

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 123	
CHAPTER: Institutional Review Board	ISSUED: 9/2004	REVISED/REVIEWED: 6/2006; 7/2009; 7/2010, 9/2012, 11/2013
POLICY: Human Subjects Research Education Program	PAGE 1 OF 6	

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 certification as well as continuing education and recertification.

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.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 123	
CHAPTER: Institutional Review Board	ISSUED: 9/2004	REVISED/REVIEWED: 6/2006; 7/2009; 7/2010, 9/2012, 11/2013
POLICY: Human Subjects Research Education Program	PAGE 2 OF 6	

3. WHO IS REQUIRED TO COMPLETE THE PROGRAM?

Individuals in the following categories who are conducting human research must complete Creighton University's Human Subject Research Education Program:

- 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 who do not have certification of training from their institution's IRB

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

- 4.1. All new members appointed to the IRB shall complete Creighton University's [Human Subjects Research Education Program](#). Initial certification in the Program shall include the following:
 - 4.1.1. Verification of access to and agreement to abide by the Creighton University IRB Policies and Procedures for the Use of Human Subjects in Research.
 - 4.1.2. Acknowledgement of access to the Research and Sponsored Programs Compliance Plan.
 - 4.1.3. Completion of the web-based Collaborative Institutional Training Initiative (CITI) Human Subjects Research Basic Biomedical or Social-Behavioral Education Modules..

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 123	
CHAPTER: Institutional Review Board	ISSUED: 9/2004	REVISED/REVIEWED: 6/2006; 7/2009; 7/2010, 9/2012, 11/2013
POLICY: Human Subjects Research Education Program	PAGE 3 OF 6	

- 4.1.4. Completion of the web-based HIPAA (Health Insurance Portability and Accountabilities Act) training – CITI Health Information Privacy and Security (HIPS) Education Modules.
- 4.1.5. Completion of the web-based CITI Biomedical or Social-Behavioral Course in the Responsible Conduct of Research (RCR).
- 4.1.6. Completion of the web-based CITI Conflicts of Interest Course.

This certification is valid for three years; at the end of three years, if the individual continues in his/her role in research, s/he shall recertify. See section 9 of this policy, “Recertification.”

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

5. INITIAL CERTIFICATION REQUIREMENTS FOR INVESTIGATORS, RESEARCH COORDINATORS, AND RESEARCH PERSONNEL INVOLVED WITH A BIOMEDICAL PROTOCOL

Initial certification shall be provided when investigators and study personnel have met the following criteria:

- 5.1. Verification of access to and agreement to abide by the Creighton University IRB Policies and Procedures for the Use of Human Subjects in Research.
- 5.2. Acknowledgement of access to the Research and Sponsored Programs Compliance Plan.
- 5.3. Completion of the web-based CITI Human Subjects Research Basic Biomedical Education Modules.

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 123	
CHAPTER: Institutional Review Board	ISSUED: 9/2004	REVISED/REVIEWED: 6/2006; 7/2009; 7/2010, 9/2012, 11/2013
POLICY: Human Subjects Research Education Program	PAGE 4 OF 6	

- 5.4. Completion of the web-based HIPAA (Health Insurance Portability and Accountabilities Act) training – CITI Health Information Privacy and Security (HIPS) Education Modules.
- 5.5. Completion of the web-based CITI Biomedical Course in the Responsible Conduct of Research (RCR).
- 5.6. Completion of the web-based CITI Conflicts of Interest Course.
- 5.7. Completion of the NIH Financial Conflict of Interest Online Tutorial (if involved in an NIH-funded project).

This certification is valid for three years; at the end of three years, if the individual continues in his/her role in research, s/he shall recertify. See section 9 of this policy, “Recertification.”

6. INITIAL CERTIFICATION REQUIREMENTS FOR INVESTIGATORS, RESEARCH COORDINATORS, AND RESEARCH PERSONNEL INVOLVED WITH A SOCIAL-BEHAVIORAL PROTOCOL

Initial certification shall be provided when investigators, staff, and students have met the following mandatory criteria. The HIPAA training may be required if Protected Health Information (PHI) is collected or accessed in the study:

- 6.1. Verification of access to and agreement to abide by the Creighton University IRB Policies and Procedures for the Use of Human Subjects in Research.
- 6.2. Acknowledgement of access to the Research and Sponsored Programs Compliance Plan.
- 6.3. Completion of the web-based CITI Human Subjects Research Basic Social-Behavioral Education Modules.
- 6.4. Completion of the web-based CITI Social-Behavioral Course in the Responsible Conduct of Research (RCR).

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 123	
CHAPTER: Institutional Review Board	ISSUED: 9/2004	REVISED/REVIEWED: 6/2006; 7/2009; 7/2010, 9/2012, 11/2013
POLICY: Human Subjects Research Education Program	PAGE 5 OF 6	

6.5. Completion of the web-based HIPAA (Health Insurance Portability and Accountabilities Act) training – CITI Health Information Privacy and Security (HIPS) Education Modules may be required if the investigator is using or collecting PHI (see to IRB Policy 119, “[HIPAA for Researchers](#)”).

6.6. Completion of the web-based CITI Conflicts of Interest Course.

6.7. Completion of the NIH Financial Conflict of Interest Online Tutorial (if involved in an NIH-funded project).

This certification is valid for three years; at the end of three years, if the individual continues in his/her role in research, s/he must recertify. See section 9 of this policy, “Recertification.”

7. HIPAA FOR RESEARCH CERTIFICATION REQUIREMENTS

7.1. The following individuals shall complete HIPAA training:

- 7.1.1. Individuals who participate in research projects that are exempt and in which the use of PHI is part of the project, such as retrospective chart reviews.
- 7.1.2. Individuals who do not meet the above requirements for IRB Certification training, but who work in a department in which they may be privy to PHI and have not previously completed clinical HIPAA training (this training is at the discretion of the Principal Investigator).

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

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

Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 123	
CHAPTER: Institutional Review Board	ISSUED: 9/2004	REVISED/REVIEWED: 6/2006; 7/2009; 7/2010, 9/2012, 11/2013
POLICY: Human Subjects Research Education Program	PAGE 6 OF 6	

- 8.1. Research personnel, including students, who conduct only exempt research that does not include the use of PHI.
- 8.2. Research staff who perform only standard-of-care procedures in connection with a protocol (e.g., EKG technicians, hospital nursing staff).
- 8.3. Research staff whose sole role is to analyze data, if the data does not contain identifying information (see HIPAA guidelines for use of identifiers).

9. 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.

- 9.1. CURE (Creighton University Research and Education) meetings for investigators/coordinators are held monthly to inform research personnel about current issues in research at Creighton University.
- 9.2. Additional training may be required by external organizations per agreements (e.g., NIH, DOD, EPA, pharmaceutical companies, etc.).

10. RECORDS RETENTION

- 10.1. Human Subjects Research Education Program records of faculty and staff remain in active files until the individual terminates employment.
- 10.2. Human Subjects Research Education Program records of students remain in active files for four years.