Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 104	
CHAPTER: Institutional Review Board	ISSUED: 10/2009	REVISED/REVIEWED: 5/2013; 11/2013
POLICY: Federal-wide Assurance/IRB Registration	PAGE 1 OF 2	

1. PURPOSE

This policy describes the agreement with the Department of Health and Human Services Office of Human Research Protection (OHRP) through the Federal-wide Assurance (FWA), and to describe IRB registration with both the OHRP and the Food and Drug Administration (FDA).

2. POLICY

2.1. It is the policy of Creighton University that the IRB shall file and maintain an agreement with OHRP through an FWA. Creighton University has declared that all federally funded institutional components listed under the CU FWA (#00001078) shall comply with this assurance.

2.2. Creighton University has determined that human subjects federally funded research shall be governed by Health and Human Service regulations at 45 CFR 46 and ethical standards.

2.3. Creighton University has determined that its activities related to human participant research, regardless of funding source, shall be guided by the ethical principles found in the Belmont Report.

2.4. Creighton University has designated establishment and registration of two IRBs with provisions for sufficient meeting space and staff to support the IRBs' review and recordkeeping duties:

2.4.1. IRB-01 (IRB00000155 – Creighton University – Omaha IRB #1) – Biomedical

2.4.2. IRB-02 (TIRB20067 – Creighton University – Omaha IRB #2) – Social-Behavioral

2.5. Creighton University shall maintain a list of IRB members identified by name, earned degree, and representative capacity, and shall also maintain a current curriculum vitae for each IRB member. Changes in IRB memberships shall be reported to OHRP through filing an IRB Registration Update.

2.6. Creighton University has established human research protection program written policies and procedures, as required under Health and Human Services

regulations at 45 CFR 46.103, and Food and Drug Administration regulations 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 812.

2.7. The IRB shall conduct initial and continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. The investigator and the Institution shall be provided written notification of the findings and actions taken by the IRB.

2.8. The IRB shall determine which projects require review more often than annually, as well as which projects require verification, from sources other than the investigators, that no material changes have occurred since the previous IRB review.

2.9. The IRB shall ensure that proposed changes in approved research protocols are reported promptly and are not initiated without IRB review and approval, except when necessary to eliminate immediate risk to the participant.

2.10. The IRB shall have the authority to observe, or have a third party observe, the consent process and the research.

2.11. The IRB shall ensure prompt reporting to the appropriate institutional officials and appropriate federal regulatory officials (OHRP, FDA, and other department or agency heads, if that agency has oversight of the research):

2.11.1. Any serious or continuing noncompliance with federal or IRB requirements.

2.11.2. Suspension or termination of IRB-approved projects (see IRB Policy 135, "Suspensions and Terminations.")

2.12. The IRB administrators shall review and approve research proposals qualifying for exempt status (see IRB policy 114, "Exempt Research").