SOP: 602D
OFFICE OF RESEARCH SERVICES

1. POLICY (applies to OU-NC only)

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

The ORS tracks all projects involving human research participants and requests current information on the status of protocol approval from the IRB. Open communication between the IRB and the ORS is essential in order for each entity to fulfill their function.

Specific Procedures

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

The IRB recognizes that certain types of proposals or contracts are submitted to funding agencies with the knowledge that human participants may be involved within the period of support, but definite plans are not set forth in the application or proposal. In these instances, protocols are to be submitted to the IRB with as much information as is available. The protocols must include assurances that additional information will be submitted when developed and in the case of training grants, that all trainees will submit individual protocols if human participants are to be used. Involvement of human participants in any research project supported by these awards may be allowed only after the IRB has reviewed and approved the research project. Grant Proposals lacking definite plans for human participant involvement may include the following:

- Research training programs or grants in which the activities involving human participants remain to be selected or designed.
- Research, pilot or developmental projects in which the involvement of human participants depends on such things as the completion of instruments or prior studies.

1.2 Research Without the Intention of Human Research Participant Involvement

Occasionally research activities are undertaken without the intention of human participant involvement, but it is later proposed to involve human participants. The proposed research activity involving human participants must first be reviewed and approved by the IRB before initiation of the research.

1.3 IRB Project Quality Assurance

It is not uncommon to find that principal investigators try to obtain funding from various sources, as well they should. However, to save time, some investigators submit only one protocol for IRB approval. When investigators receive feedback from granting agencies, it is not uncommon to "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 may have changed significantly. This becomes a problem when the Investigator fails to re-submit this changed protocol for IRB approval; this is contrary to University and Federal policy.

Each study is assigned a unique IRB number based on grantor/ sponsorship information; i.e. one IRB number for each grant proposal/ sponsor. This is particularly necessary for all federally sponsored research; this numbering system assures that each federally funded project has been reviewed, in entirety, by an Assured IRB body. This is mandated in the Federal regulations under 45CFR46.103(f)

2. SCOPE

These policies and procedures apply to human research participant research projects routed through the IRB and ORS at OU-Norman campus.

3. RESPONSIBILITY

Communication primarily is initiated within the ORS. If there is an outstanding project that requires IRB approval and has not begun the review process, ORS will notify the principal investigator as well as the HRPP office. ORS employees also contact the IRB 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

Not applicable

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 Investigator submits research project to IRB and IRB Administrator processes as per SOP 301 and 302.

7.2 IRB identified issues are communicated and resolved with ORS.

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APPROVED BY:_____ DATE:_____

NEXT ESTABLISHED REVIEW DATE: MAY 2009