## Form A

For IRB use only

IRB File No.: \_\_\_\_\_\_\_\_\_\_

Date received: \_\_\_\_\_\_\_\_\_\_

Approval expires: \_\_\_\_\_\_\_

Eastern Illinois University

Institutional Review Board

New Application for Review of Research Involving Human Subjects

Federal regulations and Eastern Illinois University’s IRB policy require that all research involving humans as subjects be reviewed and approved by the University’s Institutional Review Board (IRB) prior to the commencement of the data collection. Approval of this project by the IRB only signifies that the procedures adequately protect the rights and welfare of the subjects.

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| --- | --- |
| **Title of Project:**  | Click or tap here to enter text. |
| **Principal Investigator\*:**  |  Principal Investigator |
| \*Note: Students engaging in research are required to have a faculty sponsor or executive, administrative, or professional (EAP) staff sponsor. List sponsor below. |
| **Status:**  |  Choose an item. |
| **Mailing address:**  |  Address |
| **Phone:**  |  Phone |
| **Email:**  |  Email |
| **Department or Unit:** |  Department |
| **Has PI completed CITI training?** |  Choose an item. |
| [Prior to IRB approval, all PI’s, Co-PI’s, and sponsors must complete the CITI Program training](http://www.citiprogram.org/) |
| **Co-Investigator:**  |  Co-Investigator |
| **Status:**  |  Choose an item. |
| **Mailing address:**  |  Enter Address |
| **Phone:**  |  Phone |
| **Email:**  |  Email |
| **Department or Unit:** |  Department |
| **Has Co-PI completed CITI training?** |  Choose an item. |

 \*List additional co-investigators, including above information, on a separate sheet.

Level of Review Sought: [ ]  Exempt (submit Form B) [ ]  Expedited (submit form C) [ ]  Full Committee

Is this research being conducted to meet requirements of a course or to complete an academic degree?

 [ ]  Yes (do NOT submit your dissertation or thesis proposal) [ ]  No

Estimated Project Start Date: Start Date Estimated Project Completion Date: End Date

Extramural Funding:

|  |  |
| --- | --- |
| Principal Investigator of Contract or Grant:  | Click or tap here to enter text. |
| Funding Source: | Click or tap here to enter text. |
| Contract or Grant Title:  |  Click or tap here to enter text. |
| Contract or Grant Number:  |  Click or tap here to enter text. |

Indicate the categories of subjects and controls to be included in the study: Check ALL that apply:

 [ ]  Abortuses/Fetuses [ ]  Normal Volunteers

 [ ]  Decisionally Impaired [ ]  Patients

 [ ]  Decisionally Impaired (Institutionalized) [ ]  Pregnant Women

 [ ]  Minors (17 yrs or less) [ ]  Prisoners
 Give age range: Age Range [ ]  Students

Approximate number of human subjects: Number of Subjects

Indicate which of the categories listed below accurately describes this protocol:

[ ]  Not greater than minimal risk

[ ]  Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects

[ ]  Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition

[ ]  Research not otherwise approvable, but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of subjects

Does this research involve any of the following? (Check all that may apply)

[ ]  Past, present, or future physical health of the participants

[ ]  Mental health (as defined in DSM-IV TR)

 [ ]  Provision of health care to the participants

 [ ]  Past, present, or future payments for the provision of health care to the participants

If any of the above categories are checked, please refer to Appendix 4, HIPAA Information, in the EIU Policy and Procedures for the Review of Research Involving Human Subjects

Will a public use data file be created? [ ]  Yes [ ]  No

 **Complete all items in the following Research Description section**.

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the study’s protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB in writing within 5 days of occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

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Principal Investigator’s Signature Date

Faculty or EAP Staff Sponsor Assurance (required when a student is the PI)

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

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Faculty or EAP Staff Sponsor’s Signature Date

**RESEARCH DESCRIPTION**

Provide responses to the following items. If an item does not apply to your research project, simply indicate “Not applicable.”

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| PROJECT DESCRIPTION |
|  1. DESCRIPTION—Provide a brief description in layperson’s terms of the proposed research. Include the purpose and research questions/hypotheses. |
|  |
| 2. DISSEMINATION—Describe how the results of the research will be disseminated. Dissemination includes, but is not limited to: honor’s, master’s or doctoral theses; presentation at a scientific/professional meeting or conference; submission to or publication in a scientific/professional journal (paper or electronic); and internet postings. |
|  |
| METHODOLOGY |
| 3. PARTICIPANTS—Describe the characteristics (e.g., age, gender, ethnicity, health status) of the subject population whom you are targeting and the approximate number of participants. Provide exclusion and inclusion criteria. Will there be any special populations (see 45 CFR 46, subparts B, C, and D), such as children, mentally incapacitated individuals, prisoners, or others whose ability to give voluntary informed consent may be in question included?—If yes, explain the rationale for their inclusion. |
|   |
| 4. RECRUITMENT—Describe how you will identify and recruit prospective subjects. Attach a draft or final copy of any planned advertisements, flyers, letters, and emails to potential subjects. |
|  |
| 5. LOCATION OF STUDY—Identify specific sites or agencies to be used. For research conducted at a facility other than one owned and operated by Eastern Illinois University, additional information is required.  |
| a. Non-federally funded research—If the research project will not receive federal funds, a letter from the appropriate administrator of each facility should be submitted on the facility’s letterhead stationary and should contain the following: agreement for the study to be conducted; identification of someone at the site who will provide information about appropriateness for its population; assurance of adequate capabilities to perform the research as approved by the IRB; and if applicable, assurance that facility personnel involved in data collection have appropriate expertise and will follow IRB approved procedures*. For exempt research, a letter from the administrator is only needed when children are directly involved*. If the approval letters are not available at the time of IRB review, IRB approval will be contingent upon receipt of the letters. |
| b. Federally funded research—If the research project receives federal funds from an agency such as the National Institutes of Health (NIH), each study site must have a Federal Wide Assurance (FWA) with the Office for Human Research Protections (OHRP). FWAs are a requirement of OHRP or NIH and not EIU’s IRB or EIU’s Office of Research and Sponsored Programs. EIU has negotiated a FWA. Contact ORSP for the information to enter on the funding agency’s application form regarding FWA documentation. If the study is a collaborative project and another organization in addition to EIU is engaged in human subjects research (as defined by DHHS), then the PI must obtain information on the other organization’s FWA and provide it in this section of the EIU application. A search for another organization’s FWA may be found at OHRP’s web site, http://ohrp.cit.nih.gov/search/asearch.asp#ASUR.  |
|   |
| 6. INSTRUMENTS, RESEARCH MATERIALS, RECORDS, & PROCEDURES—Describe the study design and research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Describe the setting and mode of administration (e.g., group, telephone, individual); describe the duration of administration, intervals of administration (if multiple administrations), and overall length of participation. Identify the sources of research material (e.g., specimens, records, data) to be obtained from subjects. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data. If applicable, differentiate between procedures that involve standard or routine procedures for care or treatment from those which will be performed specifically for the conduct of this research project. |
| **\*NOTE:** **Attach a copy of all questionnaires, tests, surveys, or other materials to be administered to the subjects**, i**f applicable.** |
|   |
| 7. DATA COLLECTION, STORAGE, AND CONFIDENTIALITY—Describe how data will be collected and recorded. State whether data will be recorded with or without names or identifiers. If subjects are identifiable by name or other means, explain special steps that will be taken to ensure confidentiality. Describe how data will be stored during the study and how it will be secured. Delineate who will have access to the data or to subject identifiers. Describe what will happen with data from subjects who formally withdraw from the study. Describe what will happen to the data when the research has been completed. [Note: Records (e.g., signed informed consent forms, data) relating to the research project must be retained for at least three years after completion of the research. See 45 CFR 46.115(b)] |
| If all or some of the subject(s) of the proposed research will be audio or videotaped, justify why the use of audio or videotaping is necessary to the study. Who will have access to the tapes and for what purposes? Where will the tapes be stored and what security measures will be taken to prevent unauthorized persons from accessing the tapes? What are your plans for the ultimate use and disposal of the tapes? |
|  |
| 8. INFORMED CONSENT—Describe the informed consent procedures to be followed, including circumstances under which consent will be sought and obtained, who will seek it, and the method for documenting consent. **Include applicable informed consent forms for review purposes.** **If the informed consent process is to be waived, or if written consent or a signed informed consent is not to be obtained, specifically point this out and complete and submit Form I, Request for Waivers of Informed Consent** [see 45 CFR 46.116(e)(f) and 45 CFR 46.117(c)]. |
| **Special Considerations:**  Minors: If the study involves minor participants (17 years of age or under), describe the process for obtaining parent permission, and include the parent informed consent form. Also describe the child assent process (written assent may not be required in every case). On-line Research: If the research is to be conducted completely on-line (such as surveys or questionnaires administered via the internet or email), it may be possible to waive the written documentation of informed consent. Complete Form I, Section B, to request a waiver.   |
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| RISKS/BENEFITS |
| 9. RISKS—Describe the short-term and long-term potential risks (physical, psychological, social, legal, or other) to subjects and assess their likelihood and seriousness. Where appropriate, describe alternative treatments or procedures that might be advantageous to the subjects.  |
|   |
| 10. SAFETY PRECAUTIONS—Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subject(s) and attach a referral list. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. |
|   |
| 11. BENEFITS—Describe the potential direct benefits subjects may receive as a result of participating in this research. Describe the potential benefits to society that may be expected from this research. |
|   |
| 12. BENEFITS VS. RISKS—Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. |
|   |
| 13. INCENTIVES AND RESEARCH RELATED COSTS—Describe the incentives, if any, being offered to subjects for their participation in the research study. If monetary compensation is offered, indicate how much subjects will be paid and describe terms of payment. Describe what will be done if subjects withdraw before completion of the research (e.g., will monetary payments be prorated or payment in full?). Also, if applicable, describe any costs which will be accrued by the subjects as a consequence of participating in the research. |
|   |
| QUALIFICATIONS OF INVESTIGATORS |
| 14. Briefly describe the qualifications of the investigators(s) conducting this research project.  |
|   |
| OTHER (Provide information regarding the following if applicable) |
| 15. DATA SAFETY AND MONITORING FOR NIH SPONSORED RESEARCH—The National Institutes of Health policy requires that grantees have in place procedures for data safety monitoring of clinical trials. The IRB is required to review and approve the data safety monitoring plans. For NIH funded clinical trials, include a description of the Data Safety Monitoring Plan. |
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| 16. Describe any requirements imposed by funding agencies that are not already covered in this application. |
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