UNT DIVISION OF RESEARCH & INNOVATION Research Integrity & Compliance	**Institutional Review Board Standard Operating Procedures**

Title: Radiation Safety Review

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Approval/Date:

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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 Radiation and Laser Safety program.

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

1.2 LASER: An acronym for Light Amplification by Stimulated Emission of Radiation. Light can be produced by atomic processes, which generate laser light. The laser safety program establishes requirements for protection against all classes of laser radiation and intense-pulsed light (IPL) device hazards according to the TDSHS regulations. Class IIIB and Class IV lasers must be registered with the Radiation Safety Office prior to

acquisition.

1.3 *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.

1.4 Radiation Producing Device: A radiation producing device is any equipment that produces or contains sources of ionizing radiation. This equipment may be used in the disciplines of the healing arts—medicine, dental or veterinary, or non-healing arts—education or research. This device contains a sealed source of radiation or an X-ray producing vacuum tube or housing. Ionizing radiation producing devices are regulated by TDSHS and UNT operates its device-produced ionizing radiation safety program according to TDSHS regulations and UNT's Radiation Safety Manual.

1.5 *Radiation Safety Committee*: The committee responsible for the oversight of all research and teaching activities involving radioactive materials and radiation producing devices.

1.6 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 IRB: Institutional Review Board
2.2 OHRP: Office for Human Research Protections
2.3 PI: Principal Investigator
2.4 RIC: Research Integrity and Compliance
2.5 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 Radiation 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 Radiation Safety Committee approval or Radiation Safety Officer review of study protocols prior to initiating or modifying any research involving the use of Radiation Producing Devices or LASERS.

1.1.2 Maintaining radiation safety approval throughout the conduct of a study involving the use of Radiation Producing Devices or LASERS.

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

1.2.1 The Principal Investigator is responsible for directly contacting the Radiation Safety Officer, by emailing the radiation safety officer, for this correspondence.

1.3 The Principal Investigator is responsible for ensuring any correspondence with the Radiation Safety Officer or Radiation Safety Committee 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 Radiation Safety Officer or Radiation Safety Committee, 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 radiation safety review:

1.4.1 The IRB Analyst or IRB committee member may contact the Radiation Safety Officer or Radiation Safety Committee for assistance in determining if radiation safety review is required.

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

REFERENCES

1. US Department of Health and Human Service, Office for Human Research Protections (OHRP)
2. 45 CFR 46
3. Food and Drug Administration (FDA) regulations
4. UNT Policy 13.004
5. UNT Radiation Safety Manual