Completing & Submitted the IRB Approval of Human Subjects Form

All areas of the form should be completed. Once completed it must be submitted to the IRB by sending it to the EU IRB Chairperson. The following will provide a step-by-step instruction with explanations for various sections. All forms and templates are available at http://gradschool.edinboro.edu/graduate-home/research/human-subjects.dot.

IRB Approval of Human Subjects Form

Date - Enter the date of application
Type – Enter the correct type of application.
   A ‘New’ application means that the protocol has never been submitted to the IRB for review/determination.
   A ‘Revision’ application means that the protocol previously has been submitted and reviewed by the IRB. The IRB either requested revisions or the Principal Investigator (PI) is requesting IRB review and determination for the revisions.
   A ‘Renewal’ application may be used to request a renewal of a previously approved IRB protocol.
Title of Study – Enter the title of your research study.
Researchers’ Information – Enter all the information for each investigator. All persons listed in the ‘Researchers’ Information’, ‘Students’, and/or ‘List any other individuals…’ area must complete the CITI training. Information about CITI training is available at http://gradschool.edinboro.edu/graduate-home/research/human-subjects.dot
Principal Investigator (PI) – This is the Edinboro University of Pennsylvania employee who is responsible for the project. If it is a student project, the PI is the faculty member who has oversight of the project.
Co-Investigator – The next two columns is for the co-investigators or the student investigators. If it is a student, make sure the email address is correct as most correspondence from the IRB will be via email.
Students – this is where the PI would list any students that would be working on the project who are not listed as Co-Investigator. Should they be a Co-Investigator, make sure that their email address is included.
Project Type – Select the appropriate type that applies to your project. If your project does not fit into any of the listed categories, then select ‘Other’ and provide a brief statement defining your project.
Special Considerations – In this section you need to identify any categories of human subjects that may apply to your project.
Types of Review – This is where the PI determines the type of review that is required. All reviews take at least three weeks. Only the IRB has the authority to determine which type of review will occur. Expedited and/or Full may take much longer due to the
complexity of the projects. The following are general guidelines. The full regulations are used by the IRB to make the determination.

**Exempt** - Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy: 1) conducted in educational setting involving normal educational practice, 2) Use educational tests, survey or interview procedures, 3) Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior involved elected or appointed public officials or candidates for public office 4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens that are publically available, 5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine public programs, 6) Taste and food quality evaluation and consumer acceptance studies.

[http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101)

**Expedited** - 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 nine (9) categories, may be reviewed by the IRB through the expedited review. 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. It may not be used for classified research. Categories 1) clinical studies of approved drugs and/or devices, 2) Collection of blood samples by finger, heel stick as described in regulations, 3) biological specimens by noninvasive means, 4) Collection of data through noninvasive means, 5) research involving materials that had been collected, 6) collection of data from voice, video digital or image recordings made for research purposes, 7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies, 8) Continuing review of research previously approved, 9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption. Regulations found at [http://www.hhs.gov/ohrp/policy/expedited98.html](http://www.hhs.gov/ohrp/policy/expedited98.html)

**Full** – Research projects that do not meet exempt nor expedited review criteria.

**Permission from Agency/Institution** – You must attached a letter of approval from the authorized representative of the site in which you intent to conduct your project. For example: You intend to survey a high school class at The Best High School. You will need a letter from the Principal of The Best High School on their letterhead indicating that you have his/her approval to conduct the research.

**Purpose and Significance of the Research Study** - Clearly explain the purpose of this study, including its significance. Give brief description of the research in this area, (cite sources) and how your purpose relates.
**Participants in this Study** - Identify all participant groups (undergraduate students, teachers, elementary school students, administrators, other groups). Describe the basic characteristics of each group (including anticipated number of participants from each group, age range, etc.). Describe any specific requirements for including or excluding individuals from participation (e.g., particular gender or racial/ethnic background) and rationale for the exclusion. If this research involves vulnerable populations (minors, mentally disabled, questionably competent persons, vision impaired, non-English speaking individuals, prisoners, pregnant women, or any others who might be considered questionable for fully informed consent) justify their importance to be included in the research. Describe any relationships between any researchers involved in this study and potential participants (professor-student, resident assistant-resident, supervisor-employee). Please note that existing relationships between a researcher and potential research participants create special concerns related to recruitment, informed consent, and confidentiality of research data that must be addressed in subsequent sections of this protocol.

**Identification and Recruitment of Potential Participants** - Attach all copies of material that can be used to recruit participants: letters, advertisements, flyers, posters, and email scripts. Describe how you will gain access to potential participants, how participants will be contacted, and what information will be given during the recruitment process. If participants will receive compensation in any way for their participation (money, course credit), indicate the type and the amount, the method of distribution of compensation and identify the source(s) of funds used for the compensation. Will participants and/or data be accessed from a cooperating institution (school, university, business, or agency)? If yes, a permission letter signed by an appropriate official (on the cooperating institution’s letterhead) granting access to participants and/or data must be provided to the IRB committee.

**Research Methodology** - Attach copies of everything that is being used for the purpose of this study (tests, surveys, observational recording sheets, interview questions, laboratory reporting sheets, and debriefing material). Describe your procedure, including all testing, observations, interviewing, interventions, educational programs, or laboratory procedures. Describe how data will be recorded (video, audio, or notes) and any coding procedures. Give approximate amount of time needed from subjects. What data or information will be collected? If this study is using archival data (data that have already been collected for other purposes than this study), describe the nature of the data archive. Explain which data are to be accessed for this study and how it will be accessed. If data are publicly available, state this. If not, explain how you will get access to the data and attach documentation that you have authorization to do so. Is the research involving the collection and/or use of health (physical or psychological) data from a healthcare provider (hospital, physician’s office, health departments, etc)? If yes, you may need to follow guidelines established by the Health Information Portability and Accountability Act.
Act (HIPAA). If this study is a qualitative or oral history project that involves unstructured or semi-structured interviews or observations, provide a detailed description of the nature and scope of these procedures. Include the purpose of the interviews or observations, who will conduct the research, expected length of time of the interview, type of information and general areas of information to be covered and sample questions and/or behaviors to be observed. Where will the study take place? What is the timeframe need to complete the study?

**Potential Risks to Participants and Procedures to Minimize These Risks** - Discuss any physical, psychological, financial, social/economic or legal risks, or harm from breaches of confidentiality that might result from participation in this study and assess the likelihood and seriousness of these risks. Explain why it is necessary to expose participants to potential risks. For each risk identified, describe actions that will be taken to minimize the risk. If deception is involved, or if information will be withheld from participants, describe the type of deception or the information being withheld and explain why this is necessary. Describe your procedures for debriefing participants. Include a copy of the debriefing statement with this application.

**Benefit/Risk Assessment** - What are the potential benefits of the research? (Please note, if participants will not benefit directly in any way from their participation, state this. Compensation, including course credit, is not considered a benefit.) Do benefits outweigh potential risks? If benefits do not outweigh potential risks, explain why this project is justified. If no known risks have been identified, how will this study be of benefit to the individual participant and/or society as a whole?

**Procedures Used to Protect the Anonymity and/or Confidentiality of Participants and Records Management** - Records (including consents) must be maintained for as long as applicable regulations require. - Will anyone besides the principal investigator and co-investigator have access to the raw data or any other form of data (please describe). Explain any limits to confidentiality (child abuse reporting laws, individuals besides the researchers who will have access to the data). If Internet or web-based surveys are being used, describe procedures for ensuring that confidentiality is protected. How will all data be stored during the study (including video, audio, photographs, etc)? Until records are destroyed, they must be kept in a secure place, accessed only by the investigator, co-investigator, or sponsor/advisor. What will happen to data at the conclusion of the study? (Please refer to IRB website for the policy and procedure on record retention). If records will not be destroyed, please explain why not? How will data be reported if presented or published (particularly important- will identifying information be masked)?

**Informed consent** – Attach consent and assent forms and/or script for oral explanation: (If any), More information about what is required is on the IRB website. All forms should be readable and must be presented in age and developmentally appropriate language. Describe the process involved in obtaining informed consent (when, where, who, and
how). If subjects include members of vulnerable populations or are vulnerable because of their relationship with the researcher, explain what special procedures will be followed to ensure informed and voluntary consent. If potential participants are minors, describe procedures for obtaining their assent to research and procedures for obtaining parental or guardian consent. If you believe your project requires a waiver or alterations of informed consent, or a waiver of the requirement to obtain a signed consent, you must request a waiver. Complete the appropriate form provided on the IRB website and attach it to the end of this application.

**Advertisement** – If you intend to advertise your project, please provide a sample.

**Signatures** – Read the terms for which you are agreeing to with the submission of the IRB protocol. ALL PIs (PI & co-PIs) must endorse the protocol application.

**Submitting the Protocol**

Once the approval form has been completed and endorsed by all the applicable people, forward the following items to the IRB Chair to begin the review process:

- ✔ Fully completed approval form
- ✔ Survey or questions that will be used (if applicable)
- ✔ Informed consent (if applicable)
- ✔ Assent form (if applicable)
- ✔ Institutional approval letter (if applicable)

**Forwarding packet to the IRB Chair**

The protocol may be submitted either in paper or via electronic.

**Paper**
If it is a paper submission, it must have all the original signatures. Forward the packet to current EU IRB chair, Name and Office location listed on the IRB membership page.

**Electronic**
If it is an electronic submission, then all the items that apply must be included in the email to **irb-chair@edinboro.edu** The signature page may be scanned and included or you may route the proposal through your PI.

Routing the protocol through PI – This occurs when a co-PI prepares the documents for review and approval of the PI. What must occur is that the email but route through each co-PI and PI before being sent to IRB Chair. Each person my specifically indicate that they approve the
submission. It must be sent from an email that is listed on the protocol application in order to verify the authenticity of the approval.

What IRB Chair should receive is an email that is something similar to the following example from one (1) PI and one (1) co-PI. The example is not exactly how the email will appear for routing information will be included and depending on the email system, the headers/footers will vary.

September 1, 2014
From: Principal Investigator
To: irb-chair@edinboro.edu
Subject: Re: IRB submission

I approve this application.

PI
Principal Investigator, PhD
Department

__________________________
Fowarded
Date: September 8, 2012
From: Student, Co-PI
To: Principal Investigator
Subject: IRB submission

Dear Dr. PI,

I have attached all the components of my IRB protocol for your review and approval. Should you approve, please forward this email to the EU IRB Chair. Thank you.

Sincerely,
Co-PI
Co-PI Student
Student Investigator