ECHN Institutional Review Committee

Protocol Application for the Involvement of Human Participants in Research

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SECTION I: General Information

Study Title: _____

Study Objective (2-3 sentence summary of study): _____

_____

_____

Principal Investigator Information:

Name (First, Last, Degree):_____

Department: _____

Mailing Address: _____

Phone #: _____

E-mail address: _____

Co-Investigator(s) Information: (add additional co--investigators, if necessary)

Name (First, Last, Degree):_____

Department: _____

Mailing Address: _____

Phone #: _____

E-mail address: _____

Student/Resident Researcher(s) Information: (add additional student researchers, as necessary)

Name (First, Last, Degree):_____

Department: _____

Mailing Address: _____

Phone #: _____

E-mail address: _____

Other study personnel:

Name (First, Last, Degree):_____

Department: _____

Mailing Address: _____

Phone #: _____

E-mail address: _____

Section II: Collaborating Institutions/Facilities and Other IRB Reviews

Will the research be conducted only at ECHN? _____**Yes** _____**No (If yes, skip to section III)**

Other Collaborating Institutions/Facilities
If you are collaborating with other sites, provide the name of each institution/facility (e.g., other university, nursing home, etc) and describe the type of involvement of each institution (e.g., recruitment, enrollment/consenting, study procedures, follow-up, data analysis). Indicate if IRC approval/site permission is attached (indicate yes, no or pending). You will need to obtain IRC approval from every collaborating institution that has an IRC before you can initiate research there. Before initiating the research protocol here, the ECHN IRC may request copies of the other site(s) IRC approvals.

Name of Institution	**Describe Involvement**	**IRB Approval/Site Permission Attached?**

If the PI has an affiliation/appointment with an Institution listed above, please explain:
Provide additional comments as needed:

SECTION III: Funding

It is the responsibility of the Principal Investigator to notify the IRC via an Amendment or at Re-Approval, if the funding source changes in any way.

Funding Source: (Place an "X" in the column next to the funding source.)		Departmental Funds		Investigator out-of-pocket
		External – Please specify below:		Unfunded
		Faculty Grants (Large/Small)		Other – Please specify below
		Graduate School Award		
		Undergraduate Research Award		

Provide additional comments as needed:

For Externally Funded Studies:

If the research is supported either in whole or in part by external funds (federal, state or private), one COMPLETE copy of each grant application or contract must be included with this application.

For each funding source, please identify the following:
NOTE: If the PI on the grant/contract is not the PI on this IRC protocol, submit an e-mail with this application in which the PI who is receiving the grant acknowledges use of this protocol under the grant**.**

Name of Funding Source I (if ECHN is the recipient of a subaward, list the institution providing the funding then list the primary source of funds):	
Principal Investigator of Contract/Grant**:**	
Contract/Grant Title: (if different from protocol title)	
FRS Account Number:	
OSP Proposal Number:	
Grant/Contract Status: (i.e., pending/awarded)	

Provide additional comments as needed:

SECTION IV: Conflict of Interest (IRC will make a determination if this form is not required)

At the time of protocol submission to the IRC, all investigators are required to review the ECHN Conflict of Interest Policy and complete the attached questionnaire (available on the ECHN portal). For certain studies, this requirement may be waived. For more information, contact sgusy@echn.org

SECTION V: Human Participants

How many participants will be enrolled?
If you are enrolling more than one population describe the total enrollment for each. Note: Participants are generally considered to be 'enrolled' when they sign the consent form or have gone through an oral consent process. Therefore, be sure to account for attrition in your enrollment number.

If applicable, how many potential participants will be screened?
When screening procedures are conducted as part of the consent process, participants that fail to screen will be counted as being enrolled in the study.

Participant Population(s):
Describe the participant population(s) including gender, ethnicity, and age range.

Recruitment:
Describe the recruitment process including *who* will recruit, *when* and *where* recruitment will take place and *how* participants will be identified and recruited (e.g., direct recruitment by study team in person, on the phone, by mail/email/internet, random sampling, referrals from other participants, snowball sampling and/or healthcare providers). Attach copies of all advertisement/recruitment materials for IRB review including phone scripts, web postings, newspaper advertisements. If recruiting at off-ECHN facility sites, written permission and/or local IRC approval may be required.

Special Population(s):
Identify any special participant population(s) that you will be **specifically targeting** for the study.

Check **all** that apply: (Place an "X" in the column next to the name of the special population.)				
		Minors		Economically/Educationally Disadvantaged
		Prisoners		Members of the Armed Forces
		Pregnant Women/Neonates		Non-English Speaking
		Decisionally Impaired		Individuals Living with AIDS/HIV
		Employees		Other (Please identify):

Employees:
Are you recruiting employees who report to you? **Yes** **No**

If 'Yes," explain why this population is necessary to the study:

SECTION VI: Drugs/Devices, Genetic Testing, Radiation and Biological Samples

Drug/Device Use
Does the study involve the use of any of the following (check all that apply)?

- An FDA approved drug or medical device **Yes** **No**
- An investigative/unapproved drug or medical device **Yes** **No**
- A non-medical device **Yes** **No**
- A proprietary product **Yes** **No**
- A biological agent **Yes** **No**

SECTION VII: Research Plan

Purpose
State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s).

Introduction
State the background information that led to the plan for this project. Please provide references as appropriate and any other related research previously conducted, if applicable.

Design, Procedures, Materials and Methods
Describe the study design, including the sequence and timing of all study procedures. Indicate expected start and completion dates. Include screening procedures, if any. The IRC strongly suggests that investigators incorporate flexibility into the study design to accommodate anticipated events (i.e. explain how missed study appointments can be made up by participants). If the research involves study of existing samples/records, describe how authorization to access samples/records will be obtained. **IF A WAIVER OF AUTHORIZATION IS REQUESTED, PLEASE EXPLAIN THE REASONS.** If applicable, describe the use of audiotape and/or videotape and provide justification for use. **If the study includes measures, survey instruments and questionnaires**, identify each and, if available, provide references for the measures. Describe what they intend to measure (relate to purpose/hypothesis) and their psychometric properties (e.g., reliability and validity). Identify any that were specifically created for the study.

Data Analysis/Justification of Sample Size
For all studies, explain how the data will be analyzed. For qualitative and pilot studies, describe how the proposed sample size is appropriate for achieving the anticipated results. For quantitative studies, provide a power analysis and references for how the sample size was determined. Explain rate of attrition.

Inclusion/Exclusion Criteria
List major inclusion and exclusion criteria. Any proposed exclusion based on gender (women of childbearing potential), age, or race must include justification for the exclusion. Describe the conditions under which participants may be removed from the study, i.e., noncompliance with study rules, determined to be in the best interest of the participant by the P.I., study termination, etc.

Risks and Inconveniences
Describe the potential risks to participants (and secondary participants, if applicable) and steps taken to minimize risks. Assess the likelihood of the risk occurring and, if it were to occur, the seriousness to the participant. Types of risks to consider include: physical, psychological, social, legal, employment, and financial. Also describe any anticipated inconveniences the participants may experience (time, abstention from food, etc.).

Benefits
Describe anticipated benefits to the individual participants. If individual participants may not benefit directly, state so here. Describe anticipated benefits to society (i.e., added knowledge to the field of study) or a specific class of individuals. Do not include compensation or earned course credits in this section.

Risk/Benefit Analysis
Describe the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of anticipated risks to participants and steps taken to minimize these risks, balanced against anticipated benefits to the individual or to society.

Economic Considerations
Describe any costs to the participants or amount and method of compensation that will be given to them. Describe how you arrived at the amount and the plan for compensation; if it will be prorated, please provide the breakdown. Experimental or extra course credit should be considered an economic consideration and included in this section.

Data Safety Monitoring
This is a prospective plan set up by the study investigators to assure that adverse events occurring during studies are identified, evaluated, and communicated to the IRC in a timely manner. Although the investigators initially propose a Data Safety Monitoring **Plan** (DSMP), the IRC must approve the plan and may require revision of the plan. A DSMP is required for all human studies at ECHN except for studies determined to be exempt from continuing IRC review. For studies that

present more than minimal risk to participants, the IRC will review and determine on a case-by-case basis whether a data safety monitoring **Board** is most appropriate.

Issues that should be addressed in the DSMP include the following:
1) frequency of the monitoring
2) who will conduct the monitoring (Under ECHN policy a student/resident cannot be the sole person responsible for monitoring the data and safety of the protocol procedures.)
3) what data will be monitored
4) how the data will be evaluated for problems
5) what actions will be taken upon the occurrence of specific events or end points
6) who will communicate to the IRC and how communication will occur

Sample response to issues listed above for minimal risk/slight increase over minimal risk – "Survey results will be monitored by the PI in conjunction with the student investigator once every two weeks (items 1, 2 and 3). Survey responses will be reviewed to monitor for clarity (i.e., the same question is skipped by 5 or more participants). In that case, the question will be revised and an amendment will be submitted to the IRC (items 4, 5 and 6)."

Privacy/Confidentiality
Explain how the privacy interests of participants will be maintained during the study (note that privacy pertains to the individual, not to the data). Describe procedures for protecting confidentiality of data collected during the study and stored after study closure. Describe how data will be coded. Describe plans for storage and security of electronic data. If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained. Be sure to state whether any limits to confidentiality exist and identify any external agencies (study sponsor, FDA, IRC, etc.) that will have access to the data for monitoring/auditing purposes. If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.

SECTION VIII: Informed Consent

As PI, you are responsible for taking reasonable steps to assure that the participants in this study are fully informed about and understand the study. Even if you are not targeting participants from "Special Populations" as listed on page 3, such populations may be included in recruitment efforts. Please keep this in mind as you design the Consent Process and provide the information requested in this section.

Consent Setting
Describe the consent process including who will obtain consent, where and when will it be obtained, and how much time participants will have to make a decision. Describe how the privacy of the participants will be maintained throughout the consent process. State whether an assessment of consent materials will be conducted to assure that participants understand the information (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk).

Capacity to Consent
Describe how the capacity to consent will be assessed for participants with limited decision-making capacity, language barriers or hearing difficulty. If a participant is incapable of providing consent, you will need to obtain consent from the participant's legal guardian.

Parent/Guardian Permission and Assent
If enrolling children, state how many parents/guardians will provide permission, whether the child's assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained.

Documentation of Consent
Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, child assent form (written form or oral script) or an information sheet. Copies of all forms should be attached to this application in the same format that they will be given to participants.

Waiver or Alteration of Consent
The IRB may waive or alter the elements of consent in some minimal risks studies. If you plan to request either 1) a **waiver of consent** (i.e., participants are not aware of their participation in the study and will not be asked to give consent), or 2) a **waiver of signed consent** (i.e., participants participation in the study after reading a study information sheet implies consent; however, no signed consent is obtained), please answer the following questions using specific information from the study:

Please complete all questions in <u>either</u> #1 or # 2 (as applicable):

1) Waiver of consent:

- Why is the study considered to be minimal risk?

- How will the waiver affect the participants' rights and welfare? The IRC must find that participants' rights are not adversely affected.

- Why would the research be impracticable without the waiver?

- How will important information be returned to the participants, if appropriate?

2) Waiver of signed consent:

- Why is the study considered to be minimal risk?

- Does a breach of confidentiality constitute the principal risk to participants?

- Would the signed consent form be the only record linking the participant to the research?

- Does the research include any activities that would require signed consent in a non-research setting? For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.

HIPAA Authorization

At ECHN, the following sites are covered entities under the Health Insurance Portability and Accountability Act:

1. Manchester Memorial Hospital
2. Rockville General Hospital
3. Woodlake at Tolland

If research participants are recruited through these entities, it may be necessary to obtain an Authorization to use and disclose Protected Health Information (PHI). If a Waiver of Authorization is requested, the following elements must be satisfied:

- Use or disclosure involves no more than minimal risk to the privacy of the individuals, based on the presence of at least the following elements:
  a. an adequate plan to protect health information identifiers from improper use or disclosure,
  b. an adequate plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them, and
  c. adequate written assurances that the PHI will not be used or disclosed to a third party

except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the private rule.
• Research could not practicably be conducted without the waiver or alteration; and
• Research could not practicably be conducted without access to and use of PHI.

A "Partial Waiver" may be sought and granted during the recruitment/screening phase of a study. If it is then determined that the participant is eligible for the study, an authorization would have to be obtained prior to or at the first visit.

Required Attachments:

1. The original study protocol with this completed ECHN Protocol Submission form.
2. Copy of the approval letter from outside IRB (if applicable, eg. UNECOM, CCMC, UCONN)
3. Informed Consent form
4. Any Recruitment Materials
5. Letter of support from Department Chair/Director
6. Principal Investigator's CV
7. CITI training or NIH training certificate
8. HIPAA form (if applicable)

Principal Investigator Certification

I understand Eastern Connecticut Health Network (ECHN) policies concerning research involving human participants and I agree:

1. To comply with all IRC policies, decisions, conditions, and requirements;
2. That this study has been designed, to the best of my knowledge, to protect human participants engaged in research in accordance with the standards set by Eastern Connecticut Health Network, the United States Department of Health and Human Services, the Food and Drug Administration, and any other sponsoring agency;
3. To obtain prior approval from the IRC before amending the research protocol or the approved consent/assent form;
4. To report to the IRC in accordance with IRC policy, any serious adverse event(s) and/or unanticipated problem(s) involving risks to participants;
5. To submit the Re-Approval letter at least yearly, or as needed;
6. That my participation and the participation of any co-investigators does/do not violate Eastern Connecticut Health Network's policy on Individual Conflicts of Interest in Research;
7. That each individual listed as study personnel in this application has a) completed the required human subjects training, and b) are knowledgeable of the study procedures described in the protocol;
8. That each individual listed as study personnel in this application possesses the necessary training and experience for conducting research activities in the role described for them in this research study.
9. All external researchers are required to sign the ECHN Confidentiality Statement for Researchers ` (available on the ECHN Portal).

Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting the study.

Original Signature of Principal Investigator	**Date**

Original Signature of Student/Resident Investigator (Only for Student/Resident-Initiated Research)	**Date**