

# **Instructions for Submitting a Protocol Application for the Involvement of Human Subjects in Research**

## **Background Information**

1. ECSU adheres to U.S. federal regulations covering research on human subjects as described in the Code of Regulations, Title 45, Part 46 Protection of Human Subjects (aka 45CFR46, or "The Common Rule"):

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

Additional information about federal policies covering research on human subjects can be found at the Office of Human Research Protections (OHRP), Dept of Health and Human Services, website: <http://www.hhs.gov/ohrp>

2. The ECSU Committee on the Use of Human Subjects in Research (CUHSR) is registered as an Institutional Review Board (IRB) with the OHRP. Our registration number and name are as follows:

IORG Number: IORG0004941

IRB Number: IRB00005900

IRB Name: Eastern Connecticut State U IRB#1.

Federalwide Assurance Number: FWA00011898

ECSU Human Protections Administrator: Dr. Rhona Free,  
Vice President for Academic Affairs

3. Researchers (faculty, staff, and students) planning to conduct research on human subjects must submit a Protocol Application for the Involvement of Human Subjects in Research. This form may be obtained from the CUHSR Chair (contact information given below), or downloaded as a Word file from the ECSU Academic Affairs website:

<http://www.easternct.edu/academicaffairs>

## Submitting a Protocol Application

1. On the Protocol Application form, you may enter text in the gray boxes, or skip the boxes and enter the text as you would in any Word document. Check-off boxes can be filled by double clicking to open a dialog box, and checking the appropriate item. You can save the completed form as a Word document.

NOTE: Please do not reformat the Protocol Application form, or delete any sections that are not applicable to your research; any form that has been reformatted, or has sections missing, will be returned without review.

3. All investigators must provide documented evidence of having completed an NIH-approved tutorial on conducting research on human subjects. The following tutorial is available for anyone to take (free registration is required; it takes about 90 minutes to complete):

Protecting Human Research Participants (PHRP) Course  
<http://phrp.nihtraining.com/users/login.php>

Upon successful completion of the tutorial, you can print out a certificate of completion; one copy of this should be included with each Protocol Application submission; save a copy and/or the URL for future submissions. The CUHSR will accept documentation of other NIH-approved training sessions (*e.g.*, from another institution) in lieu of the tutorial listed above.

4. A copy of the consent form to be signed by each subject or the subject's legally authorized representative must accompany the proposal. The consent form should be printed on official letterhead and should contain the following information:

- a) A statement of the purpose and procedures of the research.
- b) An explanation of the subject's responsibilities and the duration of participation.
- c) A description of any foreseeable risks and benefits to the subject. If the research poses only minimal or no risk, this should be clearly stated.
- d) A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
- e) A statement indicating that participation is voluntary, and that the subject can refuse to participate or terminate his/her participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- f) A statement that the results of the investigation will be made available to the subject upon request.
- g) A statement of whom to contact for answers to pertinent questions about the research, or to request a copy of the research results, and an institutional address for the person to be contacted. For student projects, the name and address of a faculty supervisor should be included.
- h) A statement of whom to contact with questions about one's rights as a research subject. The CUHSR

recommends the following statement (or something similar): "If you have questions about your rights as a research participant, please contact Dr. Charles Booth, Chair of the ECSU Committee on the Use of Human Subjects in Research (Ph: 860-465-5260; Email: booth@easternct.edu)."

**Note:** Consistent with the Code of Federal Regulations Title 45, Part 46- Protection of Human Subjects, Section 46.116c-d, the requirement for an informed consent document signed by the subject may be waived **if**

- i) the investigator can clearly show why the research could not practicably be carried out without the waiver; **and**
- ii) the research involves no more than minimal risk to the subject, **and**
- iii) the waiver will not adversely affect the rights and welfare of the subject.

Investigators using human subjects under the age of 18 must normally obtain signed consent from the child's parent or guardian. Samples of all necessary consent forms (*e.g.*, from parents, teachers, administrators, daycare supervisors) should accompany research proposals using children as subjects.

Note: In certain exceptional cases, investigators using children as research subjects may be exempt from the requirement for obtaining informed consent from the child's

parent or guardian; investigators should refer to the Code of Federal Regulations Title 45, Part 46- Protection of Human Subjects, Section 46.401-409 for more information.

5. Please submit **eight** (8) hard copies of the completed Protocol Application and any supporting documents to:

Dr. Charles Booth, Chair  
Committee on the Use of Human Subjects in Research  
c/o Biology Dept., Science Building, ECSU

Note: Submitting a digital version of the Protocol Application will facilitate the review process, but the CUHSR still requires **eight** hard copies of the form.

6. Upon receiving submitted copies of the Protocol Application, the CUHSR Chair will determine if the Application qualifies for expedited review. Expedited review typically takes about a week, and a decision is not tied to the CUHSR's regular meeting schedule.
7. Proposals that do not qualify for expedited review will be reviewed by the full committee at one of its regular meetings.
8. The CUHSR normally meets once a month during the academic year, and at least once during summer break; additional meetings may be scheduled as required. A Protocol Application should be received at least two weeks prior to the next CUHSR meeting in order to be reviewed at that meeting.
9. If you have questions about conducting research on human subjects at Eastern Connecticut State University, please contact the CUHSR Chair, Dr. Charles Booth,

Department of Biology, ECSU (Ph: 465-5260; Email: [booth@easternct.edu](mailto:booth@easternct.edu)).

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