**Office of Clinical Research (OCR)**

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| Effective: May 27, 2021 | Revised: N/A | Revision: 0 |
| Responsibility: OCR | | Page 1 of 3 |
| Policy 1.8.1 | | |

## RESEARCH SCOPE OF PRACTICE FOR STUDY PERSONNEL

1. PURPOSE: This policy provides procedures for the approval of the designated roles and responsibilities for research personnel engaged in research involving human subjects at the University of Texas Health Science Center at San Antonio (UT Health San Antonio). The Research Scope of Practice (RScOP) for Study Personnel is not protocol specific and does not expire but must be reviewed on a regular basis and include the duties required for all studies in which the individual is engaged in research. This component of the UT Health San Antonio Human Research Protection Program is designed to ensure that research personnel are qualified to conduct the research.

2. POLICY: Research personnel involved in human subject research at UT Health San Antonio receive approval for their participation through the Office of Clinical Research (OCR).

   Approval to participate in human subject research is limited to the roles, activities and responsibilities identified and documented on the RScOP form located on the VPR website.

   Personnel may work only in the roles and responsibilities that are appropriate to their individual level of training, specific license, credentials.

   - Non-licensed research personnel may not be trained to do procedures that require a medical license.
   - Non-licensed researchers with degrees, e.g., MD, DO, BSN, MSN, without licensure, are not allowed to perform duties and procedures that would require licensure and/or consent of the patient in a standard patient care setting (non-research).

   UT Health San Antonio research personnel may not interact or intervene with living individuals in a non-exempt human subject research protocol until all requirements of this policy are met, including an approved RScOP form.

   The RScOP form will be required for the following UT Health San Antonio personnel who are interacting or intervening with living individuals for non-exempt human subject research:

   - Students
   - Residents
   - Fellows

- Non-licensed MD's
- Other Non-Licensed professionals/personnel*

*This includes all research staff, including but not limited to Principal Investigators (PI), sub-investigators, research coordinators, and research assistants who do not hold an active license that can be verified.

RScOP is not required for licensed personnel who are conducting research activities within the limits of their license and approved clinical privileges, if applicable. Licensed research personnel may not be trained to do procedures outside of those allowed under their respective license that would require licensure and/or consent of the patient in the standard patient care setting (non-research).

Non- UT Health San Antonio research personnel will be reviewed on a case-by-case basis by the OCR Director or his/her designee.

Non-licensed physicians may not display their degree (i.e. MD) in any way that would convey to the research participant or personnel that he/she is a licensed practicing clinician, to include institutional Review Board approved study information given to research participants (e.g. consents, personnel contact lists).

3. RESPONSIBILITY: The supervisor and/or supervising investigator, as applicable, is responsible for verifying qualifications and competencies of research personnel to perform the roles and responsibilities identified on the RScOP form.

   When a new protocol is submitted for approval or when a previously approved protocol is submitted for continuing review or modification, the PI is responsible for verifying that the approved RScOP on file with OCR contains all the routine duties with respect to the study. If there have been changes relative to the assigned duties and/or approved RScOP, the PI must submit an updated RScOP prior to the individual conducting the research related activities.

   In the case of foreign national personnel, the Office of International Services (OIS) is responsible for reviewing RScOP prior to approval by the OCR Director or his/her designee.

   The OCR Director or his/her designee is responsible for final review and approval of each RScOP.

4. PROCEDURE: A RScOP form is required to be sent to the OCR when the following occur:

a. An individual is first added to a protocol(s),
b. The duties of an individual are modified, or
c. There is a change in the employee's supervisor or supervising investigator.

Research personnel engaged in human subject research at UT Health San Antonio must submit the RScOP form. OCR staff reviews and processes the RSCOP for electronic signature through DocuSign. The supervisor and/or supervising investigator signs and initials for competency verification attesting to each delegated duty and the OCR Director or his/her designee provides final signature for approval. DocuSign provides the employee, supervisor and/or supervising investigator, a signed copy of the approved RScOP automatically.

The OCR Director or his/her designee, may contact the PI, supervisor and/or supervising investigator to discuss any questions regarding personnel qualifications or propose any changes to delegated duties.