INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH
Request for **Expedited / Full Review** for a new research project
Involving no more than minimal risk to human subjects

INSTRUCTIONS:

ALL ECSU research using living human subjects, or samples or data, obtained from them, directly or indirectly, with or without their consent, must either be approved in advance by the ECSU Institutional Review Board (IRB), or be found to meet narrow criteria for exemption from IRB oversight by the IRB office. This Form will help the PI to determine if the project is likely to meet the criteria for expedited review and to document the decision on this request.

Expedited Review procedures are described in 45 CFR 46.110. In short, the IRB Chair or one or more experienced reviewers, designated by the Chair from among members of the IRB, review the research and approve it or refer it to the convened IRB for full IRB discussion. Attached is the list of activities that may be reviewed through expedited review procedures (**Federal Register 46**: 8392; Jan. 26, 1981).

For a new research project to qualify for expedited review, the following must apply:

(A) Research activities that **(1) present no more than minimal risk to human subjects*, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110.** The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

***Minimal Risk** is defined as "the risk of harm anticipated in the proposed research that is not greater, considering the probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

If, after reading the application, your human subject research protocol does appear to meet the requirements for expedited review, complete the checklist below to ensure a complete application is submitted for review.

Remember: ***You may not start your research (contacting prospective participants) until you receive a written communication from the ECSU IRB that your research has received IRB approval. It is NOT ACCEPTABLE to assume that since you may not have received any notification from the IRB, that your research has been approved. Do not start your research until you have your approval memo(s) in hand. This is especially important if you must seek approval from more than one IRB.***

Incomplete applications will be returned. Use the following checklist to ensure you are submitting a complete application to prevent delays in the review process.

Section I: Application Checklist

- ☐ Appropriate Expedited Category(ies) checked
- ☐ Obtained the needed signatures: Applicant(s), Faculty Advisor, Department Chair, Department Review Committee Chair
- ☐ Indicated funding status
- ☐ Attached a research Protocol
- ☐ If an anonymous survey study is proposed, please provide a cover letter to be attached to the survey. The letter should contain the usual elements of informed consent (purpose, procedures and duration, number of subjects/participants, voluntariness, confidentiality, how to ask questions), except for the signature lines. It should clearly state how anonymity will be maintained, that participation is completely voluntary and that a participant can choose not to answer some questions, and that return of the survey will imply consent to participate. If applicable, information about a second mailing should also be given.
- ☐ Attached copies of all data collection tools.
- ☐ Attached copies of all survey instruments, questionnaires, other such study materials
- ☐ Attached copies of all recruitment materials, such as fliers, newspaper ads, brochures, posters etc. that must be approved by the IRB prior to use.
- ☐ Submit a permission letter from each performance site. Approval for specific performance sites will be granted on a site-by-site basis as the permission letters are received and approved by the IRB.
- ☐ Training Verification forms submitted for all study personnel – (if not already on file with OSP).

Section II: General Information

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

Study Title: _____

Principal Investigator or Faculty Advisor: _____

Department: _____

Campus Address: _____

Email Address: _____ Phone: _____

Co-Principal Investigator: _____

Department: _____

Campus Address: _____

Email Address: _____ Phone: _____

Co-Principal Investigator: _____

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
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
e. Analyzing data with identifiable information
f. Collecting biological specimens
g. Conducting physical exams
h. Conducting interviews
i. Entering subject data into research records
j. Conducting study procedures
k. Educating participants, family or staff
l. Supervising exercise
m. Dispensing medication
n. Other: _____

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

Section III: Assurances

Principal Investigator's Assurance Statement:

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

☐ I understand that as Principal Investigator, I have the ultimate responsibility for the protection of the rights and welfare of human subjects, and the strict adherence to any study-specific requirements imposed by the IRB.

☐ I agree to comply with all IRB and Institutional policies and procedures, as well as with all applicable Federal, State, and local laws and regulations regarding the protection of human subjects in research and the conduct of clinical research.

☐ I also agree to the following:

1. to accept responsibility for the scientific and ethical conduct of this research study;
2. to accept responsibility for ensuring that all members or the research team: 1) complete the required CITI Training and any other necessary training to fulfill their study responsibilities;
3. to obtain prior approval from IRB before amending or altering the research protocol or implementing changes in the approved consent form, study sites or study personnel, recruitment procedures (**all protocol changes will be prospectively reviewed by the IRB**);
4. to immediately report to the IRB any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study;
5. to train study personnel in the proper conduct of human subjects research;
6. to complete the Continuing Review and Final Report Forms required by the ECSU IRB;
7. to adhere to standards of Good Clinical Practice (GCP)*, developed by the International Conference on Harmonization (ICH).

