



TEXAS TECH UNIVERSITY HEALTH SCIENCES CENTER

Operating Policy and Procedure

HSC OP: 73.08, **Requirements for Principal Investigator Status**

PURPOSE: The purpose of this Health Sciences Center Operating Policy and Procedure (HSC OP) is to define the criteria for principal investigator status for all research projects, sponsored programs, or grants to be conducted at TTUHSC.

REVIEW: This HSC OP will be reviewed on September 1 of every odd-numbered year (ONLY) by the Associate Vice President for Sponsored Programs and the Associate Vice President for Research Integrity, with recommendations for revisions forwarded to the Senior Vice President for Research & Innovation (SVPRI) by October 15.

POLICY/PROCEDURE:

"Principal Investigator" (PI) means the individual identified by TTUHSC to have the appropriate level of authority and responsibility to direct a research project program or grant and who is responsible for the scientific and technical direction, and all compliance requirements for a research project, sponsored program or grant.

1. **Background and Rationale:** Because a significant degree of authority and responsibility are vested in the PI, specific criteria are required for one to attain this status. Only PIs are permitted to submit applications to the Office of Sponsored Programs, and apply for research privileges and licenses or approvals through the Institutional Review Board, Institutional Animal and Care Use Committee, Radiation Safety Committee, and Institutional Biosafety Committee.

2. **Requirements:** The PI must have the requisite training, expertise and resources, as well as approval from the appropriate compliance committees for the proposed research. For example, a full-time faculty member may not be granted permission to work with select agents or radioactive materials unless specific training is documented. Similarly, a full-time faculty proposing to conduct clinical research using human subjects or animals must also comply with the responsibilities set out in the IRB or IACUC policies and procedures manuals available on the TTUHSC home page.

a. A TTUHSC PI must be a full-time (greater than 50%) employee of TTUHSC (compensated) with one of the following faculty appointments:

Professor
Associate Professor
Assistant Professor
Research Professor
Research Associate Professor
Research Assistant Professor
Research Instructor

b. Or, for research studies that (1) qualify as *minimal risk* or *exempt* under federal Human Subject Research regulations, including 45 CFR 46 as applicable, (2) are not externally funded clinical research (e.g., industry-sponsored clinical trials), and (3) do not fall under FDA regulation, a TTUHSC PI must be Core Faculty as defined by the ACGME with one of the following clinical appointments:

Clinical Assistant Professor;
Clinical Associate Professor; or
Clinical Professor.

In addition, if the PI holds one of the above clinical appointments which is uncompensated or less than full-time at TTUHSC they must (1) have an appointment letter from TTUHSC School of Medicine which specifically states their ability to act as PI and (2) be a practicing physician appropriately licensed in the State of Texas and credentialed to practice facility-based services (i.e., emergency medicine, radiology, or hospitalist services) at Lubbock County Hospital District (dba UMC).

- c. Persons who do not meet the requirements for PI status may request an exception by submitting a “Request for Exceptions to Requirements for Principal Investigator Status” to the Assistant Vice President for Research Integrity on [Attachment A](#).
- i. Students and Postdoctoral Fellows may submit proposals for research projects, programs or grants with the primary function to support the training of the applicant. Students and postdoctoral fellows submitting these types of proposals must submit **Attachment A** to identify a sponsoring Principal Investigator who meets the requirements above, and who will assume budgetary and reporting responsibilities at the institutional level. Only the signature of the Sponsoring PI is required in these situations.
 - ii. Exceptions will be reviewed by the applicant’s Department Chair, a Sponsoring Principal Investigator, and Dean, with final approval at the discretion of the Assistant Vice President for Research Integrity.
 - iii. In no case will an exception be granted for requests to conduct externally funded clinical research (for example, industry-sponsored clinical trials) or projects involving human subjects which are deemed greater than minimal risk (as defined in 45 CFR 46.102(i) and 21 CFR 50.3(k).