NORTHLAND COMMUNITY AND TECHNICAL COLLEGE
RESEARCH INVOLVING HUMAN SUBJECTS:
APPLICATION FOR EXEMPT RESEARCH DESIGNATION BY IRB

Please complete this application as thoroughly as possible.
HANDWRITTEN DOCUMENTS WILL NOT BE ACCEPTED.

**COMPLETE 1 OF THE 8 EXEMPTION CATEGORIES FROM SECTION A BEST DESCRIBING
YOUR RESEARCH PROJECT; THEN COMPLETE THE RESEARCH PROJECT
AREA IN SECTION B STARTING ON PAGE 2.**

SECTION A:

EXEMPTION I: FOR PROTOCOLS INVOLVING ESTABLISHED OR COMMONLY ACCEPTED EDUCATION SETTINGS AND NORMAL EDUCATIONAL PRACTICES

Ia. **Where will the research activity take place?** *(Check all that apply.)*
☐ At an established/commonly accepted educational setting   ☐ Other, please explain below.

Ib. **What type(s) of activities will be used?** *(Check all that apply.)*
☐ Oral history, journalism, biography, literary criticism, legal research, and/or historical scholarship
☐ Research on the effectiveness of instructional techniques, curricula or classroom management methods
☐ Research comparing instructional techniques, curricula or classroom management methods
If the research involves other activities, it is not eligible for this exemption. Do not proceed.
You must complete the Standard NCTC IRB application.

Ic. Will the research adversely impact student's opportunity to learn required education content? ☐ Yes ☐ No

Will the research adversely affect the assessment of educators who provide instruction?   ☐ Yes ☐ No

EXEMPTION II: FOR PROTOCOLS INVOLVING TESTS, SURVEYS, INTERVIEWS, OR OBSERVATION OF PUBLIC BEHAVIOR

IIa. What type(s) of instruments/activities will be used *(Check all that apply.)*
☐ Educational (cognitive, diagnostic, aptitude, achievement)
☐ Tests *Type of test:* ☐ *published/standardized or* ☐ *researcher-created*
☐ Questionnaire Survey *Type of survey:* ☐ *paper* ☐ *telephone* ☐ *online*
☐ Interviews *Type of interview:* ☐ *face-to-face* ☐ *telephone* ☐ *e-mail/online*
☐ Observation of public behavior
If the research involves other activities, it is not eligible for this exemption. Do not proceed.
You must complete the Standard NCTC IRB application.

IIb. Will information be recorded in a manner that participants can be identified or linked back to? ☐ Yes ☐ No

If the answer to the question under b. is "Yes," the research is eligible for exemption,
but limited IRB review must include privacy and confidentiality protection

IIc. Would disclosure of information obtained put participants at risk of harm, including civil or criminal liability or damage to their financial standing, employability or reputation?   ☐ Yes ☐ No
If the answer to "b" and "c" is "Yes," the research is not eligible for this exemption. Do not proceed.
You must complete the Standard NCTC IRB application.

EXEMPTION III: FOR PROTOCOLS INVOLVING BENIGN BEHAVIORAL INTERVENTIONS WITH ADULTS WHO PROSPECTIVELY AGREE, AND WHEN INFORMATION COLLECTION IS LIMITED TO VERBAL OR WRITTEN RESPONSES (OR DATA ENTRY) OR AUDIOVISUAL RECORDINGS

IIIa. Can information be linked back to subjects? ☐ Yes ☐ No
Would information disclosure place subjects at risk of harm? ☐ Yes ☐ No
If the answer to either question under a is "Yes," the research is not eligible for this exemption. Do not proceed.
You must complete the Standard NCTC IRB application.

IIIb. Will identifiable information be recorded?   ☐ Yes ☐ No
If the answer to the question under b. is "Yes," the research is eligible for exemption,
but limited IRB review must include privacy and confidentiality protection

EXEMPTION IV: FOR PROTOCOLS INVOLVING THE COLLECTION OR STUDY OF EXISTING DATA, DOCUMENTS, RECORDS OR SPECIMENS

IVa. What will be collected or studied? *(Check all that apply.)*   ☐ Existing data   ☐ Existing documents
☐ Existing records   ☐ Existing pathological specimens ☐ Existing diagnostic specimens
If the research involves other types of data, it is not eligible for this exemption. Do not proceed.
You must complete the Standard NCTC IRB application.

IVb. Is this information publicly available?   ☐ Yes ☐ No

IVc. Will information be recorded in a manner that research subjects will not be identified, directly or through identifiers linked to the subjects?   ☐ Yes ☐ No

IVd. Is the Research regulated by HIPAA as "health care operations", "research", or "public health? ☐ Yes ☐ No

IVe. Is the research conducted by, or on behalf of, a Federal agency using information collected or generated by the government for nonresearch purposes, and the information is protected by federal privacy standards? ☐ Yes ☐ No

If the answer to "b", "c", "d", or "e" is "No," the research is not eligible for this exemption. Do not proceed.
You must complete the Standard NCTC IRB application.

EXEMPTION VI: FOR PROTOCOLS INVOLVING TASTE AND FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES

VIa. What is the purpose of this study? *(Check all that apply.)*
☐ To evaluate the taste or quality of food   ☐ To test consumer acceptance of a food.

If neither of these apply, do not proceed. The research is not eligible for this exemption.
You must complete the Standard NCTC IRB application.

VIb. What type of food will be consumed during the research? *(Check all that apply.)*
☐ Wholesome food without additives
☐ Food that contains an ingredient at or below the level and for a use found to be safe by the FDA or approved by the EPA or Food Safety and Inspection Service of the USDA.
☐ Food that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA   or approved by the EPA or Food Safety and inspection Service of the USDA.

If the food to be consumed is not in one of these categories, it is not eligible for this exemption. Do not proceed.
You must complete the Standard NCTC IRB application.

EXEMPTION VII: FOR PROTOCOLS INVOLVING STORAGE OR MAINTENANCE OF IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS FOR SECONDARY RESEARCH

VIIa. What will be stored or maintained? ☐ Existing data   ☐ Existing documents
☐ Existing records ☐ Existing pathological specimens   ☐ Existing diagnostic specimens ☐ Other, please explain below.

This exemption requires a one-time expedited review for safeguards related to privacy and confidentially protection, and broad consent

EXEMPTION VIII: SECONDARY RESEARCH USING IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS

Ia. What type of information will be used for the secondary research? ☐ Existing data   ☐ Existing documents
☐ Existing records ☐ Existing pathological specimens   ☐ Existing diagnostic specimens ☐ Other, please explain below.

This exemption requires a one-time expedited review for safeguards related to privacy and confidentially protection, and broad consent

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. Faculty sponsors must complete training in line with the student's research approval request. If training has been completed, please attach certification with this protocol application or indicate that certification is already on file.

SECTION B. All Information Below Must Be Completed Regardless of Exemption Category

1. Research Project	☐ New ☐ Modification

(This section to be completed for ALL exemptions.)

Protocol Title:	
Research project start date*: *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*: *The project end date should be the date after which you will no longer be working with human subjects data collected for this project.*
☐ Unfunded	
☐ Internal Funding (NCTC)	Source:
☐ External Funding *(provide grant title and award # below)*	Sponsor/Agency:
Grant Title:	Grant Award #:

2. Principal Investigator (PI)	*(This section -- 2a OR 2b – to be completed for ALL exemptions.)*

2a. STUDENT PI*		
Name:	Telephone: **xxx-xxx-xxxx**	e-mail:
Course # and Name**:	Training certification ☐ Attached ☐ On file	

***Use "Independent Student Research" for course name if research is not for 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 the protocol before it is submitted, and indicate their approval by signing and submitting a Faculty Sponsor Assurance Form

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	*(This section to be completed for all exemptions, if applicable.)*

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

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

4. Cooperating Institutions *(This section to be completed for all exemptions.)*

4 (a) Will the research be conducted on the 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 *(This section to be completed for all exemptions.)*

5 (a) Provide 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   *Type of test:* ☐ *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.

6. PARTICIPANTS *(This section to be completed for Exemption I, II, III, VI. VII, and VIII)*

6a Participant Population

Research involving study participants who are likely to be vulnerable to coercion or undue influence (such as minors under the age of 18, prisoners, pregnant women, human fetuses, neonates, persons with mental disabilities, or persons whose economic status would leave them susceptible to coercion) is not eligible for exempt status.

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

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

6a(3) What will the ratio of males to females be?

6a(4) Please list inclusion and exclusion criteria for study participants

6(b) 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 student body   ☐ Postings, flyers   ☐ Radio, TV
☐ E-mail solicitation. Indicate how the e-mail addresses will be obtained and describe the sampling technique that will be used.

☐ Web-based solicitation. Specify sites.

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

☐ Other. Please specify.

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

6(c) 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.

6(d) 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?

Describe how confidentiality will be protected.

Describe how the research will be explained to participants.

NOTE: If using a consent form or oral consent script to tell participants about the study, their right to withdraw, how confidentiality will be protected and the risks and benefits of the study, please attach.
If debriefing is used, please attach script or form.

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.

SECTION 8   *(This section to be completed for Exemption IV ONLY.)*

8a. Data/Documents/Records/Specimens

From where will the data/documents/records/specimens be obtained?

Is de-identified information being provided to the investigator?   ☐ Yes ☐ No
If the information being recorded by the investigator?   ☐ Yes ☐ No
If "yes," describe how the investigator will record data without identifiers.

Is the information related to the provision of healthcare?   ☐ Yes ☐ No
Does the data meet the HIPAA de-identification requirements?☐ Yes ☐ No   ☐ Don't know   ☐ N/A
Describe the information being used in the research.

8b. Confidentiality and Data Security

Describe how you will protect anonymity and secure research records.

9. Food   *(This section to be completed for Exemption VI ONLY.)*

Specify what food(s) will be provided to participants.

How will the food be prepared?

How will the food be stored?

Describe your plan to deal with food allergies.

(Rev. 1/2019)

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

For submission to be complete, all applicable documents must be sent as attachments. 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 documentation (**not mandatory for exempt research**).
☐	☐	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.
☐		Consent form

ADDITIONAL SUBMISSION REQUIREMENTS FOR ALL STUDENT PRINCIPAL INVESTIGATORS (including students conducting independent research projects):

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

** *Please type in name and date.*

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

COMMENTS: