THOMAS EDISON STATE UNIVERSITY

Research/Project Review and Approval Form: Parts A and B

This form serves as both a decision-making tool and application for IRB approval of research projects involving human subjects.

RESEARCH/PROJECT INFORMATION

Principal Investigator Name: _____

Street: _____

City: _____ State: _____ ZIP/Postal Code: _____

Phone Number: _____ Email Address: _____

Research/Project Title: _____

Research/Project Duration: from _____ to _____

A research/project is a systematic investigation designed to develop or contribute to generalizable knowledge, through dissemination by publication or presentation. Human subjects are living people about or from whom an investigator conducting a research/project obtains data through interaction or identifiable private information. The principal investigator is the person conducting the research/project who is responsible for assuring that all research/project procedures are followed correctly. The principal investigator is under the auspices of the University, such as a staff member at the University or New Jersey State Library. When systematic data about human subjects are collected, especially for the purpose of dissemination, an IRB review and approval process must be followed according to federal regulation 45 CFR *(ohsr.od.nih.gov/guidelines/45cfr46.html)*.

TYPES OF IRB REVIEW

I) Types of IRB Review: Depending on the level of risk of the research/project protocol and the participant population, IRBs may conduct either full-board review or expedited review.

- a) Expedited Review
  - i) For certain kinds of research/project involving no more than minimal risk and for minor changes in previously approved research/projects, the IRB chair and a designated voting member or group of voting members review the proposed research/project rather than the entire IRB.
  - ii) It cannot be assumed that research/project poses minimal risk because it involves only interview or survey data collection. Sensitive questions may lead to distress that exposes participants to greater than minimal risk. Loss of confidentiality can cause harm to participants, their relatives, and others. The IRB determines the designation of Expedited Review.
  - iii) See the following website for a list of procedures that may be approved through expedited review: *www.hhs.gov/ohrp/policy/expedited98.html*
- b) Full-Board Review
  - i) When full-board review is necessary, the research/project proposal is presented and discussed at a meeting at which a quorum of IRB members is present.
  - ii) For the research/project to be approved, it must receive the approval of a majority of those voting members present.
  - iii) IRB members may participate by means of electronic and/or telephonic communication and need not be present physically.
- c) Research/Project Exemptions from IRB Review
  - i) Under federal regulations [45 CFR 46.101 (b)], certain categories of activity are considered research/project but may be declared exempt from review by the IRB. This determination must be made by the IRB prior to the research/project being conducted.
  - ii) Certain low-risk research/projects are exempt from the requirements in the federal regulations concerning IRB review and approval. If a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights.

The researcher should not make the final determination of exemption from the applicable federal regulations or the provisions of the institution.

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Research/Project Review and Approval Form Part A: Decision-Making Tool

Does the research/project fall under the category of human subjects research?

Directions: Provide a research/project summary and complete the questionnaire, in order to help you determine if your research/project requires an application submission to the IRB. When you have completed Part A submit this form to the appropriate IRB member. The IRB website has a list of IRB member, and the unit of the University and New Jersey State Library that they service.

Summary of Research/Project: Submit a one-page summary (or abstract) of your research/project with the following form. Include the following information in the summary: who are the participants, what you will do, when the research/project will occur, where it will occur, and what you hope to determine by completing the research/project.

Questionnaire: Complete the following questionnaire to determine if the proposed research/project could be considered human subjects research. Human subjects are called participants in a research/project study.

1) Will the participants in the research/project be identifiable through records, responses, or personal information to anyone else but the researcher?
☐ YES ☐ NO

2) Could participants' reputations, financial standing or legal standing be at risk if their responses were identified? ☐ YES ☐ NO

3) Does the research/project ask questions about or explore sensitive aspects of participants' lives, such as illegal conduct, drug and alcohol use, mental health issues, abuse, or sexual issues? ☐ YES ☐ NO

4) Does the research/project involve the taking of any images or audio of the participants, via any means, camera, audio, cell phone, etc.?
☐ YES ☐ NO

5) Does the research/project target any of the following types of participants, who are considered vulnerable populations?

☐ Children who are under the age of 18	☐ Physically challenged	☐ Economically disadvantaged
☐ Legally incompetent adults	☐ Pregnant women	☐ Terminally ill
☐ Cognitively or mentally impaired individuals	☐ Traumatized or comatose	☐ Prisoners

6) Does the research/project involve any of the following activities?

☐ Administration of drugs	☐ Taking tissue samples	☐ Drawing blood
☐ Administration of alcohol	☐ Use of medical devices	☐ Giving injections
☐ Administration of nutritional supplements	☐ Invasive procedures	

7) Is any of the data to be collected online with identifiable email addresses or electronic signatures? ☐ YES ☐ NO

8) Will any identifying information that may link the data to individual participants be included in your research/project records?
☐ YES ☐ NO

9) Does the research/project involve the study of existing databases where the individual participant data is identifiable? ☐ YES ☐ NO

10) Are participants voluntarily participating, and are they free to withdraw at any time? ☐ YES ☐ NO

A ***yes*** answer to any of the above questions except question #10 places the research/project in the category of human subject research. If a ***yes*** is answered to any of the above questions except question #10, proceed to Part B: Application for IRB Approval.

IRB member submitted to: _____ Date reviewed: _____

The research/project is determined to be: ☐ Research ☐ Not Research

IRB member signature: _____

Communicated to principal investigator: Method of communication and date: (IRB member to attach communication)

_____

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Research/Project Review and Approval Form: Part B

Application for IRB Approval

DIRECTIONS: *IRB member to forward electronic copy to IRB when form is completed.*

The following items must be supplied and submitted to the IRB member identified on the University web site. All information is to be included. Questions can be directed to the IRB member or IRB Chair, contact information is identified on the web site.

1. Research/Project Title
2. Contact Information for Principal Investigator
    a. Contact information for Additional Investigators/team members
    b. Report of Human Participant Protection Education for PI and Research/Project Team members
3. Funding Status
4. Research/Project Time Line (Estimates are acceptable)
    a. Start of data collection
    b. End of data collection
    c. Period of data analysis
    d. End of study
5. Participants in the study: Provide a description of the participants in the study; include age, sex, ethnicity, race, and other identifying characteristics. Provide rationale for the use of vulnerable populations. Describe any precautions that would be taken to minimize risk to participants. Describe procedures for obtaining consent/assent. If consent is not to be obtained, provide a rationale.
    a. Attach consent form if applicable
6. Location of the study:
    a. Name, address, description
    b. Attach letter of agreement from appropriate facility personnel
7. Research/Project Proposal (attach): The proposal should include the following information, in the order indicated, from your research/project.
    a. Specific Aims of the Study
    b. Sample characteristics:
        i. Statement regarding the processes that you will use to recruit participants
        ii. Describe sample demographics and sampling plan
    c. Methods of Data Collection and Analysis
        i. Be sure to include a description of any quantitative and/or qualitative techniques.
        ii. Attach any questionnaires, surveys, tests, tools or research/project instruments
    d. Statement of potential risks to participants that are inherent in this research/project protocol.
        i. For example, identify possible sources of: breaches of confidentiality, treatment complications, psychological distress
    e. Statement regarding precautions and safeguards that are incorporated into the design to minimize potential risks.
    f. Statement of potential benefits to the participants.
    g. Statement regarding precautions and safeguards that are incorporated into the design to maximize potential benefits. h. A step-by-step description of the procedures that will be used in this research/project.
    h. A step-by-step description of the procedures that will be used in this research/project.

Signature of the Principal Investigator:

The undersigned accepts responsibility for this study, including adherence to DHHS, FDA *(www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)* and Thomas Edison State University policies regarding the rights and welfare of individuals who serve as participants in this study.

Signature _____ Date_____

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Research/Project Review and Approval Form: Part B

Application for IRB Approval

IRB USE ONLY

IRB Use Only: For Approvals

Date of Review form submitted: _____ Date of Application submitted: _____

Type of Research/Project *(www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)*

☐ Exempt ☐ Expedited ☐ Full-board review

IRB member signature approval for exempt or expedited research: _____

IRB chair signature for research/project for full-board approval: _____

IRB Use Only: For Approvals with Modifications

Date of Review form submitted: _____ Date of Application submitted: _____

Type of research/project *(www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)*

☐ Exempt ☐ Expedited ☐ Full-board review

IRB member signature approval for exempt or expedited research/project with following modifications: _____

Modifications to be listed here:

IRB chair signature for research/project for full-board approval: _____

IRB Use Only: For Denial of Application

Date of Review form submitted: _____ Date of Application submitted: _____

IRB member signature for denial of application: _____

Rationale:

Denials go to full-board review: _____

Date of full-board review: _____

Disposition: