

SOP: 603B
OFFICE FOR HUMAN RESEARCH PROTECTION (OHRP)

1. POLICY

The Common Rule for the protection of human participants at [Section 103\(a\)](#) of 45 CFR 46 Subpart A requires that each institution "engaged" in federally-supported human participant research file an "Assurance" of protection for human participants. The Assurance formalizes the Institution's commitment to protect human participants.

Institutions engaged in human participant research that is conducted or supported by DHHS must provide written Assurances of Compliance to DHHS describing the means they employ to comply with the DHHS Regulations. OHRP negotiates and approves the Assurances on behalf of the Secretary of DHHS. An Assurance approved by OHRP commits the Institution and its personnel to full compliance with the regulations. The University shall maintain Assurances with OHRP and uphold its Assurances as filed.

Specific Policies

1.1 Assurances

The University shall maintain Assurances for both the HSC IRB and the Norman Campus IRB and uphold its Assurances as filed with OHRP. A copy of the Assurance for each campus shall be maintained in the office of the HRPP Director and on the website for each campus.

In order to maintain an active Assurance approved by OHRP, all information provided under the Assurance shall be updated at least every 36 months, even if no changes have occurred. The HRPP Director for each campus shall report promptly to OHRP all amendments to the Assurance. Amendments to the Assurance include changes to the IRB membership rosters, the addition or deletion of an IRB Chair, or a change in the signatory official.

The University is the IRB of record for a number of affiliate institutions through arrangements documented in writing. Authorization agreements for these affiliate institutions shall be maintained by the HRPP Director of each campus.

1.2 DHHS Regulations

The University shall uphold the ethical principles of the Belmont Report and apply DHHS regulations (45 CFR 46, including Subparts A, B, C, & D) to all research involving human participants regardless of the source of funding.

1.3 Noncompliance and Participant Safety

The HRPP Director for each campus shall act as the liaison between OHRP and the Institution and shall report incidences of noncompliance or participant safety concerns and/or suspension or termination of research. Refer to SOP 407, Unanticipated Problems Involving Risk to Participants or Others and Protocol Deviations; SOP 903, Non-Compliance/Scholarly Misconduct; or SOP 411, Suspension or Termination of IRB Approval; respectively, regarding the reporting of these occurrences.

1.4 OHRP Compliance Oversight Evaluations

The institution and HRPP office shall cooperate fully in the event of a compliance oversight evaluation. Refer to SOP 902, Audits by Regulatory Agencies.

1.5 Guidance from OHRP

The Office of HRPP shall communicate with OHRP for guidance as needed in all matters of human research.

2. SCOPE

This policy applies to interactions between OHRP and the Office of HRPP.

3. RESPONSIBILITY

The HRPP Director is responsible to report incidences of noncompliance and concerns of participant safety to OHRP.

The HRPP Director is responsible for maintaining the FWA with DHHS and for updating it at least every 36 months.

The HRPP Director is responsible for providing guidance to HRPP and IRB staff, IRB members, and Investigators regarding DHHS regulations.

The IRB Education Coordinator includes information regarding DHHS regulations and research in the education program.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

21 CFR 50 and 56

Compliance Oversight Procedures, Letter from Dr. Koski, Director, OHRP 12/04/00

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other policies.

6. ATTACHMENTS

603B-A Federalwide Assurance-Oklahoma City Campus

603B-C Federalwide Assurance –Norman Campus

7. PROCESS OVERVIEW

7.1 The HRPP Director maintains the assurance with OHRP and negotiates authorization agreements with approved affiliate institutions. The HRPP Director seeks review of such agreements by the Office of the Legal Counsel. The assurance and authorization agreements are signed by and filed with the HRPP Director. The IRB operates under DHHS regulations 45 CFR 46, OHRP guidance documents, and the Belmont Report.

7.2 The HRPP Director reviews and updates the Assurance periodically as needed, or at least every 36 months. All information provided under the FWA must be renewed or updated at least every 36 months, even if no changes have occurred, in order to maintain an active FWA.

The University shall complete a DoD addendum to its FWA when human research is conducted or funded by the DoD. See SOP 603F, Department of Defense.

7.3 The HRPP Director discusses and reviews incidences of unanticipated problems involving risks to participants or others, serious or continuing noncompliance, and suspension or terminations with the Director of Compliance as per SOP 407, Unanticipated Problems Involving Risk to Participants or Others and Protocol Deviations; SOP 903, Non-Compliance/Scholarly Misconduct; or SOP 411, Suspension or Termination of IRB Approval.

7.4 The HRPP Office communicates with the OHRP to evaluate research proposals when appropriate or to seek guidance as needed. The HRPP Director may seek guidance from Legal Counsel as needed. The Director of Compliance is consulted by Legal Counsel prior to communicating with the OHRP.

7.5 When OHRP initiates a compliance oversight evaluation, SOP 902, Audits by Regulatory Agencies, is followed.

7.6 All correspondence to and from OHRP is filed with the HRPP Director.

APPROVED BY: _____ **DATE:** 01/15/2009

NEXT ESTABLISHED REVIEW DATE: MAY 2012