NORTHLAND COMMUNITY AND TECHNICAL COLLEGE
STANDARD IRB APPLICATION FOR NON-EXEMPT RESEARCH INVOLVING HUMAN SUBJECTS

(Not for exempt research)

Please complete this application as thoroughly as possible.

FORM MUST BE TYPED

All investigators (faculty, staff and students – anyone named as personnel on a new or existing (renewals) *non-exempt* research project) and faculty serving as faculty sponsor for non-exempt student research projects are required to complete human subjects research training before human subjects research can begin. Training is *recommended* for exempt research but not mandatory at this time. However, if a request for exemption is deemed to be non-exempt, training must be completed prior to approval. Please submit training certification with this protocol application or indicate that certification is already on file.

1. Research Project Protocol ☐ New ☐ Renewal (and/or) ☐ Modification

Protocol Title:

Research project start date[1]: *[1]The project start date cannot be earlier than the protocol's approval date. If you want to start your research as soon as your protocol is approved, you may put "upon approval" for the project start date.*	Research project end date[2]: *[2]The project end date should be the date after which you will no longer be working with identifiable human subjects data.*
☐ This study has previously been approved by the IRB.	Original Protocol #:
☐ Unfunded project	Previous Protocol #:
☐ Internally funded project (NCTC College award)	Source:
☐ Externally funded project *(provide grant title and award # below)*	Sponsor/Agency:
Grant Title:	Grant Award #:

2. Principal Investigator (PI) [Complete 2a OR 2b]

2a. STUDENT PI *

Name:	Telephone: xxx-xxx-xxxx	e-mail:
Course # and Name[3]:		Training certification ☐ Attached ☐ On file

[3]Use "Independent Student Research" for course name if research project is not for a specific course.

Faculty Sponsor:	Faculty Sponsor e-mail:
Training certification ☐ Attached ☐ On file	

***ALL** student investigators must have a faculty sponsor for their project. Faculty sponsor needs to review and approve of the protocol before it is submitted.*

2b. FACULTY/STAFF PI (Do not complete this section if you are a student.)

Name: e-mail:	Department:
☐ Class Research Project	Course # and Name:
☐ Independent Research Project	Training certification ☐ Attached ☐ On file

3. Co-Investigators

Name: e-mail:	Institution *(if not NCTC)*: Training certification ☐ Attached ☐ On file
Name: e-mail:	Institution *(if not NCTC)*: Training certification ☐ Attached ☐ On file
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Name: e-mail:	Institution *(if not NCTC)*: Training certification ☐ Attached ☐ On file

4. Cooperating Institutions

4 (a) Will the research be conducted on a NCTC campus? ☐ Yes ☐ No
If "no," please indicate the location(s):

4 (b) Have you obtained permission to conduct the research at the off-campus location? ☐ Yes ☐ No
If "yes," please attach a copy of the documentation of permission if it was provided.

4 (c) Is this research being done in cooperation with any institutions, individuals or organizations not affiliated with NCTC? ☐ Yes ☐ No If "yes," please list:

4 (d) Have you received IRB approval for this study from an IRB at another institution? ☐ Yes ☐ No
If "yes," please attach a copy of the IRB approval.

5. Research Project Description

5 (a) Provide, in lay terms, a detailed summary of your proposed study. Clearly state the purpose of the study. Describe the research procedures. You may attach the research project description to this form if you like or type in the box below.

For protocols involving tests, surveys or interviews: ☐ **N/A**

5 (b) What type(s) of instruments/activities will be used *(Check all that apply.)*

☐ Educational (cognitive, diagnostic, aptitude, achievement)
☐ Tests ☐ *published/standardized or* ☐ *researcher-created*
☐ Questionnaire Survey *Type of survey:* ☐ *paper* ☐ *telephone* ☐ *online*
☐ Interviews *Type of interview:* ☐ *face-to-face* ☐ *telephone* ☐ *e-mail/chat room*

*****Please attach a copy of any tests, questionnaires, interview questions, surveys, scripts, etc. that will be used.*****

NOTE: If your research is being conducted in a language other than English, these documents must be submitted in the original language and in an English translation.

Please verify the accuracy of the original documents by selecting one or more of the following statements:
☐ I am a native speaker.
☐ I have studied _____(language) for _____ (number) years.
☐ Documents have been reviewed by a native speaker or individual fluent in _____ (language).

6. PARTICIPANTS

6a. Participant Population

6a(1) What is the age range of participants in the proposed study?

6a(2) How many participants are needed for the study?

6a(3) What do you estimate the ratio of males to females to be?

6a(4) Please list inclusion and exclusion criteria:

6a(5) Will the participants be capable of understanding the nature of the study and the consent process? ☐Yes ☐No
If "no," explain.

6a(6) Will any of the following classes of vulnerable subjects be involved in the proposed study?

Class of vulnerable subjects	*Comments*
☐ Yes ☐ No Pregnant women or ☐ *Pregnant women will not be specifically included or excluded.*	
☐ Yes ☐ No Human fetuses	
☐ Yes ☐ No Neonates	
☐ Yes ☐ No Prisoners	
☐ Yes ☐ No Children	
☐ Yes ☐ No Individuals with compromised mental status *If "yes," indicate how this will be determined.*	
☐ Yes ☐ No Other *If "yes," please describe.*	

6b. Participant Recruitment

Describe how participant recruitment will be performed. Include how and by whom potential participants are introduced to the study. *Check all boxes below that apply.*

☐ NCTC directory ☐ Postings, flyers ☐ Radio, TV
☐ E-mail solicitation. Indicate how the e-mail addresses will be obtained and describe the sampling techniques that will be used.

☐ Web-based solicitation. Specify sites:

☐ Participant Pool. Specify what pool (ex. PSY 101 students).

☐ Other. Please specify:

*****Please attach any recruiting materials and/or the text of e-mail or web-based solicitations you will use.*****

6c. Participant Compensation and Costs

Are participants to be compensated for the study? ☐ Yes ☐ No *If "yes," what is the amount, type and source of funds.*
Amount: Type (ex. gift card, cash, etc.): Source:

Will participants who are students be offered class credit? ☐ Yes ☐ No ☐ N/A

If you plan to offer course credit for participation, please describe what alternative assignment(s) students may complete to get an equal amount of credit should they choose not to participate in the study?

Are other inducements planned to recruit participants? ☐ Yes ☐ No *If "yes," please describe.*

6d. Participant Risks and Benefits

What are the benefits, if any, to participants in this study?

What are the risks (physical, social, psychological, legal, economic), if any, to participants in this study?

If deception is involved, please explain.

[NOTE: Research involving deception requires debriefing (oral or written). If not using deception, debriefing is optional.]
***** Please attach debriefing script if used. *****

Indicate the degree of risk (physical, social, psychological, legal, economic) you believe the research poses to human subjects *(check **the one** which applies).*

☐ MINIMAL RISK: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

☐ GREATER THAN MINIMAL RISK: Greater than minimal risk is greater than minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

7. Confidentiality and Data Security

Will personal identifiers be collected? ☐ Yes ☐ No Will identifiers be translated to a code? ☐ Yes ☐ No

Will audio or video recordings and/or photographs, be made of your participants? ☐ Yes ☐ No
If "yes," please describe.

If any type of audio or video recording, or photograph, will be made of your participants, please describe how you will obtain the participants' consent to obtain these recordings, and how you will maintain a record of this consent.

Who will have access to data (surveys, questionnaires, recordings, interview records, etc.)?

Describe how you will protect participant confidentiality and secure research records.

8. Consent

8a. Informed consent (If seeking waiver of informed consent, please go to 8c.)

8a(1) Does the consent form provide potential participants information needed to make an informed decision about whether to participate? ☐ Yes ☐ No

Does the consent form start with the following key information: Why one might or might not want to participate, including information about purposes, risks, benefits, and alternatives? ☐ Yes ☐ No

Does the consent form notify prospective subjects that their information can be used for future research without their consent OR that their information will not be used for future research?. ☐ Yes ☐ No

Does the consent form contain information about possible commercial profit associated with the project, and whether subjects would share the potential profit? ☐ Yes ☐ No ☐ Not Applicable

Does the consent form include notice about whether clinically relevant research results, including individual research results, will be given to subjects? ☐ Yes ☐ No ☐ Not Applicable
If Yes, under what conditions?

Does the project involve whole genome sequencing? ☐ Yes ☐ No

8a(2) If the participants are minors, will parental consent forms be used? ☐ Yes ☐ No
If "no," please explain.

8a(3) Will the consent form be presented on paper or online? ☐ Paper ☐ Online

Please attach the consent form(s) that the participants and/or parent/guardian will be required to sign.*

8b. Retention of signed consent forms

8b(1) How and where will the written, signed consent forms be stored?

8b(2) For how long?

8b(3) If these forms will later be destroyed, specify how and when (**consent forms must be retained for at least three years following completion of the research**:

8c. Waiver of written informed consent

Are you requesting a waiver of written documentation (signed) of informed consent? ☐ Yes ☐ No
If "yes," please answer the following questions:

8c(1) Will the only record linking the participant and the research be the consent document and the principal risk to the participant would be from breach of confidentiality? ☐ Yes ☐ No

8c(2) Do you consider this a minimal risk study that involves no procedures for which written consent is normally required outside of research? ☐ Yes ☐ No

8c(3) Explain how you plan to obtain consent.

SUBMISSION CHECKLIST (This section must be FULLY completed.):

For submission to be complete, all applicable documents must be sent as attachments to
Incomplete protocol submissions will not be sent out for review and will be returned to the investigator.
My submission contains the following documents (IF APPLICABLE, DOCUMENT MUST BE ATTACHED):

Attached	N/A	
☐		This application form, fully completed and signed by researcher.
☐		Training certification **mandatory** for all named researchers and, if student researcher, their faculty sponsor.
☐	☐	Documentation of permission to conduct research in a location other than NCTC.
☐	☐	IRB approval documentation from another institution.
☐	☐	Research project description **(**check N/A if typed on form).
☐	☐	Tests, questionnaires, interview questions, surveys, scripts, etc.
☐	☐	Recruiting materials, text of e-mail or web-based solicitation.
☐	☐	Debriefing script.
☐	☐	Consent and/or assent form(s).
☐	☐	(#8a) **If using oral consent,** researcher must provide a copy of the consent document that will be read to research participants and, if required, the name and address of the individual who will witness the oral consent. The oral consent document should include a statement indicating that completion of the research exercise will confirm the participants' consent to participate.

ADDITIONAL SUBMISSION REQUIREMENT FOR ALL STUDENT PRINCIPAL INVESTIGATORS (including independent research projects):

☐ Application and all other related documentation has been reviewed and signed by faculty sponsor.

Principal Investigator's* Assurance Statement for Using Human Subjects in Research

I certify that the information provided in this IRB application is complete and accurate.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of IRB approved studies, the ethical performance of protocols, the protection of the rights and welfare of human participants, and strict adherence to the study's protocol and any stipulations imposed by the Northland Community and Technical College Human Subjects Institutional Review Board.

If applicable, I understand that it is my responsibility to ensure that the human participants' involvement as described in the funding proposal(s) is consistent in principle, to that contained in the IRB application. I will submit modifications and/or changes to the IRB as necessary.

I agree to comply with all Northland Community and Technical College policies and procedures, as well as with all applicable federal, state, and local laws, regarding the protection of human participants in research.

Principal Investigator Name and Signature	Date
Faculty Sponsor Name and Signature (If applicable)	Date

***** Please type in name and date.***

Questions? E-mail Justin.berry@northlandcollege.edu or David.christian@northlandcollege.edu

COMMENTS: