

# **ECHN Institutional Review Committee**

## **#3 – Protocol Application for the Involvement of Human Participants in Research (Surveys, Interviews, Questionnaires and/or Focus Group Studies)**

Manchester Memorial Hospital, 71 Haynes Street, Manchester, CT 06040 (860) 646-1222, ext. 2234

[tbuck@echn.org](mailto:tbuck@echn.org); [pdombek@echn.org](mailto:pdombek@echn.org)

### **Surveys, Questionnaires, and Interview Studies- Important Points to Consider**

Not all survey, questionnaire, or interview research is minimal risk. For example, a survey or interview that asks questions about sensitive topics (e.g., childhood abuse, sexual functioning or illegal behavior) that could possibly cause emotional stress or discomfort may require full IRC review (versus expedited review).

#### **Survey Research –Exempt Studies**

Some survey research may be classified as exempt from the regulations if the information obtained is recorded in a way that the subject cannot be identified (either directly or through a code numbers or link); in other words, if the research data are anonymous. The term anonymous is sometimes confused with the term confidential. In human subject research, anonymous means that at no time during the data collection could someone determine who provided the information. If a link existed at any time, even if the link is subsequently destroyed, the IRC cannot consider the information anonymous.

A survey or interview study may also be considered exempt from the regulations even when the data are not anonymous if the information being gathered could not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

#### **Survey Research –Expedited Studies**

If the study is not anonymous and contains information that, if known, could be damaging as described above, but it does not rise to the level of more than minimal risk, it may be given expedited approval. Although the IRC application gives the investigator the opportunity to request exempt status or expedited review, the chair makes the final determination as to the classification of exempt or expedited.

#### **Waiver for Documentation of Informed Consent in Survey Studies**

For minimal risk mail-out or web-based surveys or questionnaires, it may be appropriate to request that the chair waive the requirement for the subject's signature on an informed consent form. When the subject's signature requirement is waived, generally the investigator provides all of the required elements of consent in a cover letter, with a statement that returning the survey or questionnaire will be considered voluntary agreement to participate.

### *Surveys, questionnaires or interviews conducted by students*

Medical students often seek IRC approval to conduct surveys in surrounding schools. All surveys/questionnaires/interviews conducted by students must be preceded by a disclosure of the following points to the respondent. If an informed consent form is used, these points must be included in that document.

- The student identifies him/herself as an ECHN student who is performing the activity to fulfill a course and program requirement, and the course and program are specifically identified.
- The name and phone number of the Principal Investigator (i.e. the supervising faculty member) to contact for questions is provided.
- The persons who have access to the individual data and/or summarized results are specified (e.g., instructor only, company/organization/agency).
- Participants are informed that their participation is completely voluntary, that they can skip any questions they do not wish to answer, and that they can stop answering questions at any time.
- Any survey that is to be conducted in a school setting must have the approval of the school board.
- Parental consent must be sought for any survey of children.
- Major Advisors and students should note that any survey collecting sensitive information may be subject to review by the full committee and should plan in advance to leave enough time for that review to occur.

### ***GUIDE FOR WRITING A RESEARCH PROTOCOL FOR A SURVEY STUDY***

A research protocol is a document which sets out a plan for a research project. A well written protocol works like a road-map. It helps to focus ideas and provides direction to guide a project through all phases of planning, implementation and evaluation of a research activity.

The following document should be completed for all investigator-initiated survey studies, including student survey projects.

# ECHN Institutional Review Committee

## #3 – Protocol Application for the Involvement of Human Participants in Research (Surveys, Interviews, Questionnaires and/or Focus Group Studies)

Manchester Memorial Hospital, 71 Haynes Street, Manchester, CT 06040 (860) 646-1222, ext. 2234  
[tbuck@echn.org](mailto:tbuck@echn.org); [pdombek@echn.org](mailto:pdombek@echn.org)

### **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: 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.

<b>Funding Source:</b>		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 III: 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/academic-affairs>

For certain studies, this requirement may be waived. For more information contact [pdombek@ech.n.org](mailto:pdombek@ech.n.org)

### **SECTION IV: Background**

This section constitutes the scientific justification (rationale) for the study; i.e., the need for the research and how it will 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, including its probable cause, prevalence and distribution.
- Summarize the work others have done in this area (Provide a brief bibliographic review of the subject).

### **SECTION V: Hypotheses**

A hypotheses is a logical supposition, a reasonable guess, or a suggested answer to a problem. A hypotheses may provide further direction for the research effort by setting forth a possible explanation for an occurrence.

*Example of Hypotheses for one study:*

- The proportion of immunization rates in children between the ages of 19 and 35 months living in the United States at the time of the National Immunization Survey (NIS) conducted by the Center for Immunizations and Respiratory Diseases (NCIRD) in 2012 will be 90% or higher.

## **Research Question**

Research questions are generally used in lieu of hypothesis. Sometimes the use of research questions indicates that the research project is not experimental and does not lend itself to the formulation of hypotheses. The research question is specific as to topic and population.

*Example of a research question for one study:*

- Are childhood immunization rates in the United States remaining stable at high levels?

## **Goal**

This is a concise statement about what you aim to demonstrate by conducting this project.

*\*Example Goal for one study: (\*[http://www.cdc.gov/nchs/nis/nis\\_faq.htm#PURPOSE](http://www.cdc.gov/nchs/nis/nis_faq.htm#PURPOSE))*

- *“The goal of the National Immunization Survey (NIS) is to monitor the immunizations of children across the country.”*
- *“By monitoring immunization across the country, the Centers for Disease Control and Prevention will be able to assess the extent to which the country, States, and certain metropolitan areas are reaching the immunization goals of the Childhood Immunization Initiative.”*

## **Specific Objectives**

The specific objectives reflect the study milestones to be reached to achieve the primary goal. 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 Objectives for one study: (\*[http://www.cdc.gov/nchs/nis/nis\\_faq.htm#PURPOSE](http://www.cdc.gov/nchs/nis/nis_faq.htm#PURPOSE))*

- *“The study will collect data by interviewing households in all 50 States, the District of Columbia, and selected large urban areas. The interviews will be conducted by telephone with households selected by random chance.”*
- *“The National Immunization Survey (NIS) data will provide current, population-based, State and local area estimates of vaccination coverage produced by a standard methodology. Each quarter, estimates of vaccination coverage levels will be calculated and valid comparisons of State efforts to deliver vaccination services will be made.”*
- *“As well as evaluating progress towards national vaccination goals, the Centers for Disease Control & Prevention (CDC) will use the NIS data to identify States with the highest and lowest rates.”*

- *“To assure the accuracy and precision of the estimates, immunization data for surveyed children will also be collected through a mail survey of their pediatricians, family physicians, and other health care providers. The parents and guardians of NIS-eligible children are asked during the telephone interview for consent to contact children’ vaccination providers.”*

## **SECTION VI: Study Design and Procedures**

Describe your proposed study design (e.g., conducting a survey). Describe in order of occurrence, the procedures (e.g. physical exams, blood draw, surveys, interviews etc.) that will be done and by whom. This section should describe how you would accomplish the goals and objectives of the study, and the means by which the data will be collected.

### **Methods**

The methods section should describe the steps that will be taken to achieve the goal and objectives of the study.

#### **A- Subjects**

- a) Who will be studied? (Population from which sample will be taken).
- b) Include the expected number of subjects to be recruited.
- c) Justify the sample size.
- d) Describe expected duration of the subject’s participation.
- e) Describe inclusion/exclusion criteria.
- f) Describe demographics, age, gender, ethnicity, health status (if applicable) and any specific characteristic of the subjects to be recruited.

## B- Recruitment

- a) How will potential subjects be identified and
- b) By whom (e.g. study coordinator, nurse, student) and where will they be approached for participation? (Procedures that will be used to recruit subjects).
- c) Describe any relationship that the recruiters have with potential subjects other than in their role as staff for the survey study, and how this will be handled if it might lead potential subjects to feel pressure to participate (e.g., in small communities they may be neighbors, friends, or parents with children in the same school)
- d) Describe recruitment materials (ads, letters, flyers, recruitment script, etc) to be used and if applicable, attach a copy of these materials as an appendix to the protocol.
- e) If your project falls within one of the exempt categories (see IRC Request for Exemption Form), you should be prepared to provide the subjects with an information sheet/cover letter that describes the following items: (see ECHN IRC cover letter for a survey template)
  1. Name and number of PI to contact if the subject has questions.
  2. A brief description of the study purpose.
  3. A statement that participation is voluntary.
  4. A statement that subjects may skip any questions they wish to, for any reason. Explain that choosing to not participate will not affect any services which the person is receiving at the study site or for which s/he would otherwise be eligible.
  5. Confidentiality considerations.
  6. Participation in the survey implies consent.

*In addition, surveys that will be administered by students must include:*

1. The name of the student
2. The student's school and class affiliation
3. A description of the curriculum activity that is being fulfilled by the survey.

## C- Survey Instrument

- a) Submit the survey(s), instrument or interview questionnaire that will be used (**e.g.**, see attached Survey Instrument titled: "-----.") and describe the instrument including key points such as:
  1. Whether it is hard copy, or web-based survey,
  2. The rationale for your questions, i.e. why the type of information you are collecting is necessary to achieve the goal (e.g., demographics, feeling, beliefs, health status, diagnosis, opinions, pain management, knowledge, etc.).
  3. The type of questions (multiple choice, Likert rating scales, open-ended questions)
  4. Who designed and/or reviewed the survey prior to submission (did you give this survey to an expert for his/her input, is this a standardized survey for which its validity has already been assessed?)
  5. How long you think this survey will take to be completed by each participant?



6. Whether data in the survey will be recorded with or without identifiers (i.e., will the subjects be identified directly, will there be a link back to their identity, or will the data be anonymous (i.e. no identifiers, no codes)? If your data is to be coded, describe how the code is derived.
7. If applicable, strategies to get surveys completed and submitted (e.g., reminder letters to return self-stamped envelope with Survey)
8. If applicable, explain that your data is to be collected in the field (e.g., in schools, hospital, etc.) and if applicable, explain that your survey/interview questions may need to be “fine-tuned” in the field to improve clarity of questions or to address cultural sensitivities for the local context. Explain that you will submit the “fine-tuned” versions to the IRC office. NOTE: You cannot change the objective of the survey or significantly alter the questions being asked without IRC approval.

#### **D- Research Location**

Provide the name and location of the place(s) (description of the area) where the project will be conducted. If your project is conducted in the U.S. but in a place other than ECHN, describe who will grant permission to conduct the research on the premises of that facility and confirm their authority to do so (e.g. superintendent of schools). Explain that you have obtained a permission letter and provide such letter as an attachment.

#### **SECTION VII: Consent Process**

If applicable to the study, describe in detail the process for obtaining consent including elements such as the following:

- When consent will be obtained (e.g., after potential participants have made a phone call to the recruiters in response to a flyer, or in response to a poster/ad)
- Where the consent process will take place, giving consideration to the need for privacy of the subject.
- Who will be authorized to obtain consent from subjects.
- The step-by-step process for obtaining consent (e.g., The person obtaining consent will review the information presented in the [information sheet/cover letter or inform consent] with the potential subjects, section-by-section; after reviewing the material the subjects will be asked if

they have any questions, if not they will be asked to summarize their understanding of what enrollment in the study involves. If they cannot do this adequately, the material will be reviewed again. If after three tries the potential subject still cannot adequately summarize the information, s/he will not be enrolled).

- The estimated time allotted for discussion, and how it will be ensured that subjects must have enough time to consider their decision regarding participation prior to consenting.
- The plans to minimize the possibility of coercion or undue influence during the consent process (ensuring voluntary participation).
- If non-English speaking subjects are likely to be enrolled, describe plans for ensuring that information in the Consent form or Information sheet is presented in a language understandable to the subjects.

### ***Waiver or Alteration of Consent***

The IRC 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 Healthcare Center

If research participants are recruited through these entities:

- Obtain an Authorization to use and disclose Protected Health Information (PHI), or
  - Request Waiver of Authorization. To request a waiver, the following elements must be satisfied:
    -
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:
    - 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.
  2. Research could not practicably be conducted without the waiver or alteration; and
  3. Research could not practicably be conducted without access to and use of PHI.

## **SECTION VIII: Screening for Eligibility**

If applicable, describe how study staff will screen potential subjects to determine eligibility. Describe who will conduct screening for subjects. Explain if any screening will be conducted prior to obtaining informed consent. Describe the necessity of this information prior to informed consent. Describe what will be done with identifiable information collected on screened failures.

Survey Implementation: Describe in detail how and where will your survey be administered (e.g., web-based, in a classroom, face-to-face, phone, mail). Describe how the survey will be implemented, e.g., the time points at which the procedures occur (How often will subjects be contacted, and why).

## **SECTION IX: Risks**

- If applicable, describe any potential benefits to the individual participants. If individual participants may not benefit directly, state so here. Describe potential benefits to society (ie., added knowledge in the field of study) or a specific class of individuals. Do not include compensation or earned course credits in this section.
- If applicable, describe any potential risks associated with this protocol, and the procedures to protect against or minimize potential risks; consider all types of risk (e.g. physical, sociological, economical, psychological, etc.)

*Note:* the two most common risks, although not the only ones, are that subjects may feel uncomfortable answering some questions and that people other than authorized research personnel may see personal information that is collected.

## **SECTION X: 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.



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

### **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 from ALL key personnel, including those authorized to obtain consent
9. Data Collection Form (if applicable)
10. Certificate for De-Identification Form for Research (if applicable)

### **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.

<b>Original Signature of Principal Investigator</b>	<b>Date</b>

<b>Original Signature of Student/Resident Investigator (Only for Student/Resident-Initiated Research)</b>	<b>Date</b>

Rev. 12/22/14, 1/2016, 6/2016, 8/2017, 5/2018