

1: Principles and Purpose

1.4 FederalWide Assurance and IRB Registration

Effective Date: 8/9/2019

Revised:

North Dakota State University maintains an approved FederalWide Assurance (FWA00002439) with the Office of Human Research Protections (OHRP) that describes procedures for protecting the rights and welfare of research participants. In addition, the Institutional Review Board (IRB) is registered to review federally supported research.

1.0 FWA Maintenance and Renewal

- 1.1 The FWA is effective for 5 years and must be renewed every 5 years, even if no changes have occurred, in order to maintain an active FWA.
- 1.2 Any renewal or update that is submitted electronically, and approved by OHRP, begins a new 5-year effective period.
- 1.3 Updates to the FWA must be made when there is a change in:
 - One or more of the components over which the Institution has legal authority and that is covered by the FWA.
 - Human Protections Administrator (i.e. the person who serves as primary point of contact for your institutions system for protecting human subjects).
 - Institutional Official.

2.0 IRB Registration Updates

- 2.1 IRB Registration must be updated with changes in:
 - Institutional Official,
 - Human Protections Administrator,
 - IRB Chairperson,
 - IRB Membership.
- 2.2 Additional information provided in the Registration includes:
 - Approximate number of active protocols involving FDA-regulated products, and
 - A description of the types of FDA-regulated products involved in FDA protocols (such as biological products, color additives, food additives, human drugs, or medical devices) involved in the protocols.

Resources:

[Update/Renew FWAs](#)

[IRB Registration Instructions](#)