Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 122	
CHAPTER: Institutional Review Board	ISSUED: 9/2004	REVISED/REVIEWED: 11/2018
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1. PURPOSE

This policy describes the Human Subjects Research Education Program that assists investigators, (faculty, staff, and students) in meeting federal regulations and University education requirements. The Human Subjects Research Education Program includes initial training as well as re-training.

2. PROGRAM OBJECTIVES

The program is designed to:

2.1. Help investigators (faculty, staff, and students) understand the special requirements associated with the use of human subjects in research.

2.2. Clarify the responsibilities of those involved in human subjects research.

2.3. Clarify the responsibilities of the IRB.

2.4. Increase recognition of the basic ethical principles for the use of human subjects: respect for persons, beneficence, and justice.

2.5. Provide education on three major components:

2.5.1. The protection of human subjects as mandated by the DHHS (OHRP) in Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46)

2.5.2. Creighton University IRB review, informed consent, and policies and procedures applicable to human subjects research

2.5.3. The Health Insurance Portability and Accountability Act (HIPAA) as it applies to the researcher

3. WHO IS REQUIRED TO COMPLETE THE PROGRAM?

Individuals in the following categories who are conducting human subjects research must complete Creighton University's Human Subjects Research Training:

3.1. Creighton University faculty serving as investigators

3.2. Creighton project staff/students conducting research

3.3. Creighton project staff/students designated by the Principal Investigator

3.4. Investigators from non-Creighton facilities/sites

Principal Investigators' mandatory training shall be completed before submission to the IRB of any new project, revisions or amendments to existing projects, or renewals of existing projects. All personnel listed on the study shall have their mandatory training completed prior to final approval of the protocol.

4. TRAINING OF IRB MEMBERS

All new members appointed to the IRB shall complete Creighton University's Human Subjects Research Training. Specific requirements can be found on the document "Required Training for Conducting Human Subject Research".

4.1. Re-training is required after a specified period of time for each course. Specific requirements can be found on the document "Required Training for Conducting Human Subjects Research".

4.2. The University shall offer an opportunity for existing IRB members to attend additional training.

5. TRAINING REQUIREMENTS FOR INVESTIGATORSAND RESEARCH PERSONNEL

5.1. Investigators and study personnel must complete the University requirements dependent on type of research. Specific requirements can be found on the document "Required Training for Conducting Human Subjects Research".

5.2. Re-training is required after a specified period of time for each course and is dependent on the type of research. Specific requirements can be found on the document "Required Training for Conducting Human Subjects Research".

6. TRAINING REQUIREMENTS FOR COMMUNITY MEMBERS WHO ACT AS INVESTIGATORS OR STUDY PERSONNEL

6.1. See IRB Policy, "Community-Based Research".

7. WHO IS EXEMPT FROM HUMAN SUBJECTS RESEARCH EDUCATION REQUIREMENTS?

7.1. The following individuals are exempt from human subjects research education requirements:

7.1.1. Research staff who perform only standard-of-care procedures in connection with a protocol (e.g., EKG technicians, hospital nursing staff)

8. ADDITIONAL TRAINING

The Creighton University Human Research Protection Program (CUHRPP) may provide additional training as needed, addressing such issues as regulatory changes and issues identified through the current CUHRPP internal monitoring process.

8.1. CURE (Creighton University Research and Education) meetings for investigators/coordinators are held to inform research personnel about current issues in research at Creighton University.

8.2. Additional training may be required by external organizations per agreements (e.g., NIH, DOD, EPA, pharmaceutical companies, etc.).

9. RECORDS RETENTION

9.1. The training records shall be placed in the User Profile in the electronic IRB system and maintained indefinitely. CITI training is automatically updated after the initial verification in the electronic system.