PROPOSED RESEARCH**

**D1. POSSIBLE RISKS POSED BY RESEARCH METHOD:**

Please indicate ANY potential RISKS that the participants/informants, either as individuals or as part of an identifiable group or community, MIGHT experience due to their participation.

*(\* I****F*** *more than* ***TWO*** *methods, append additional pages for the risk matrix for those methods).*

Research Method #1:

(a) Physical risks (e.g., ANY bodily contact, physical distress or administration of any substance)

 [ ]  Low [ ]  Medium [ ]  High

(b) Psychological and/or emotional risks (e.g., feeling uncomfortable, embarrassed, anxious or upset)

 [ ]  Low [ ]  Medium [ ]  High

(c) Social risks (e.g., possible loss of social status, privacy and/or reputation)

 [ ]  Low [ ]  Medium [ ]  High

(d) Risks posed by researcher(s) being in a dual/multiple relationship with study participants/informants?

 [ ]  Low [ ]  Medium [ ]  High

(e) Data security risks (i.e., risk to participant from data exposure)?

 [ ]  Low [ ]  Medium [ ]  High

(f) IF DECEPTION is used, risks posed by this (See DEBRIEFING section below)

 [ ]  Low [ ]  Medium [ ]  High [ ]  NOT APPLICABLE

Research Method #2:

(a) Physical risks (e.g., ANY bodily contact, physical distress or administration of any substance)

 [ ]  Low [ ]  Medium [ ]  High

(b) Psychological and/or emotional risks (e.g., feeling uncomfortable, embarrassed, anxious or upset)

 [ ]  Low [ ]  Medium [ ]  High

(c) Social risks (e.g., possible loss of social status, privacy and/or reputation)

 [ ]  Low [ ]  Medium [ ]  High

(d) Risks posed by researcher(s) being in a dual/multiple relationship with study participants/informants?

 [ ]  Low [ ]  Medium [ ]  High

(e) Data security risks (i.e., risk to participant from data exposure)?

 [ ]  Low [ ]  Medium [ ]  High

(f) IF DECEPTION is used, risks posed by this (See DEBRIEFING section below)

 [ ]  Low [ ]  Medium [ ]  High [ ]  NOT APPLICABLE

**D2. RISK MATRIX:** *(\* Please consult the Instructions for Ethics Review Protocol Submission Form)*

**REB Review Type based on RISK analysis:**

\* The level of risk determines type of REB review (Expedited or Full) AND level of continuing REB review.

\*\* **ALSO,** the REB ultimately determines the review types and/or level of ANY ongoing REB review.

**Overall Risk level = 1:** Expedited Review

**Overall Risk level = 2:** Expedited Review or Full Review at the discretion of the REB

**Overall Risk level = 3:** Full Review

Complete matrix for each method used.

|  |  |
| --- | --- |
| Method #1:       |  |
|  | **Risk Level**  |  |  |
|  | **Low** | **Medium** | **High** |
| **Participant/informant Vulnerability**  |  |  |  |
| **Low** | [ ]  **1** | [ ]  **1** | [ ]  **2** |
| **Medium** | [ ]  **1** | [ ]  **2** | [ ]  **3** |
| **High** | [ ]  **2** | [ ]  **3** | [ ]  **3** |

Briefly explain/justify assessment of the level of risk and vulnerability.

|  |
| --- |
|       |

Briefly describe how the potential risks will be managed and/or minimized for participants/informants

|  |
| --- |
|       |

|  |  |
| --- | --- |
| Method #2:       |  |
|  | **Risk Level**  |  |  |
|  | **Low** | **Medium** | **High** |
| **Participant/Informant Vulnerability** |  |  |  |
| **Low** | [ ]  **1** | [ ]  **1** | [ ]  **2** |
| **Medium** | [ ]  **1** | [ ]  **2** | [ ]  **3** |
| **High** | [ ]  **2** | [ ]  **3** | [ ]  **3** |

Briefly explain/justify assessment of the level of risk & vulnerability.

|  |
| --- |
|       |

Briefly describe how the risks will be managed and/or minimized for participants/informants

|  |
| --- |
|       |

*(\* Complete risk analysis for ALL additional methods and attach.)*

**D3. POSSIBLE BENEFITS TO PARTICIPANTS/INFORMANTS**

Discuss ANY potential benefits to the participants/informants resulting from their involvement in the research, e.g., include education received regarding research, gaining/accessing useful knowledge, etc. ALSO comment on the (potential) benefits to the scientific/scholarly community or society.

|  |
| --- |
|       |

**SECTION E: ACQUIRING INFORMED CONSENT OF PARTICIPANTS/INFORMANTS**

**NOTE:** See TCP2 Guidelines for information about required elements of ANY Information letter AND/OR Consent form.

**E1. IF** the Title of the Research Project communicated to participants/informants (e.g. on Consent Form/ Letter of Information) differs from the Title provided to the REB, provide alternate title AND rationale for this.

 [ ]  NOT APPLICABLE

|  |
| --- |
|       |

**E2. PARTICIPANTS/INFORMANTS CAPACITY TO PROVIDE INFORMED CONSENT**

(\* *Indicate and check the box(s) which best apply to your participants/informants):*

|  |  |
| --- | --- |
| **COMPETENT PARTICIPANTS/INFORMANTS** | **NON-COMPETENT PARTICIPANTS/INFORMANTS** |
| [x]  **ADULT** | [ ]  **ADULT** |
| [ ]  Member of Vulnerable Population (See TCP2 criteria) | [ ]  *Assent* will be obtained from participants /informants[ ]  Consent required from authorized party |
| [ ]  **YOUTH** | [ ]  **YOUTH** |
| [ ]  Consent required of **BOTH** youth & parent/guardian [ ]  Consent required from youth & parent/guardian **ARE** informed[ ]  Consent required from youth & parent/guardian **ARE NOT** informed  | [ ]  *Assent* will be obtained from youth[ ]  Consent required from parent/guardian |
| [ ]  **CHILD**  | [ ]  **CHILD** |
| [ ]  Consent of parent and child[ ]  Other:       | [ ]  *Assent* will be obtained from the child[ ]  Consent required from parent/guardian |

**F3.** **PROCESS FOR OBTAINING INFORMED CONSENT**

Describe the process whereby researcher(s) obtain informed consent. If written consent is NOT possible (e.g., due to discipline, cultural appropriateness, poses a risk, etc.) explain reason for AND alternate method of documenting consent.

|  |
| --- |
|       |

*(\* Attach a copy of the Information Letter, Consent Form(s), Audio/Video Recording Consent Form, AND the script for any telephone or email communication, letters of administrative consent or authorization and/or any other material(s) used in the informed consent process.)*

**E4.** **ONGOING CONSENT** (\* IS required if research occurs over multiple occasions or an extended period.)

Does the research occur over multiple occasions and/or an extended period? [ ]  NO [ ]  YES

**IF YES,** describe the process of how you intend to obtain *ongoing* consent?

|  |
| --- |
|       |

**E5. CONSENT FROM AN AUTHORIZED 3rd PARTY**

If the participants/informants are youth, children OR non-competent individuals, describe the alternate method of ASSENT of youth, child OR non-competent individuals AND acquiring informed consent from authorized party. *(\* Attach a copy of any permission/information letters provided to the authorized person(s) providing alternate consent and the assent process for the actual participants/informants)* [ ]  NOT APPLICABLE

|  |
| --- |
|       |

**E6.** If the research takes place within a recognized community or an organization requiring that consent be acquired prior to the involvement of individual participants/informants, describe the process for acquiring this and attach ALL relevant documentation. If consent was **not** sought, provide a justification for this; describe any alternative forms of consultation that may take place.

|  |
| --- |
|       |

**E7. PROVIDING POST-PARTICIPATION INFORMATION, FEEDBACK AND/OR A DEBRIEFING PROCESS.**

Briefly describe the process whereby *post-study information* is provided to participants/informants AND the rationale for providing this information (e.g. resource list, links, information about the study, etc.) (\* **NOT** applicable in studies utilizing deception). [ ]  NOT APPLICABLE

|  |
| --- |
|       |

**E8.** Upon study completion how will participants/informants be informed of the study results?

|  |
| --- |
|       |

**E9. CONDITIONS FOR PARTICIPANT/INFORMANT WITHDRAWAL**

Where applicable, describe the rights of participants/informants to *withdraw* from the project. Outline the procedures which will be followed to allow them to exercise this right.

|  |
| --- |
|       |

**E10.** Indicate how the data or contribution of the participants/informants will be handled should they withdraw, e.g., data removed, data rendered anonymous, etc. Indicate ANY consequences of their decision to withdraw.

|  |
| --- |
|       |

**E11.** If at some point, participants/informants can NO LONGER withdraw, describe this AND how their data or contribution will be handled, (e.g., data removed, data rendered anonymous, etc.)

|  |
| --- |
|       |

**E12.** Are there ANY additional limitations on a participant’s/informant’s ability to withdraw from participation or withdraw their data or contribution? [ ]  NOT APPLICABLE

|  |
| --- |
|       |

**E13.** **IF DECEPTION HAS BEEN USED:** (\* Forresearchers completing **QUESTION: B9)**

If deception has been employed in the research study, explain what and how ANY, information/feedback will be provided to participants/informants *after* their participation. [ ]  NOT APPLICABLE

|  |
| --- |
|       |

*\* Please attach a copy of the written debriefing form (if applicable).*

**E14.** **IF DECEPTION HAS BEEN USED:** (\* Forresearchers completing **QUESTION: B9)**

How will the participants/informants and/or communities be informed, assured, that deception has terminated? [ ]  NOT APPLICABLE

|  |
| --- |
|       |

**SECTION E: CONFIDENTIALITY, ANONYMITY & DATA PROTECTION SAFEGUARDS**

**NOTE:** Review TPC2 guidelines for further information on distinguishing confidentiality and anonymity.

**Confidentiality** is the ethical and/or legal responsibility to safeguard information entrusted to researchers, HERE Researchers, research team, staff, etc. actively LIMIT who can access data, participant-identifiers, etc.

**Anonymity** involves actively ensuring that participants’ identification, individuality, distinction, or any recognisability features, are UNKNOWN & REMAIN UNKNOWN to all researchers, research team, staff, funders, etc.

**F1. CONFIDENTIALITY and ANONYMITY**

Will the data or contribution of participants/informants be rendered Confidential? [ ]  NO [ ]  YES

**F2.** Will identity, etc. of participants/informants be Anonymous to the researcher, research team, etc.?

[ ]  NO [ ]  YES

**F3.** If confidentiality OR anonymity of participants/informants is NOT employed in this research, explain why.

|  |
| --- |
|       |

**F4.** Describe the procedures for ensuring participants/informants confidentiality OR anonymity AND/OR the confidentiality/anonymity of data or contribution during the research process, dissemination of results, etc.

|  |
| --- |
|       |

**F5.** Describe ANY limitations to protecting the confidentiality OR anonymity of participants/informants whether due research methods, legal issues, nature of the sample population, or other reasons (e.g., a duty to report).

|  |
| --- |
|       |

**F6.** Identify all parties who will have access to the data or contributions of participants/informants.

|  |
| --- |
|       |

**F7. DATA & RESEARCH DOCUMENT(S) PROTECTION SAFEGUARDS** (E.g., access limits, storage, etc.)

Explain how AND where records, video/audio recordings, artifacts, questionnaires, etc. will be secured, stored? How long will recordings, documents, data, etc. be retained? How will documents, data, etc. be destroyed? IF data is to be stored beyond the common standards of your discipline, provide a justification for this. IF documents, data, etc. is to be archived, etc. when and where will they be stored. (\* IF archiving is to be undertaken, participants/informants had to have consented to this in consent form.)

|  |
| --- |
|       |

**SECTION G: RESEARCHER(S) & CO-INVESTIGATOR(S) SIGNATURES**

**NOTE: Privacy Regulations & Applicable Laws:** Research involving collection of personal information, provincial, national and/or international laws may apply. The signature of Principal Investigator confirms that they **understand AND will comply with all relevant laws** governing the collection and use of personal information in research.

**All researchers must sign below for this application to be processed and reviewed.**

As the **Principal Investigator** on this project, my signature CONFIRMS that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant University, provincial, national and international policies and regulations that govern research involving human participants/informants; see: AU REB Web site or Tri-Council Web site) for relevant documentation.

I AGREE, to comply with the Tri-Council Policy Statement and all Algoma University policies and procedures, governing the protection of human participants/informants in research, including, but not limited to, ensuring that:

* Research is performed by qualified & appropriately trained personnel in accordance with REB protocol;
* NO changes to REB approved protocols AND/OR consent form/statement will be implemented without notifying the REB of proposed changes AND receipt of the subsequent REB clearance PRIOR to their implementation;
* Significant adverse effects will be reported to the REB within 5 working days of occurrence; and
* A progress report is submitted annually or in accordance with the terms of certification.

I CERTIFY, that the information provided in this application is complete and correct.

|  |  |
| --- | --- |
| PRINCIPAL INVESTIGATOR:        | Date:       |
| PRINCIPAL INVESTIGATOR:        | Date:       |

|  |  |
| --- | --- |
| CO-INVESTIGATOR:        | Date:       |
| CO-INVESTIGATOR:        | Date:       |
| FACULTY SPONSOR:        | Date:       |

**\*\* IF** principal investigator is a **STUDENT,** their academic advisor **MUST** sign, indicating that they have reviewed the submission.

|  |  |
| --- | --- |
| FACULTY SUPERVISOR:        | Date:       |
| FACULTY SUPERVISOR:        | Date:       |

\*\* Email copy of this submission including relevant appendices to: ethicsoffice@algomau.ca.

**NOTES ON CONDITIONS FOR REB REVIEW OF ONGOING RESEARCH**

Depending on determination of risk level (risk matrix) a LEVEL of continuing ETHICAL review will be determined by the REB; summarized below.

**Level 1**: All research that extends beyond one year WILL require the submission of an Annual Renewal Report to the REB, addressing:

* ANY changes to the protocol, forms, or research personnel (e.g., status as students or employees)
* Number of participants/informants currently involved OR who have completed the study, or who withdrew (include reasons for withdrawal)
* ANY ethical concerns that have arisen

**Level 2:** In addition to being subject to a Level 1 review, mid- and high-risk research MAY receive a site visit by the REB, including but not limited to, review of:

* Researcher’s consent files documenting participant consent, eligibility, use of withdrawal rights, etc.
* Document and data storage safeguards.

**Level 3:** In addition to being subject to a Level 1 review, potentially being subject to a Level 2 review, high-risk research MAY receive a routine site visit, including review of:

* Researcher’s data files documenting adherence to or deviation from protocols, reporting of adverse/unanticipated events, and data quality; this may include audio or video recordings, electronic or paper records, field notes, etc.

(Under UNUSUAL circumstances), REB review may also include direct engagement with research process (i.e., observing the consent or study procedures) IF the researcher has received permission from the participants/informants to do so, AND the REB HAS determined the risks to participants/informant DO NOT outweigh their potential benefits. REB may also contact participants/informants during or after participation to (e.g., by phone, or by appending relevant questions to study protocols). Questions asked of them my touch on, their recruitment, nature of interactions with researcher(s), their opportunity to ask researcher(s) questions, overall experience of as participants/informants and any questions/comments they have. Such procedures however, are NOT expected to be the norm.

# REB Submission Checklist

* **ALL SUBMISSIONS MUST CONTAIN A COMPLETED CHECKLIST**
* Some items are **REQUIRED** for **ALL** submissions.
* Incomplete submissions may cause delays.

**Check all appropriate boxes items & attach relevant documentation.**

|  |  |  |
| --- | --- | --- |
| [ ]  YES | ***Required*** |  Information Letter Explaining Research Study. |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | ***Required*** |  Participant/Informant Consent Form. |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | ***Required*** |  Signatures of Investigator(s) And/or Faculty Supervisor(s) |

|  |  |  |
| --- | --- | --- |
| [ ]  YES Inc.[ ]  ON File | ***Required*** | Certificates of Completion for TCP2-Core Online Tutorial for all investigators.  |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | ***Required*** |  Questionnaire(s) And/or Test Instruments. |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | ***Required*** |  Recruitment Materials (e.g., posters, letters, online postings, emails, etc.) |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | [ ]  N/A | Letters of Permission Allowing YOUR Research to Take Place on Site. |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | [ ]  N/A |  Letters of Permission for Obtaining Personal Information. |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | [ ]  N/A |  Decisions REQUIRED of Other REB Boards. |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | [ ]  N/A |  Funding Agreements, Contracts, etc. |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | [ ]  N/A |  Photography, Audio OR Visual Recordings(s) Consent Form.  |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | [ ]  N/A |  Debriefing Letter or Materials. (\*\* Required IF Deception is Used) |

|  |  |  |
| --- | --- | --- |
| [ ]  YES | [ ]  N/A |  Checklist for On-line research. |

***NOTE:*** *If submitting an REB application to another institution, a final version of that application is to be submitted FIRST to the AU REB. AFTER review, it may then be sent to the other institution.*

**! ! NOTE !!** Research continuing beyond one year, requires the submission of an **Annual Renewal Application.**

Upon research completion, a **Research Project Completion Report** must be submitted. Failure to do so or delays in doing so may cause delays in futures REB Reviews or funding.

**APPENDIX 1: CONSENT FORM.** REVISE TO SUIT YOUR STUDY HOWEVER CONTENT MUST CONTAIN ALL RELEVANT INFORMATION FROM REB SUBMISSION.

* **REMOVE** INSTRUCTIONAL BULLETS.



(Appropriate letterhead should be inserted)

 **CONSENT TO PARTICIPATE IN RESEARCH**

**Title of Research Project:**

* *(If the study involves using different consent forms for different community of interest, identify the community as the subtitle of the study.)*

**Principal Investigator(s) and/or Co-Investigator(s):** You are asked to participate in a research study conducted by…:

* *(Insert names and identify all investigators - faculty, student and other AND the department affiliation at Algoma University AND/OR any other* sponsoring agencies/organizations, etc.)

**PURPOSE OF THE RESEARCH:**

* *Outline the purpose of the study in language that an educated layperson could understand.)*

**RESEARCH PROCEDURES:** If you agree to participate in this study, you will be asked to…:

* *Describe the procedures step-by-step, using simple clear language. Medical and scientific terms should be defined and explained. Identify any procedures which are experimental.* *Specify if participant’s is assigned to study groups, participation time required for each procedure, total time required for participation, frequency of procedures, location of the procedures, etc. Provide details about any debriefing, follow-up or information sessions for participants/informants.*

**POTENTIAL RISKS & DISCOMFORTS TO PARTICIPANTS/INFORMANTS:**

* *Describe any reasonably foreseeable risks, discomforts, inconveniences* ***(e.g. physical, psychological, emotional, financial and social impacts****), and how these will be managed.)*
* *If there are significant physical or psychological risks to participants/informants that might cause the researcher to terminate the study, please describe them.*

**POTENTIAL BENEFITS TO PARTICIPANTS/INFORMANTS AND/OR TO SOCIETY:**

* *Describe benefits to participants/informants expected from participating in the research. If the participant will NOT benefit from participation, clearly state this**fact.* ALSO state any potential benefits, if any, to science, society, etc. expected from the research.

**COMPENSATION FOR PARTICIPATION:**

* *State whether the participant will receive compensation of any kind. If NOT, state this. If participant will receive payment, describe remuneration amount and process for receipt*

**CONFIDENTIALITY AND/OR ANONYMITY:** Any information obtained during this study AND that would identify your and/or reveal your participation—will remain confidential and ONLY disclosed with your permission.

To ENSURE your personal information remains confidential and/or your identity/participation remain anonymous, the research instigators will…:

* *Describe procedures to ensure confidentiality and/or anonymity of data or other contributions from participants/informants. Describe how data or contributions will be secured and how long they will be kept.*
* *If information will be released to any other party for any reason, state the person/agency to whom the information will be released, the nature of the information, and the purpose of the disclosure.*
* *If participation, research, etc. activities are to be photographed, audio- or videotaped, ALSO describe the participant’s right to review and/or edit this material, who will have access to these, etc. Describe any future use (IF participants/informants have CONSENTED) outside of the research process (e.g., for education purposes, conference presentation, publication, etc.) that their data or contributions will be used and destroyed.*

**PARTICIPATION AND WITHDRAWAL:** As a participant/informant you may withdraw (i.e., not longer to participate) from the study…:

* *Indicate ANY conditions and/or limitations on participant’s right to withdraw and/or how their data will be handled.* IF *appropriate, describe the anticipated circumstances under which the participant’s involvement may be terminated by the investigator. If participant will receive payment, describe remuneration amount and/or how withdrawal impacts this.*

In addition, the researcher may withdraw you and/or your data or contribution from this research if circumstances warrant doing so.

**FEEDBACK OF THE STUDY RESULTS TO THE PARTICIPANTS/INFORMANTS:**

* *Describe whether a summary of the research findings will be available to participants/informants and how/where/when they will be made available to participants/informants, e.g., a presentation, publication, etc.*

Date when research results are available:

**SUBSEQUENT USE OF DATA:**

* Describe how participant’s/informant’s data and/or contributions may be used in the future, e.g., other studies, in publications, in presentations, etc.)

**RIGHTS OF RESEARCH PARTICIPANTS/INFORMANTS:** If you have questions regarding your rights as a research participant, contact: Research Ethics Board, ethicsoffice@algomau.ca

If you have any questions or concerns about the research, please contact:

* Provide contact information for Principal Investigators and/or Co-Investigators, *Faculty Supervisor(s), etc. Include daytime phone numbers, cell numbers (if appropriate) AND email addresses for all listed individuals.*
* *For projects posing greater than minimal risk, also include research team night/emergency phone numbers AND any local medical or mental health crisis services, e.g., a support line with consent form.*

**SIGNATURE OF RESEARCH PARTICIPANT AND/OR LEGAL REPRESENTATIVE**

I understand the information provided to me regarding the (INSERT TITLE OF STUDY) as described herein. My questions have been answered to my satisfaction, and I therefore agree to participate in this study.

I have been provided both an information letter outlining the study AND a copy of this consent form for my own records.

**NAME OF PARTICIPANTS/INFORMANTS:**

|  |  |
| --- | --- |
| NAME:        | SIGNATURE:       |
| DATE:        |

**SIGNATURE OF INVESTIGATOR OR DESIGNATE**

I, acknowledge the above represents the terms under which the research will be conducted.

|  |  |
| --- | --- |
| NAME:        | SIGNATURE:       |
| DATE:        |