SOP 602F: INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

1. POLICY

The IRB shall not grant final approval of human participant research projects involving recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins until the project has been reviewed and approved by the Institutional Biosafety Committee (IBC).

The IBC shall review all human participant research involving recombinant or synthetic nucleic acid molecules (recombinant DNA), gene transfer, microorganisms, viruses, or biological toxins. The IBC review shall include a scientific review and determination on whether research projects involving recombinant DNA activities meet the requirements of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and other health and safety guidelines. All projects involving gene transfer shall also be reviewed by the National Institutes of Health Recombinant DNA Advisory Committee (RAC), which serves a critical role in the oversight of federally funded research involving recombinant DNA. The RAC review process is to be initiated by the sponsoring entity, and if such a review has not been initiated prior to adding the University of Oklahoma as a clinical trial site, the University must initiate this process.

Specific Policies

1.1 Committee Interaction

Reciprocal communication on a regular basis between the IRB and the IBC is essential in order for the IRB to fulfill its functions relative to human participant research. The IRB shall notify the IBC when an IRB application is received involving recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins. The IBC shall notify the IRB of its decision regarding approval of human participant research projects using recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins.

If the IRB reviews the research project before the IBC, the IBC may invite a representative from the IRB that reviewed the research project to the corresponding IBC meeting. If the IBC reviews the research project before the IRB, the IRB may invite a representative of the IBC to attend the corresponding IRB meeting.

Any modification to the protocol, informed consent documents, or personnel or other significant change during or after the review process shall be reviewed and approved by both the IRB and IBC before the research project modification is initiated.

2. SCOPE

This SOP applies to all human participant research that involves the use of recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins.

3. RESPONSIBILITY

3.1 The investigator is responsible for submission of human participant research projects that involve the use of recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins to the IBC.

3.2 The IRB and IBC independently review the research project and may do so concurrently. The IRB Administrator is responsible for verifying IBC approval or review before assigning the research project to the IRB Chair or IRB designee for final approval by the IRB. The IRB Administrator is responsible for obtaining documentation of IBC approval before finalizing the IRB approval.
4. APPLICABLE REGULATIONS AND GUIDELINES
   NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

5. REFERENCES TO OTHER APPLICABLE SOPS
   SOP 301: Research Submission Requirements
   SOP 302: Administrative and Distribution of Materials
   SOP 401: Research Exempt from Federal Regulations
   SOP 402: Expedited Review
   SOP 403: Initial Review – Criteria for IRB Approval

6. ATTACHMENTS
   602F-A  Institutional Biosafety Approval letter

7. PROCESS OVERVIEW
   7.1 The investigator shall submit all research projects that involve recombinant DNA, gene transfer, microorganisms, viruses, or biological toxins to the IBC for review.
   7.2 Upon approval, the IBC shall issue an approval letter to the investigator and shall forward the letter to the IRB.
   7.3 The investigator shall submit the research project to the IRB. The IRB Administrator shall review the documents per SOP 301: Research Submission Requirements; and SOP 302: Administrative Review and Distribution of Materials. The IRB Administrator shall initiate communication between the IRB Administrator or IRB Chair or IRB designee and the investigator if IBC review is indicated.
   7.4 Review of the research project by the IRB shall be accomplished per applicable SOP 401: Research Exempt from IRB Review; SOP 402: Expedited Review; or SOP 403: Initial Review – Criteria for IRB Approval.
   7.5 The IRB Administrator shall verify IBC approval before forwarding the research project to the IRB Chair or IRB designee for final approval by the IRB.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020