1. POLICY

The Office of Research Services (ORS) and Outreach Sponsored Programs (OSP) shall serve as a central resource to promote the research, education, and service missions of the University. ORS and OSP shall provide information and administrative assistance to faculty and staff for developing and submitting proposals to external sponsors and negotiating awards and post-award support. Consistent with NIH policy, access to funding of projects involving the use of human research participants shall be contingent upon IRB approval, including compliance with requirements for continuing review.

The ORS and OSP shall track all projects involving human research participants and request current information on the status of research project approval from the IRB. Open communication among the IRB and the ORS and OSP is essential in order for each entity to fulfill its function.

Specific Procedures

1.1 Submission to IRB After an Award Acceptance

The revised NIH policy of May 2000 that allows grant applications to be submitted to NIH for peer review without prior IRB approval is extended to all Norman Campus (NC) grant proposals where the granting agency does not require IRB approval prior to their review process. An investigator will be required to submit an IRB application “just in time” only for award acceptance and funds access.

1.2 Research Proposals With Delayed Human Participant Involvement

Occasionally, research activities are funded but human participant involvement will occur after protocol development. The investigator must receive approval from the IRB for protocol development in order for ORS to release research funds. Additional guidance about receiving IRB approval to develop the human research protocol is provided in SOP 406: Determination of Human Research and Protocol Development.

1.3 IRB Project Quality Assurance

Investigators often seek funding from various sources. To save time, some investigators may submit only one research project for IRB approval. When investigators receive feedback from granting agencies, they may “tweak” the protocol in order to receive a higher rating/score. Sometimes the titles remain the same as the title originally submitted and approved by the IRB, but the content/mechanics of the protocol have changed. This becomes a problem if the investigator does not re-submit the revised protocol for IRB approval and is contrary to University and federal policy. Investigators who revise protocols per funding agency requirements must submit the protocol with an application to the IRB as a new submission.

Each research project is assigned a unique IRB number based on grantor/sponsorship information; i.e., one IRB number for each grant
This numbering system assures that each federally funded project has been reviewed, in entirety, by an assured IRB as mandated in the federal regulations under 45CFR46.103(f).

2. SCOPE

This SOP applies to human participant research projects routed through the IRB and ORS or OSP at OU-NC.

3. RESPONSIBILITY

If there is an outstanding project that requires IRB approval and has not begun the review process, ORS or OSP notifies the investigator as well as the HRPP office. ORS or OSP employees also contact the HRPP office periodically in order to check on project titles, approval dates, and continuing review dates.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301, Research Submission Requirements
SOP 302, Administrative Review & Distribution of Materials
SOP 406, Determination of Human Research and Protocol Development

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 The investigator submits a research project to the IRB, and the IRB Administrator processes per SOP 301: Research Submission Requirements; and 302: Administrative Review & Distribution of Materials.

7.2 The IRB staff communicate and resolve issues related to the Investigators research project with ORS or OSP.

APPROVED BY: ___________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016