

WESTERN CONNECTICUT STATE UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Research Application Guide

Note: Applicants should read the **WCSU IRB Guidelines for Researchers** to gain the best possible understanding of the process for human subjects research review and the federal requirements for the protection of human subjects involved in research. This document can be found on the WestConn IRB home page: <http://www.wcsu.edu/irb/>

Your **Research Application** will consist of the following:

1. Title.
2. Abstract. Explain the proposed research activity in 1-2 paragraphs. See page 3.
3. Rationale. Provide a scientific rationale (in simple language for the benefit of lay members of the IRB) for conducting such research. See page 3.
4. Protocol. Describe the hypotheses and measures and explain how the study will be carried out. See page 3.
5. Human subjects - describe subject selection, recruitment procedures, and anticipated number of subjects. See pages 4 to 5.
6. Risks and Benefits. Explain any potential risks to human subjects and the potential benefits of carrying out this research. See pages 5 to 7. Describe the consent procedures to be followed in your research, or explain why consent is not needed.
7. Protection of human subjects. Describe the steps you will take to protect subjects. See pages 7 to 8.
8. Reports. How will results be reported? See page 8.

A more detailed explanation of each of these sections begins on page 3.

Your submitted Application must be no more than 3 pages, double-spaced, with 1” margins, using a 12-point font. You may include supporting materials as necessary in Appendices.

Is your Project Research?

Before submitting an application for IRB review, you need to indicate whether you are carrying out research as a WCSU faculty member, staff person, student, or on WCSU property or with WCSU funds or under WCSU sponsorship. The following may be helpful. If in doubt, contact the IRB Chair for further consultation.

Definition of Research:

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.1 02(d)]

Examples of projects that would NOT be considered research according to the definition cited above:

Using research methods for program evaluation without intent to distribute the results outside of the program.

- Administering surveys to youth in 4-H programs to determine whether the program was successful.
- Evaluating an established program, for compensation, and providing a report to program administration only.
- Administering surveys to seminar attendees to elicit feedback about how the program was received or might be improved.
- Surveying potential program participants to learn their needs and interests for courses, programs, and training.
- Collecting information about program participants before and after participation in the program (e.g., financial management outreach programs) to assess the impact of the program.

Student Research

The WCSU IRB is often asked whether student research projects should be submitted to the IRB for review, especially when they are used to teach students the principles of scientific research. This question has been addressed in the WCSU IRB Guidelines for Researchers and the relevant paragraph follows:

If a course, as part of the curriculum, regularly requires research involving human subjects, the course instructor for each section must complete an Approval Form for Student Research Involving Human Subjects, signed by the instructor and by the department chair, only once per academic year unless the curriculum is substantially changed or a new instructor is assigned to the course. (This document can be found on the WCSU IRB website).

Note that the Student Research form may be used **ONLY** for projects that are eligible for the exempt category. A general

statement of the requirements for the projects for the course and copies of the instructor's and the chair's NIH or CITI certificate must be on file with the Office of Grant Programs. The faculty member must maintain a Protocol File for each course assignment involving human subjects research.

If a student research project is not exempt, it must be submitted for expedited or full review.

Step-by-step Guide to Submitting a Satisfactory Human Subjects Research Application

The following suggestions are provided to help you put together a concise and clear Research Application for the IRB to consider when evaluating the potential for risk or harm to human subjects. Your submitted Application must be no more than 3 pages, double-spaced, with 1" margins, using a 12-point font. You may include supporting materials as necessary in Appendices.

1. Title. Of your project.

2. Abstract

Provide a **summary** of your proposed research. In 1-2 paragraphs describe the reason for your research, what you hope to learn, and how the study will be carried out.

3. Rationale

Provide a **scientific rationale** (in simple language for the benefit of lay members of the IRB) for conducting such research (150 words or less).

4. Protocol

State your research objectives or questions. Define the research hypotheses if appropriate. Describe your research method. Describe any procedures, evaluations or processes your human subjects will undergo, and attach complete copies of any questionnaires, surveys, instruments, or data collection protocols that will be used in your research. Provide references for the origin of any such instruments and provide references indicating previous use of such instruments with human subjects.

Clearly define the dependent variables (outcome measures you are using) and independent variables (the experimental or manipulated conditions) if appropriate. Also indicate whether your measures will provide qualitative or quantitative data.

Indicate whether your research is being funded by a grant, or if an application for a grant has been submitted.

5. Human Subjects

Are there any **human subjects** in this research? The Federal Guidelines provide the following definition:

Definition of Human subjects:

Living individuals about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. [45 CFR 46.102(f)]

Examples of individuals who WOULD be considered human subjects for research purposes:

- a. Individuals are interviewed about their eating habits (i.e., data ABOUT a living individual are collected through interaction); these individuals would be considered to be human subjects.
- b. Data with identifiers (e.g., name, unique demographic information) are collected from hospital medical records. The individuals to whom the medical records relate are human subjects (i.e., identifiable, private information is collected ABOUT a living individual); these individuals would be considered to be human subjects.

Examples of individuals who WOULD NOT be considered human subjects for research purposes:

- c. Employees of a lawn care company are asked to complete surveys about the type and quantity of products used by the firm for weed control. These individuals would NOT be considered to be human subjects because data was collected FROM them, but not ABOUT them.
- d. Students in a Marketing class go to a local supermarket and ask shoppers which brand of laundry detergent they would be most likely to buy, Brand A or Brand B. This is not human subjects research because no individuals are asked to identify themselves and the information collected was not about the individual. (Note that if information about the age and gender of the shoppers was collected, or if they were asked their names, this would become human subjects research).

- a. Recruitment. Attach a copy of any and all recruitment materials to be used, e.g., advertisements, bulletin board notices, e-mails, letters, or phone call scripts.

b. Initial contact. Describe who will make initial contact with subjects and how it will be made. If subjects are chosen from records, indicate who gave approval for use of the records. If records are “private” medical or student records, provide the protocol, consent forms, letters, etc. for securing consent of the subjects of the records. Written documentation for the cooperation/permission from the holder or custodian of the records should be attached.

c. Inducements. Will subjects receive inducements before or rewards after the study? If yes, please describe. This information must also be included in the Informed Consent Form.

d. Descriptions. Describe the characteristics of the subject population: anticipated number, age ranges, gender, ethnic background, and health status.

e. Length of involvement. Describe how subjects will be involved (for how long, how often, etc.).

f. Special Classes of Subjects. Indicate whether any of the subjects in your research will belong to the following categories:

- Minors
- Pregnant women
- Intellectual disability (DSM IV – mental retardation)
- Developmental disability
- Physically disability
- Prisoners
- Addicts
- Parolees
- Fetuses

If your research involves any such subjects, please provide a clear and simple rationale for your use of special classes of subjects. Note that additional forms/procedures may be needed in these cases, e.g., informed consent for minors and/or person with legal guardians.

6. Risks and Benefits

Are there any **potential risks** to the human subjects involved in your research? The Federal Guidelines describe risk as follows:

“Subject at risk” means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity that departs from the application of those established and accepted methods. [45CFR 46.3(b)]

Risks and benefits are usually described to the subject by way of the Informed Consent statement. See the **WCSU Informed Consent Guidelines** for further information on informed consent (available at the IRB website).

The following checklist may help you decide if your study includes any potential risk factors. This list is NOT exhaustive or complete. Does your study include?

Deception

If deception is part of the experimental design, the proposal **must** include a debriefing procedure, which will be followed upon completion of the study or upon withdrawal of a subject. Attach a description of the debriefing protocol.

Personal material (interviews, opinions, test scores)

Stress or emotional arousal

Loss of privacy

Embarrassment, disappointment, or other disagreeable emotion

Alteration of self-concept (e.g., through knowledge of test scores)

Physical or psychological trauma or pain

Loss of legal rights

Experimental diagnostic procedures

Side effects of medications

Experimental treatment procedures

Contraction of disease

Worsening of illness

Changes in diet or exercise

Administration of physical stimuli

Use of controlled substances

Administration of drugs, chemical or biological agents, or devices

Deprivation of physiological requirements such as nutrition or sleep

Any probing for sensitive or personal information in a survey or interview

- Information collected that might jeopardize a subject's current or future employment prospects if it became known (e.g., admission of illegal drug use)
- Presentation of materials which subjects might consider offensive, threatening or degrading

If your research includes any of the above, describe this risk. (You should describe the precautions that will be taken to minimize these risks in the next section of your protocol.) Why are the risks/inconveniences described justified? Please justify the risks in relation to the anticipated benefits to the subjects, and in relation to the importance of the knowledge that may reasonably be expected to result from the research.

7. Procedures to protect the safety of human subjects in the research.

In this section, describe safeguards to assure the voluntary participation of subjects, how data will be handled to protect privacy, and any debriefing procedures used. In the case of student subjects, indicate that failure to participate in or withdrawal from the project will not affect class grade. The following are possible precautions to be included in human subjects research. This list is not exhaustive.

- Precautions in uses of stressors or emotional material
- When deception is used, subjects are fully informed as to the nature of the research at a feasible time
- Procedures to minimize changes in self concept
- Data from protected sources
- Code numbers will be used
- Individual data will be submerged in results
- No unauthorized use of data
- Debriefing on experimental purposes will be provided
- Clinical trial (describe your data monitoring)
- Sterile equipment
- M.D. or other appropriately trained individual will be in attendance
- Referrals to an appropriate resource (counselor, school program, etc.) will be provided

Explain any of these procedures that will be used in your research.

Specifically describe provisions made to maintain the **confidentiality of data**. (See the **Informed Consent Guidelines** which contain sample consent forms for suggested ways to describe this to subjects). Confidentiality suggests that only the research staff will have access to the data collected and that care will be taken never to identify any individuals in reports or descriptions of the research.

Example: A subject's data record is assigned a code, and a "master list" that links the code to the subject's identity is maintained in a secure location. This maintains confidentiality.

Describe where data will be kept and for how long. Who will have access to the data and what security provisions will be used? Will data identifying subjects ever be made available to anyone other than the PI, e.g., a study sponsor, the FDA, etc.? If so, please explain.

Data can only be **anonymous** if no identifying information is collected along with the data, e.g., subject's names, or if no data is collected that might reasonably identify some subjects (e.g., in a class, age information is collected, and only one student is older than 25).

Examples: (1) Subject fills out and mails back to the investigator a questionnaire that does not provide subject's name, social security number, phone number or any other identifier. Such data are anonymous; (2) Investigator interviews subject by phone and notes responses, but does not have any record connecting any response to any phone number. Such data is anonymous.

To summarize: Data are **anonymous** if the researchers do not know the identity of the subjects and cannot determine their identity from the information collected. If the researcher **can** associate the data collected with the names of the subjects in the study, the data are **confidential** if these identities are not disclosed without permission and if such data are protected against unauthorized or unintended access.

8. Reporting

How do you anticipate the results of your research will be reported? (Conference presentation, journal article, grant report, etc.)