

ECHN Institutional Review Committee

#2 – Protocol Application for the Involvement of Human Participants in Research (Review of Data, Documents, Medical Charts, Pathological Specimens or Diagnostic Specimens)

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SECTION I: General Information

Study Title: (The title should accurately reflect the purpose of the study. Provide the complete full-length title for the study)

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:	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 (if ECHN is the recipient of a sub award, 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)	
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. Policy and Questionnaire available at <http://www.echn.org/Medical-Professionals/Medical-Education.aspx>

For certain studies, this requirement may be waived. For more information contact pdombek@echn.org

SECTION V: Background

This section describes the scientific justification (rationale) for the study; i.e., how the research will generate further knowledge and contribute to existing knowledge.

- Describe the nature of the problem your project will address and why is it important.
- Describe the scope /magnitude of the problem/any supporting background information.
- Justify the need of this study based on existing knowledge and your research question.
- Provide a summary of any previous pre-clinical studies, relevant studies, or any epidemiological data if available. Include references from the literature.

SECTION VI: GOAL

The goal describes the purpose of the study.

- The goal is a broad statement about what you aim to demonstrate by conducting the project.
- The goal must have scientific merit.
- Preferably, the goal should address a specific hypothesis. If applicable, state the hypotheses in quantifiable terms.

Example of a Goal: To determine cancer screenings rates in at risk individuals and evaluate the quality of the family history assessment.

Specific Objectives

The specific objectives reflect the study flow or milestones to be reached to achieve the study goal/goals. They should be a concise description of what is to be determined, identified, compared, or confirmed. Each specific objective implies interpretation of the data, and the objectives overall represent the main goal of the study.

Example of Objectives:

- To determine the number of patients who have had a quality assessment of risks factors for cancer.
- To determine if those identified patients at risk of cancer have been referred for cancer screening tests.
- To evaluate the quality and documentation of family history in medical charts.

SECTION VII: METHODS

The methods section should describe the steps that will be taken to achieve the goal and objectives of the study. Describe the type of study design (e.g., retrospective cohort study).

Sample size determination

Describe your sample size (number of charts/records you are planning to review) and why this sample size is sufficient for you to reach your primary objective.

Target study population specifics:

Describe where you will obtain your subjects' charts/data, and over what time period. Provide details of the patient population for the study (e.g., *all patients who have undergone heart surgery by Dr. Doe at Surgical Heart Associates*).

Specify:

- Inclusion Criteria
- List the disease or disorder under study
- Describe the timeframe for data collection (e.g., diagnosed between 1/1/10—12/31/10)
- Demographic characteristics (e.g., gender, age) as applicable
- Additional test results or conditions required to satisfy target population eligibility (e.g., patients receiving Coumadin).
- Any other unique criteria for inclusion in study.

- Exclusion Criteria
- List specific criteria for excluding a particular population for your study/records review (e.g., less than 18 years of age).

SECTION VIII: PROCEDURES

Data Collection:

- List the specific data elements to be collected (i.e., demographics, lab tests, procedures, length of stay, drug/device utilized, diagnosis, etc).
- Indicate whether or not subject *identifiers* are obtained (e.g., researchers will not collect information that can link the subjects to their data, **OR** researcher will be collecting the following identifiers: name, chart #, DOB, dates, etc).
- Describe what type of record/chart/database will be reviewed (e.g., Medical Record/Chart Review, Films/X-rays, Computer/Database, Hospital administrative/billing records, Quality Improvement Records, Other types of records).

(Note: Based on the information that will be collected, create your own data collection form, i.e. the template that will be used to collect all data for the study. This form must be provided to the IRC. The data collection form should contain page numbers and a place for the person collecting the information to sign and date the form. In addition, provide a legend on the form –e.g. NA = not available at time of review, NR = not relevant, etc)

Research Location

Provide the name and location of the place(s) (description of the area) where the project will be conducted. If conducted off site, explain that you have obtained a permission letter and provide such letter as an attachment.

Timetable

Provide a detailed timetable scheduling all aspects of the research. This will include data collection (e.g. time taken to abstract data from charts), data analysis, report writing etc.

It is convenient for the reviewer to see the events of the study schedule or duration in the form of a flow chart. You may reference an attached flow diagram, including expected start and completion dates, and/or describe the time table here:

Major Research Activities

Start Date:

End Date:

	<i>Jan</i>	<i>Feb</i>	<i>Mar</i>	<i>Apr</i>	<i>May</i>	<i>Jun</i>	<i>Jul</i>	<i>Aug</i>	<i>Sept</i>	<i>Oct</i>	<i>Nov</i>	<i>Dec</i>
<i>IRB Approval</i>												
<i>Screening Enrollment</i>												
<i>Intervention</i>												
<i>Data Analysis</i>												
<i>Report Preparation</i>												
<i>Dissemination</i>												

SECTION IX: Confidentiality, Data Management & Storage

If you are going to collect **identified information**, please address the following points:

- Describe adequate steps to preserve the confidentiality of the data collected (e.g., hard copy data will be stored in locked file cabinets/within locked office at ECHN. A master list of codes and identities will be maintained in a secure location apart from research record (coded data), research file and its contents will only be labeled with a code. If linked or coded information is collected, you need to describe the process for coding.
For electronic data specify where data will be kept stored (e.g., on standalone desktop computer (not connected to network/internet, or will be stored on encrypted mobile computing device, electronic data will only be labeled with a code and/or electronic data will be stored on password protected pc/mc.
If data is stored in a portable device: describe the portable device(s) to be used (e.g., laptop, PDA, portable hard drive including flash drives). Specify whether subject identifiable data will be stored on the device. If so, justify why it is necessary to store subject identifiers on the device.
- Specify who will have access to the data. If there is a code key, specify who on the research team will hold the key, and who will have access to the key.
- Specify if, how and at what point identifiable information will be separated from data.
- Specify how long data will be retained at the conclusion of the study (3 years minimum for majority of research records, 6 year minimum for HIPAA documents).
- If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether or not a Certificate of Confidentiality was requested and obtained from the National Institute of Health and justify why that decision was made. If a Certificate of Confidentiality was obtained, attach a copy of the Certificate to this application.
- Specify 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 you are going to collect **de-identified information**, please address the following points:

- Describe that there will be NO link or code associated with the collected data which could identify the data directly or indirectly.
- Describe how data will be collected and maintained anonymously.
- Complete Certification of De-identification Form for Research.

SECTION X: RISKS/BENEFITS

Identify any risks involved while conducting the study.

Note: The most common risk, although not the only one, is a breach of confidentiality, i.e. that someone other than authorized research personnel may see personal information that is collected.

Include any benefits to the participant or to the overall research field.

SECTION XI: DATA ANALYSIS

Analysis of the data collected allows you to determine whether the goal and objectives of the study were achieved.

Describe how you will analyze your data or outcome(s), including the methods of analysis and relevant statistical procedures.

Are you going to use descriptive statistics or inferential statistics or both?

How do you plan to analyze the information that you will collect to infer conclusions?

How would you evaluate whether your study goal and objectives have been achieved?

Dissemination

Describe how you intend to disseminate the results of your research, e.g. dissertation, presentation, web site, journal article.

List any meetings or conferences where you will be presenting the data and the results of your study. Please provide timeline for finalizing manuscript and when and where you plan to submit for publication.

SECTION XII: 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 **either** #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
4. ECHN Family Health Care Center

If research participants are recruited through these entities:

- Obtain an Authorization to use and disclose Protected Health Information (PHI), or
- Request a Waiver of Authorization. To request a waiver, the following elements must be satisfied:

<p>1. 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:</p> <ul style="list-style-type: none"> 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.
<p>2. Research could not practicably be conducted without the waiver or alteration; and</p>
<p>3. Research could not practicably be conducted without access to and use of PHI.</p>

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.

SECTION XIII: REFERENCES/LITERATURE REVIEW

Compile a list of the literature that was cited in this protocol. Each literature citation must include the title, names of authors, book or journal, volume number, page numbers, and year of publication.]

Required attachments:

- 1. Original study protocol (if applicable) with this original protocol submission form.
- 2. Copy of the approval letter from any external IRB (if applicable, e.g. UNECOM, CCMC, UCONN).
- 3. Informed Consent form (if applicable).
- 4. Authorization to Use or Disclose PHI OR Waiver of Authorization (if applicable)
- 5. Any recruitment materials.
- 6. Letter of support from Department Chair/Director.
- 7. Principal Investigator CV
- 8. CITI training or NIH training certificates
- 9. Data Collection Form
- 10. Certificate for De-Identification Form for Research

SECTION XIV: PI 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

Revised 11/2014, 12/2014, 1/2016, 6/2016, 5/2018