Principal Investigator: Printed Name	Signature	Date

*For information regarding GCP's see http://www.fda.gov/oc/gcp/guidance.html

I understand my responsibility as a researcher and assure that I will comply with all instructions from Principal Investigator/Faculty Advisor to ensure adherence to ethical guidelines for human subjects research.

Co-Principal Investigator: Printed Name	Signature	Date
Co-Principal Investigator: Printed Name	Signature	Date
Co-Principal Investigator: Printed Name	Signature	Date

Departmental Review Committee Statement:

My signature as Chair of the Departmental Review Committee for this research protocol certifies that a rigorous review of the following has taken place for this research protocol.

1. scientific validity
2. validity of study design
3. safety of study subjects
4. accuracy and completeness of informed consent
5. accurate reporting of research interventions separately from therapeutic interventions
6. adequacy of literature review

Dept. Review Comm Chair: Printed Name	Signature	Date

Typically, Principal and Co-Investigators, or Departmental Chairs cannot be chair of the Departmental Review Committee. The appropriateness of the departmental review committee chair will be decided by the IRB.

Department Chair/Dean Statement:

My signature as Department Chair / Dean certifies that:

1. I have read this application, and I believe that the benefits of the proposed research outweigh the risks to the study subjects.
2. I am satisfied that the Departmental Review adequately addressed the six points defined above.
3. The Principal Investigator has appropriate training, experience, and expertise to conduct this study.
4. The Principal Investigator has adequate staff and facilities to conduct the project.
5. If I become aware of any factors which have the potential to adversely affect the risk/benefit ratio for study subjects, or any issues that may reflect noncompliance with ECSU policies, or FDA and OHRP regulations regarding research with human subjects, I will immediately report these to the ECSU IRB.

Dept. Chair/Dean: Printed Name	Signature	Date

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.

☐ Yes ☐ No ☐ N/A **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: Performance Site(s)

List all performance sites for this study. Attach permission letters and/or **current** IRB approval memos for off-campus sites. **Check box if site is "engaged in research."** A site becomes "engaged" in human subjects research when its employees or agents: (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)]. (<u>Do not</u> list non-ECSU sites in industry-sponsored multi-center studies.)

Performance Site	Address	Engaged in Research
_____	_____	☐ Yes ☐ No
_____	_____	☐ Yes ☐ No
_____	_____	☐ Yes ☐ No
_____	_____	☐ Yes ☐ No
_____	_____	☐ Yes ☐ No

Section VII: Expedited Categories

(According to OPRR Reports, Title 45, CFR 46, rev. June 18, 1991)

Please identify all that apply to your research (check applicable boxes).

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   ☐ 1a Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   ☐ 1b Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   ☐ 2a from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   ☐ 2b from other adults and children[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ 3. Prospective collection of biological specimens for research purposes by noninvasive means. **Examples**:

   a. hair and nail clippings in a non-disfiguring manner;
   b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   c. permanent teeth if routine patient care indicates a need for extraction;
   d. excreta and external secretions (including sweat);
   e. un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
   f. placenta removed at delivery;
   g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
   i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   j. sputum collected after saline mist nebulization.

☐ 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) **Examples**:

   a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
   b. weighing or testing sensory acuity;

c. magnetic resonance imaging;
d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;
e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.

☐ 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

☐ 8. Continuing review of research previously approved by the convened IRB as follows:

a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
b. where no subjects have been enrolled and no additional risks have been identified; or
c. where the remaining research activities are limited to data analysis.

☐ 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Section VIII: Study Summary

1. What is the objective of the study?

2. Provide a brief background with scientific literature and significance of the proposed research.

3. Describe the Procedures and information to be collected.

4. Describe any risks involved to the subjects.

5. Describe how risks will be minimized.

6. For use of medical records: ☐ Will you have ongoing contact with the subjects?
   ☐ Will you be recording identifiers?
   ☐ What is the timeframe of charts that you plan to review (for example, 2/1/1999 – 2/1/2001)?

NOTE: Retrospective chart review can only occur on charts that were in place BEFORE you received IRB approval. Any chart information that comes into existence after IRB approval is granted would be considered Prospective.

7. In addition to the attached research protocol, provide a 1-2 sentence description of the proposed research? (*All research approved by expedited review must be reported to the convened IRB. This description will be reported on the IRB agenda*.)

Section IX: Human Research Subjects

Participant Population

Anticipated number to be enrolled at this institution: _____

If multi-site, total number of subjects for entire project: _____

What is the gender of the subjects? ☐ Male ☐ Female ☐ Both

What is the age range of the subjects? _____

1. To what health/disease category will the human subjects belong?

2. What will be the total duration of involvement of each subject in the study?

3. Is the research limited to any particular age, gender, ethnic, or racial group? (If an equitable recruitment from among all populations is **not** anticipated, please provide justification.)

4. Will any of the following vulnerable populations be included?

☐ Minors	☐ Minorities	☐ Fetuses	☐ Pregnant women
☐ Prisoners	☐ Mentally incapacitated	☐ Terminally ill	☐ Non-English speaking
☐ Elderly	☐ Severe Psychological Disorders	☐ ECSU's students or staff	

5. What safeguards are in place to protect vulnerable populations involved with the proposed research?

6. Outline the criteria for selection and exclusion of subjects.

7. Will subjects receive compensation for their participation, monetary or otherwise? ☐ Yes ☐ No
If yes, specify.

8. What financial obligations will subjects incur as a result of participating in the research study? Identify expenses such as travel costs, drugs, devices, lab tests, etc. Be as specific as possible. (Itemize the procedures not covered by research funds and approximate their cumulative cost.)

Section X: Recruitment Procedures

What method(s) will be used to identify and recruit prospective subjects? Specify the source of potential subjects.

Check all types of recruitment material that will be utilized in the study. Attach copies of this material to the application.

☐ Advertisements ☐ Newsletters ☐ Internet
☐ Brochures ☐ Radio ☐ Contact letters to patients or physician
☐ Flyers/posters ☐ Other (Describe):

Will you access stored medical records, data, or specimens for research use? ☐ Yes ☐ No
If yes, specify the source.

Section XI: Informed Consent

Per Federal regulations, (45 CFR 46.117), informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Refer to RGA 305:IRB General Instructions for Researchers Writing Informed Consent Forms for the required elements and format of informed consent forms.

Under certain circumstances, the IRB may alter or waive the consent requirement.
ARE YOU REQUESTING AN ALTERATION OR WAIVER OF THE CONSENT REQUIREMENT?
☐ ***NO*** ☐ ***YES - GO TO SECTION XII.***

1. How and where will informed consent be obtained? (e.g., in the clinic, PI's private office, subject's home, etc.)

2. When will the potential subjects or their legally authorized representatives initially be approached for consent and by whom?

3. Will there be an opportunity for potential subject to take consent form home to consider the options and to discuss participation with family members. If not, explain why.

4. If subjects are minors or mentally disabled, describe how and by whom permission will be granted?

5. How and by whom will it be determined that the subjects or their legally authorized representatives understand the research project and their rights as participants?

6. Where will the record of consent be stored?

7. List all study personnel that is obtaining consent. Read attestation below and sign.

I, _____ do hereby attest that the above study personnel have read the protocol, understand the study, and are fully knowledgeable of ALL details of the protocol and are able to answer ALL questions from research subjects such as risks and alternative treatments and therapies. Such personnel may obtain informed consent from research subjects along with the principal investigator.

Principal Investigator: Printed Name _____ Signature _____ Date _____

ATTACH A COPY OF ALL CONSENT/ASSENT FORMS USED IN THE STUDY.

Section XII: Alteration or Waiver of Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

If you are requesting a waiver of written consent, please provide justification that either of the two conditions listed above have been met.

Attach a copy of the cover memo/information sheet that will be distributed to subjects.

The IRB may waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;
(2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) the research could not practicably be carried out without the waiver or alteration; and
(4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

If you are requesting a waiver of the consent requirement, please provide justification that **ALL** of the four conditions listed above have been met. (Address each of the four points separately)

Section XIII: Confidentiality

Data include not only paper documents, but also blood samples, tissues, etc.

1. What are the methods used to ensure confidentiality of participation and data obtained?

2. How will data be collected and recorded?

3. Where will data be stored during the study and how will it be secured?

4. Who will have access to the data and/or to the codes?

5. If data with identifiers will be released, specify the person(s) or agency to whom this information will be released?

6. What will happen to the data when the research is complete? *(All study records should be kept a minimum of three years after the completion of the study.)*

Section XIV: Conflict of Interest

Is there any real or apparent conflict of interest on the part of **any** study personnel (e.g., stock or stock options, interest in technology, consultant to sponsor)? ☐ Yes ☐ No If yes, specify:

FOR IRB OFFICE USE ONLY

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

IRB Signature: _____ Date: _____

Comments: