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 a Federalwide Assurance (FWA) of protection for human participants. The Assurance formalizes the Institution's commitment to protect human research participants. The IRB operates under DHHS regulations 45 CFR 46, OHRP guidance documents, and the Belmont Report.

For research projects funded by the Department of Defense (DoD) or that include research participants who are members of the U.S. military, a DoD Addendum to the FWA is signed by the Institutional Official.

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 applicable 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 applicable 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 NC 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 Directors 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 a written agreement signed by the Institutional Official. The HRPP Director of the respective campus for these affiliate institutions maintains the written agreements.

1.2 DHHS Regulations

The University shall uphold the ethical principles of the Belmont Report and apply DHHS regulations (45 CRF 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 serious or continuing noncompliance, unanticipated problems involving risk to participants or
others, and/or suspension or termination of research. Refer to SOP 407: Protocol Deviations and Unanticipated Problems; 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

3.1 The HRPP Director is responsible to report incidences of serious or continuing noncompliance, unanticipated problems involving risk to participants or others, and/or suspension or termination of research to OHRP.

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

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

3.4 The HRPP 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
OHRP Compliance Oversight Procedures for Evaluating Institutions, 10/14/09

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 407: Protocol Deviations and Unanticipated Problems
SOP 411: Suspension or Termination of IRB Approval
SOP 603F: Department of Defense
SOP 902: Audits by Regulatory Agencies
SOP 903: Non-Compliance/Scholarly Misconduct

6. ATTACHMENTS

603B-A Federalwide Assurance-HSC Campus
603B-C Federalwide Assurance –Norman Campus
7. PROCESS OVERVIEW

7.1 The HRPP Directors maintain their respective campus’ assurance with OHRP and negotiate authorization agreements with approved affiliate institutions. The HRPP Directors seek review of such agreements by the Office of the Legal Counsel. The assurance and authorization agreements are signed by the Institutional Official for the respective campus and filed with the respective HRPP Director.

7.2 The HRPP Directors review and update 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 Directors discuss and review incidences of unanticipated problems involving risks to participants or others, serious or continuing noncompliance, and suspension or terminations with the Director of Compliance for the NC and the HSC VPR for HSC as per SOP 407: Protocol Deviations and Unanticipated Problems; SOP 903: Non-Compliance/Scholarly Misconduct; or SOP 411: Suspension or Termination of IRB Approval.

7.4 The HRPP Directors communicate with the OHRP to evaluate research proposals when appropriate or to seek guidance as needed. The HRPP Directors may seek guidance from Legal Counsel and/or the Director of Compliance for the NC or the HSC VPR for HSC, as needed. The HRPP Directors and/or the Director of Compliance for the NC or the HSC VPR shall consult with 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 respective campus’ HRPP Director.

APPROVED BY: ___________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016