Title: Biohazard and Biosafety Review

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REVISION HISTORY

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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for coordination between the Institution Review Board (IRB) and the Institutional Biosafety Committee (IBC)/Biosafety Officer.

SCOPE

This SOP delineates systematic process activities and functions for compliance with the US Department of Health and Human Service, Office for Human Research Protections (OHRP) and Common Rule requirements, and University of North Texas (UNT) requirements for the management, coordination, and operation of the Institutional Review Board program. It applies to all staff members whom are engaged in the operations and support of the Institutional Review Board, and to all UNT Researchers performing human subjects research.

DEFINITIONS/ ABBREVIATIONS

1. Definitions

1.1 Biohazards: Any microorganism (including, but not limited to, bacteria and their phages and plasmids, viruses, fungi, mycoplasmas, rickettsia, protozoa, parasites, or prions) or infectious substance; human and non-human primate tissues, body fluids, blood, blood byproducts, and cell lines; animal remains and insects that may harbor zoonotic pathogens; or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, animal, plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment. Biohazards are often referred to as infectious agents or
etoiological agents.

1.2 *Institutional Biosafety Committee:* The committee responsible for the oversight of all research and teaching activities involving potentially hazardous biological materials, biohazards, and recombinant or synthetic DNA. The objectives of this program are to: (1) Protect individuals, research animals, facilities, and the community from exposure to pathogens, tissues, or fluids of biological origin, genetic therapy products, transgenic genes, bacteria, viruses, prions, or biological toxins that may affect health and safety; and (2) Assuring that UNT is in compliance with applicable state and federal regulatory biosafety and biosecurity requirements, e.g., rDNA research described in the NIH Guidelines for Research Involving Recombinant DNA Molecules, NIH Guidelines.

1.3 *IRB Analyst:* Staff member of Research Integrity and Compliance that performs administrative activities, pre-reviews, reviews, and approvals for the Institutional Review Board program.

1.4 *Principal Investigator:* The individual who is actively leading and/or supervising the initiation, execution, and completion of a research project in compliance with applicable laws, regulations, and institutional policy governing the conduct of research. It is ultimately the PI’s responsibility to ensure that all personnel actively working on the project and interacting with human subjects are following the guidelines of the approved protocol and are treating subjects in a manner befitting ethical use of human subjects. The PI should be the party responsible for submitting the research protocol, providing the RIC or the IRB with requested changes in order to garner approval, and for following the guidelines stipulated for annual review of the protocol and submission of any modification requests.

1.5 *Researcher:* Any individual performing various tasks related to the conduct of human subjects research activities, including but not limited to obtaining informed consent from subjects, collecting and analyzing data, interacting with subjects, and communicating with the IRB.

2. **Abbreviations**
   2.1 IBC- Institutional Biosafety Committee
   2.2 IRB- Institutional Review Board
   2.3 OHRP- Office for Human Research Protections
   2.4 PI- Principal Investigator
   2.5 RIC- Research Integrity and Compliance
   2.6 SOP/SOPs - Standard Operating Procedure(s)

**RESPONSIBILITIES**
This SOP is applicable to all members of Research Integrity and Compliance and Institutional Review Board members who are involved in record keeping, reviewing, or approving research studies for the Institutional Review Board program. This SOP is also applicable to all UNT Researchers performing human subjects research under the oversight of the UNT Institutional Review Board.

**PROCEDURE**
1. **IRB Submissions**
   1.1 University of North Texas Researchers are responsible for following the Biological Safety Manual process as developed and managed by the University of North Texas Risk Management Services.
   1.1.1 This includes, but is not limited to, obtaining Institutional Biosafety Committee (IBC) approval or Biosafety Officer Review of study
protocols prior to initiating or modifying any research involving the use of biohazards.

1.1.2 Maintaining IBC approval throughout the conduct of a study involving the use of biohazards.

1.2 Upon initial submission and modification, the Principal Investigator is required to provide verification that the Biological Safety Manual is being followed by including correspondence with the Biosafety Officer or IBC approval letters with any submission of the study protocol for IRB review.

1.2.1 The Principal Investigator is ultimately responsible for directly contacting the Biosafety Officer, by emailing biosafety@unt.edu, for this correspondence.

1.3 The Principal Investigator is responsible for ensuring any correspondence with the Biosafety Officer or IBC approval letters on file with the IRB is up to date.

1.3.1 If new correspondence or approval related to study conduct is received by a Researcher from the Biosafety Officer or IBC, the Principal Investigator is responsible for submitting this material to the IRB through a study modification in the IRB electronic submission portal.

1.4 If the IRB Analyst or IRB committee member receives an IRB submission, which in their judgement may require biosafety review:

1.4.1 The IRB Analyst or IRB committee member may contact the Biosafety Officer for assistance in determining if biosafety review is required.

1.4.2 The IRB Analyst or IRB committee member may request that the Principal Investigator initiate contact with the Biosafety Officer and provide verification that the Biological Safety Manual is being followed.

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
2. 45CFR46
3. Food and Drug Administration (FDA) regulations
5. 21 CFR 50
6. 21 CFR 56
7. 21 CFR 312
8. 21 CFR 600
9. 21 CFR 812
10. DoD Regulations
11. Texas Family Code Section 261.101
12. UNT Policy 13.004