SOP 602G: DETERMINATION OF REVIEWING OU CAMPUS IRB

1. POLICY

Investigators at the University often engage in research projects involving participants or testing procedures that may fall under the purview of multiple OU campus IRBs. The Human Research Participant Protection (HRPP) Director evaluates the role of the OU researchers and determines the appropriate OU campus IRB of record.

Research Involving Multiple OU IRBs: Human research projects involving IRBs from both the Health Sciences (HSC) and Norman campuses (NC) may include research projects that recruit participants from both campuses, involve investigators from both campuses, and/or utilize resources from both campuses. Research projects that target a specific patient population or utilize research procedures that may result in elevated physical risk may require HSC IRB approval, as determined by the HSC IRB Chair or IRB designee.

Specific Policies

1.1 Determination of Reviewing OU Campus

The investigator will submit the original application materials to the University IRB on the campus of his or her academic program. The initial determination of which IRB will be the IRB of record will be made according to the following guidelines:

1.1.1 All medical, clinical, FDA-regulated, and VA studies involving human participants will be reviewed by the OUHSC IRB unless an IRB with medical and clinical expertise is reviewing the research protocol. For example, if OU NC faculty, staff, or students conduct research in a hospital setting and the IRB from that facility will conduct an independent IRB review, OUHSC IRB review is not required.

1.1.2 Studies that include a research procedure that may result in greater than a minimal level of physical risk or that targets research participants with a specific medical diagnosis or clinical intervention may be evaluated by the IRB Chairs at both the HSC and NC campuses to determine why such participants are at increased physical risk from participation compared to a healthy population.

1.1.3 Either University IRB can require review of a research submission by an investigator whose academic program it oversees.

1.1.4 When the University investigator’s campus of record will not serve as the IRB of record, the IRB from the originating campus shall cooperate in response to requests from the IRB of record for additional information and reporting requirements, adequately support the designated IRB in its function, and abide by the designated IRB decisions. No University IRB shall administratively overrule disapprovals by another University IRB of proposed projects.

1.2 Reciprocal Campus IRB Review Policy

The University of Oklahoma Norman Campus and the University of Oklahoma Health Sciences Center shall sign and maintain a Cooperative Memorandum of Understanding (MOU) that specifies
which IRB is designated with sole IRB oversight when a research project involves both campuses and when research proposed by OU NC faculty, staff, or students requires medical oversight. At a minimum, the Cooperative MOU shall provide:

1.2.1 Unless otherwise stipulated in Section 1.1, when participants of a research project will be recruited primarily at one University campus, that campus shall be assigned IRB oversight for the research project.

1.2.2 When participants of a research project will be recruited from both University campuses, IRB Chairs at both campuses will confer to determine which IRB should retain sole oversight, taking into consideration the scope of the research.

1.2.3 If the originating University IRB determines it does not possess the necessary expertise to review a particular research project, it shall transfer the IRB review process to an IRB on the other campus.

2. SCOPE

This SOP applies to all research that involves investigators or research participants from multiple University campuses.

3. RESPONSIBILITY

The HRPP Director or the IRB Chair of the originating campus is responsible for providing initial review and recommendation concerning the appropriate campus IRB to retain oversight.

4. APPLICABLE REGULATIONS AND GUIDELINES

None

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 When a research project involves multiple University campuses, one campus IRB shall be designated as the IRB of record, as described above in Section 1.1.

7.2 The IRB Administrator reviews submitted documents per SOP 301: Research Submission Requirements.

7.3 The IRB Chairs from both campuses may confer to determine which IRB is responsible for regulatory oversight. The determination will be documented in the study file.

7.4 The IRB Administrator or IRB Chair notifies the investigator regarding determination of IRB oversight.

7.5 The investigator will submit the forms that are applicable to the assigned campus IRB.

APPROVED BY: ____________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020