INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH
Request for Certification of **Exempt Status** for a new research project

Section I: General Information

Date: _____ **IRB Number** (*Assigned by IRB office*): _____

Study Title: _____

Principal Investigator or Faculty Advisor: _____

Department: _____

Campus Address: _____

Email Address: _____ Phone: _____

Type of research, check all that apply:

☐ Faculty Research ☐ Dissertation/Thesis/Honor's Thesis

☐ Product of Learning/Capstone Research ☐ Class Project – Course Number: _____

☐ Other (describe): _____

*Research Personnel

Please list all research personnel involved in the conduct of this study. All research personnel must complete required training in human subject research and provide to the IRB office certification verifying completion of the requirement**.** **The IRB will not review a study without such forms on file for all research personnel.** Only ECSU faculty, staff, students, or registered volunteers are considered "ECSU-affiliated" and thus covered by the ECSU IRB review. All non-affiliated study personnel must have their participation reviewed by the appropriate IRB.

Name	Role (PI, Co-PI, etc.)	Responsibilities (a-n)	Department	ECSU Affiliate
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Responsibilities: (enter all that apply to section above)

a. Screening potential participants
b. Obtaining Informed Consent
c. Accessing identifiable data
d. Administering survey
h. Conducting interviews
i. Entering subject data into research records
j. Conducting study procedures
k. Educating participants, families or staff

e. Analyzing data with identifiable information
f. Collecting biological specimens
g. Conducting physical exams
l. Supervising exercise
m. Dispensing medication
n. Other: _____

All key personnel must complete the training requirement in human subject protections, from CITI Program. The certification document should accompany this application.** ***(Protocols will not be reviewed until training requirement is met.)

Section II: Investigator's Assurance

ASSURANCES

Investigator's Assurance Statement:

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

☐ I certify that the research will be conducted according to the protocol approved by the IRB, in accordance with ECSU policies and procedures, as well as with all applicable Federal, State, and Local laws and regulations regarding the protection of human subjects in research.

☐ I also agree to the following:

1. accept responsibility for the scientific and ethical conduct of this research study;
2. accept responsibility for ensuring that all members of the research team: 1) complete the required CITI Training and any other necessary training to fulfill their study responsibilities;
3. **all** protocol changes will be prospectively reviewed by the IRB;
4. immediately report to the IRB all research-related incidents to include accidents, injuries, complaints, problems, or breaches of confidentiality;
5. immediately report to the IRB any serious adverse reaction and/or unanticipated effect on p which may occur as a result of this study;
6. report in writing to the research participants and the IRB any significant new findings that may alter the risks and benefits.

Principal Investigator:	Printed Name	Signature	Date
Co-Principal Investigator:	Printed Name	Signature	Date
Co-Principal Investigator:	Printed Name	Signature	Date
Co-Principal Investigator:	Printed Name	Signature	Date
Chair, Dean or Director:	Printed Name	Signature	Date

Section III: Conflict of Interest

☐ Yes ☐ No Does the Principal Investigator, Co-Investigator, or other Key Personnel have any real or apparent conflict of interest in the results of this project? (Conflicts of interest relate to situations in which financial or other personal considerations may compromise or have the appearance of compromising objectivity in meeting University responsibilities…e.g., stock or stock options, interest in technology, consultant to sponsor)?

If Yes, please describe:

_____

Explain how participants will be protected from the influence of competing interests (i.e., how will conflict be managed).

_____

Section IV: Source of Funding

☐ Unfunded ☐ Planned ☐ Pending ☐ Awarded

☐ Intramural Funded Institutional Account #: _____

☐ Extramural Funded* Agency/Company Name: _____

Agency ID #/Protocol #: _____ ECSU Acct #: _____

Amount $: _____ Total: _____

***GRANT PROPOSAL**

If the research protocol is currently supported by a grant proposal, OR if support for the research protocol has been requested under a grant proposal, attach the research proposal/protocol that <u>was sent</u> to the agency, committee or sponsor.

(*Federally-funded projects cannot be reviewed by the exempt method*.)

☐ Yes ☐ No ☐ NA **If external funds will be used for the project, has the proposal been routed for approval through the Office of Sponsored Programs Administration?**

Section V: Exemption Screening Questions

If you answer 'Yes' to any of the questions below, your project is not eligible for a claim of exemption. You must complete the Request for Expedited/Full Board Review Form instead.

☐ Yes ☐ No 1) Does the research involve pregnant women, fetuses, or prisoners?

☐ Yes ☐ No 2) Does the research involve using survey or interview procedures with children (under 18 yrs of age)?

☐ Yes ☐ No 3) Does the research involve the observation of children in settings where the investigator will participate in the activities being observed?

☐ Yes ☐ No 4) Will a drug, biological product, medical device, or other product regulated by the FDA be used in this project?

☐ Yes ☐ No 5) Will the participants be asked to perform physical tasks?

☐ Yes ☐ No 6) Does the research attempt to influence or change participants' behavior, perception, or cognition?

For research involving survey procedures, interview procedures, observational procedures and questionnaires:

☐ Yes ☐ No 1) If data will be recorded by audiotape or videotape, is there potential 'harm' to participants if the information would be disclosed or revealed?

('Harm' means any disclosure of the subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or can be damaging to the subjects' financial standing, employability, or reputation.)

☐ Yes ☐ No 2) If the subjects are to be identifiable by name or through demographic data, is there potential harm to participants if the information is revealed?

☐ Yes ☐ No 3) Will collection include sensitive data (illegal activities, or sensitive themes such as sexual orientation, or behavior, undesirable work behavior, or other data that may be painful or very embarrassing to reveal)?

For research using 'existing' or 'archived' data, documents, records or specimens:
('Existing' means the items existed before the research was proposed, or were collected prior to the research for a purpose other than the proposed research.) ☐ N/A

☐ Yes ☐ No 1) Will any data, documents, records, or specimens be collected from subjects after the submission of this application?

☐ Yes ☐ No 2) Can subjects be identified, either directly, or indirectly, to the data, documents, records or specimens?

Section VI: Exemption Category

Identify all that apply to your research. If your research involves only those procedures listed in one or more categories below, it may be certified as exempt.

☐ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices. (This category may include children.)

☐ 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior for which subjects cannot be identified directly or through coded identifiers, or, if they can be identified, release of the information would not be harmful to the subject.

☐ a. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) for which the subjects cannot be identified, or release of the information would not be harmful to the subject. (This category may include children.)

☐ b. Research involving the use of survey procedures or interview procedures or observation of public behavior for which subjects cannot be identified, or release of the information would not be harmful to the subject. (This category may not include children.)

☐ 3. Survey or interview of public or elected officials. Testing of public officials.

☐ 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or indirectly through identifiers linked to the subjects. (This category may include children.)

☐ 5. Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads, and which are designed to study or evaluate public benefits or services. (ie, evaluation of public benefits programs: Medicare, Public Assistance). (This category may include children.)

☐ 6. Taste and food quality evaluation and consumer acceptance studies. (This category may include children.)

Section VII: Project Description & Recruitment

Provide a brief description in lay language.

1. Give an overview and explain the purpose of the project including scientific significance. (☐ attachment)

2. Describe the research setting (where the recruitment and data collection will take place). (☐ attachment)

3. Describe research procedures.

4. Number of participants sought: _____

5. Targeted Participant Population (check all that apply):

☐ Adults (>=18 yrs old)	☐ College Students (only 18 or older)
☐ Minors (<18 yrs old) Age range: _____	☐ College Students (under 18 may participate)
☐ Minorities	☐ Cognitively or emotionally impaired
☐ Non-English speaking	☐ International Research
☐ Inpatient participants	☐ Outpatient participants

6. Describe proposed participants and interaction with the participants. (☐ attachment)

7. What alternative(s) to research participation will be offered to potential participants, if any (in case, participation is a requirement for course grades or likewise) ?

8. How will potential participants be recruited?
   - ☐ Student Subject Pool: indicate pool _____
   - ☐ Email ☐ Mailing ☐ Handout
   - ☐ Website Ad ☐ Newspaper Ad ☐ Flyers ☐ Postings
   - ☐ School Children with request sent to parents
   - ☐ Participants will be approached by staff members
   - ☐ Other (explain) _____

   Provide copies of any advertisements, posters or email messages used to recruit participants.

9. Does the research include any compensation, monetary inducements, or reimbursement for participation in the study? ☐ Yes ☐ No If Yes, explain payment schedule: _____

Section VIII: Informed Consent

Subjects must be provided the required elements of informed consent, unless this requirement has been waived by the IRB.

1. Explain how informed consent will be obtained. *If applicable, include information about: who will obtain informed consent and in what setting; whether participants will have an opportunity to ask questions; if participants are non-English speaking, explain how the investigator will identify these participants and ensure their ability to understand information about the study to provide consent.*

2. The elements of informed consent will be communicated to the participant using:
   ☐ Cover Letter ☐ Oral Script ☐ Other
   ☐ Handout or Information Sheet ☐ Signed Consent Form

   Provide copies of informed consent document with application. (If needed, please review informed consent guidelines and examples of informed consent documents on Research Compliance website.)

3. Explain to the extent of how confidentiality will be maintained for participants (e.g., how will data be protected to safeguard participants, how will data be stored and destroyed).

4. Describe what will be done with the data and resulting analysis.

Section IX: Instrument(s)

What data collection instrument(s) will be used?

Provide copies of the data collection instruments (e.g., list of survey, interview or focus group questions, or oral history objectives. (☐ attachment).

Section X: Other Information

☐ Yes ☐ No 1. Will any entity outside of ECSU participate in this project in any way, including recruitment procedures, provision of research site, interaction or intervention with participants, obtaining informed consent, analysis of identifiable data, or other involvement?

If 'Yes', name entity, and their role in the research:

Include a letter of permission/cooperation from the organization, signed by an Administrator, with this protocol.

If a cooperating entity is considered to be 'engaged in research' that is federally funded, they are required to have an approved assurance on file with OHRP. All cooperating entities engaged in research must have appropriate documented mechanisms in place to protect human research participants.

☐ Yes ☐ No 2. Has this project been submitted to another IRB for review?

If 'Yes', indicate the name of the IRB, and their FWA #: _____
Submit a complete copy of the protocol reviewed and the IRB's determination.

FOR IRB OFFICE USE ONLY

IRB Protocol #: _____ ☐ Project qualifies for exemption. Category #: _____

IRB Signature: _____ Date: _____

Comments: