

Proposal # _____

WESTERN CONNECTICUT STATE UNIVERSITY
Human Subjects Research Review Form (Hum-1)

Information

Principal Investigator(s) _____

If the PI is a student, Faculty Supervisor: _____

Project Title: _____

Department _____

Address (for any mailed correspondence)

E-mail (Where the reviewed application should be sent):

Phone number: _____

Please check any of the following that apply to this proposal:

A. Proposal is an undergraduate student research project developed as part of a research methods course: _____

B. Proposal is an undergraduate student independent study or thesis or senior seminar or honors research project: _____

C. Proposal is a graduate student research project developed as part of a research methods course: _____

D. Proposal is a graduate student research project developed for a Masters or Doctoral thesis: _____

E. Proposal is WCSU faculty developed research: _____

F. Proposal is externally developed faculty research: _____

G. Research is funded or developed with a grant YES NO

If yes, name of Grant or funding agency: _____

I. Purpose of IRB Review

The role of the WCSU Institutional Review Board (IRB) is to review and to approve, when in compliance, all proposed research at WCSU or by WCSU faculty, staff or students to ensure that the research meets Federal standards for the safety and protection of any human subjects involved in the research.

The WCSU IRB operates in compliance with the U.S. Code of Federal Regulations, Department of Health and Human Services (DHHS) Title 45 Part 46, entitled, "Protection of Human Subjects." A link to the DHHS regulations may be found on the WCSU IRB website. WestConn's IRB is registered with the Office of Human Research Protections (OHRP) and has an approved assurance from OHRP (Federalwide Assurance or FWA).

The IRB is responsible for determining that:

- The rights and welfare of the subjects are adequately protected
- The risks to subjects are outweighed by the potential benefits of the research
- The selection of subjects is equitable
- Informed consent will be obtained and, when appropriate, documented

To help the IRB fulfill its role, WCSU requires all researchers to submit their research protocol for review and approval. All applications must include the completed HUM-1. The human subjects **research application** you submit must describe the research activity, including a protocol, and especially the plan for ensuring the protection of human subjects (please refer to the **Research Application Guide** for complete instructions).

The WCSU IRB is unlikely to reject an application without first discussing its concerns about the research with the investigator. However, applications may be deferred for review at another meeting if substantial issues need to be resolved. Researchers are encouraged to attend the regularly scheduled IRB meetings at which their application will be considered in order to address any concerns directly. You will be informed of the IRB's decision regarding your application as expeditiously as possible. Failure to submit applications for review by the published deadlines may result in a delay in the review process. It is required that researchers ensure that their application is submitted by the first of the month in which the next IRB meeting is scheduled.

II. Application for IRB Review Checklist

Before submitting your research application for review by the IRB, please make sure the following steps have been completed.

1. Ensure that everyone involved in the research has completed WCSU IRB human subjects research training requirements (including researcher, student's instructor, research assistants and department chair). If you have any questions concerning whom should complete human subjects research training, please contact the Office of Grants and Research for guidance.

Attach human subjects research training certificates for all such research personnel to your application.

WCSU is part of the Collaborative Institutional Training Initiative (CITI) program. You can sign up for and complete CITI human subjects training via the link on the WCSU IRB website <http://www.wcsu.edu/irb/> Information about this training is provided in the Frequently Asked Questions link on the IRB website.

2. Indicate the category under which you believe your study should be reviewed. There are three choices. See the **WCSU IRB Guidelines for Researchers** (pages 6-11) to determine the requirements for each category.

Is this a new research project? YES NO

If so, are you applying for?

- Exempt Review
- Expedited Review
- Full Review

Is this research a Continuation of previously reviewed research? YES NO

Is this research a Modification of previously reviewed research? YES NO

3. Submit a **Research Application** (see the WCSU IRB **Research Application Guide**).
4. Attach to your application any survey or questionnaire instruments that will be given to subjects, or any protocols describing assessments to which they will be subjected. When an instrument must be purchased or is not yet available, you may describe the instrument in lieu of attaching a copy.
**Note: You must cite the source for any instruments you are using if they have been developed by others.
5. Attach your Informed Consent Form, or an explanation of why the signed Informed Consent requirement can be waived (see the **WCSU IRB Informed Consent Guidelines**).

III. Signatures

The **principal investigator must** sign this form. If the P.I. is a student, his/her faculty supervisor must also sign.

Assurance of continued compliance with regulations regarding the use of human subjects.

I certify that the information provided in this application is accurate. If the procedures for obtaining consent of subjects change, or if the risk of physical, psychological, or social injury to the research subjects increases, or if there should arise unanticipated problems involving risk to subjects or others, I shall promptly report such changes to the Institutional Review Board. I shall report promptly any unanticipated injury to or harm of a subject to my Department Chair and to the Institutional Review Board.

Principal Investigator's Name _____

Principal Investigator's Signature _____ Date _____

Faculty Supervisor's Name and Department _____

Faculty Supervisor's Signature _____ Date _____
(if PI is a student)

Committee Action:

- Approved through exempt review
- Approved by full committee review
- Approved through expedited review
- Not approved; clarification/modification required

IRB Chair's Signature _____ Date _____