

Protection of Human Subjects

Academic Affairs – Research

CWU Policy 502-02

Effective: March 14, 2012

Policy Review Date: YEAR

Policy Executive: Provost and Executive Vice President of Academic Affairs

Responsible Office/Unit: Research Compliance Admin

Policy Statement:

Applicability:

Content:

Policy

(1) Introduction

- A. Researchers who use human subjects in their studies have an obligation to respect the rights of these participants. As an institution that accepts public support for its operation, Central Washington University has a legal as well as an ethical obligation to ensure that appropriate procedures for the protection of human subjects are followed in university-endorsed research studies. The Human Subjects Review Committee (HSRC) at Central Washington University has been formed to assure the U.S. Department of Health and Human Services (DHHS) that human research subjects will be protected and that CWU will comply with DHHS Regulations for the Protection of Human Research Subjects (Title 45 Code of Federal Regulations, Part 46). The HSRC is appointed by the university provost and is composed of thirteen members representing the diversity of experience and expertise specified in the Federal Regulations [45 CFR § 46.107 (a)]. The HSRC operates according to procedures specified by university policy and federal regulations and published in the CWU Human Subjects Policy and Procedures Manual.

(2) Review of Proposed Research

- A. It is the policy of CWU that all research involving human subjects will be reviewed by the HSRC. The term “research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for the purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. The involvement of human subjects in research activities conducted by faculty, staff, or students is not permitted until the HSRC has reviewed and approved the research protocol. Even if, according to

federal regulations, the research appears to be exempt from review, all researchers will nonetheless submit applications for approval of their research activities. No contact with subjects, whether for the purposes of recruitment or obtaining consent, may be initiated until the proposed research has been approved. Furthermore, unless the consent process has been specifically waived by the HSRC in accordance with 45 CFR § 46.116, no subjects may be included in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. The required elements of informed consent are established by the federal regulations (45 CFR § 46.116) and by the university. Faculty members who intend to have students collect data from human participants as part of course activities or requirements shall have these activities reviewed by the HSRC prior to student involvement. Finally, although data collected for the sole purpose of assessing or improving the quality of programs or administrative units within the institution are likely exempt from these regulations, CWU staff members who undertake such projects are encouraged to consult with the HSRC regarding procedures for protecting the rights and welfare of their respondents.

- B. In reviewing research, the HSRC will give careful consideration to the following:
1. Risks to subjects and procedures for minimizing such risks;
 2. Anticipated benefits to the subjects and others;
 3. Importance of the knowledge that may be reasonably expected to result from the research;
 4. Methods by which subjects will be recruited and compensated;
 5. Consent processes to be employed; and
 6. Procedures for providing post-study information and, where necessary, debriefing subjects regarding deception. In doing so, the HSRC will see that the requirements in 45 CFR § 46.111 are satisfied.
- C. Following its review, the HSRC shall issue one of the following decisions:
1. Approval of the research protocol;
 2. Approval conditioned on modification; or
 3. Disapproval.
- D. The results of the HSRC review shall be communicated in writing to the investigator and the appropriate institutional officials. Research that has been approved by the HSRC is subject to continuing review on at least an annual basis.
- E. Furthermore, investigators with approved research protocols shall notify the HSRC upon:
1. The occurrence of unexpected risk or harm to study participants;
 2. Proposed modifications in study procedures; and
 3. Termination of the research project.
- F. HSRC-approved research may be subject to review and disapproval or further restrictions by the president or provost for institutional reasons; however, HSRC disapprovals, restrictions, or conditions cannot be rescinded or removed except by action of the HSRC.

(3) Appeal of HSRC Decisions

- A. Researchers whose applications have been disapproved by the HSRC shall be notified in writing of:
 - 1. The reasons for disapproval;
 - 2. Recommendations for modifications in study procedures where appropriate; and
 - 3. The investigator's right to request reconsideration of a research proposal by the HSRC.
- B. Specific procedures for reconsideration of HSRC decisions shall be published in the CWU Human Subjects Policy and Procedures Manual. The Human Subjects Policy and Procedures Manual is available online (www.cwu.edu/~hsrc)

(4) Oversight of the Human Subjects Research Policy

- A. The HSRC shall have general oversight responsibility for the university policy and procedures for the protection of human research subjects. The HSRC shall consider policy changes that may be required to comply with federal regulations, to ensure fairness to investigators, or to protect more adequately the rights and welfare of human subjects in research. When appropriate, such policy changes will be recommended by the HSRC to the university president.

History:

*PAC: 04/04; Responsibility: Human Subjects Review Committee; Authority: Provost's Council/Cabinet;
Reviewed/Endorsed by: Provost's Council 03/06/12; Cabinet 03/14/12;
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