

**HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES**

Chapter 7	Research and Sponsored Programs	Effective:	May 2008
Section 7.2	Human Research Protection Program	Revised:	
<b>Policy 7.2.3</b>	<b>Research Scope of Practice for Study Personnel</b>	Responsibility:	Vice President for Research

## RESEARCH SCOPE OF PRACTICE FOR STUDY PERSONNEL

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### Overview

This policy provides procedures for the approval of the designated roles and responsibilities for research personnel engaged in human subjects research at The University of Texas Health Science Center at San Antonio (Health Science Center). The scope of practice is not protocol specific. It is intended to state the overall duties that research personnel are allowed to perform. This component of the Health Science Center Human Research Protection Program is designed to ensure that research personnel are qualified to conduct the research.

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### Policy

All individuals involved in human subject research at the Health Science Center receive approval for the participation through the Office of Clinical Research. This includes research staff who interact directly with human subjects and research staff who interact with individually identifiable human subject information.

One of the requirements for approval is having an approved [Scope of Practice for Research Personnel](#) form that specifically defines the roles and responsibilities in research activities. Personnel may work only in the roles and responsibilities, as defined by the approved [Scope of Practice for Research Personnel](#) form, that are appropriate to the personnel's level of training, specific license, and clinical credentials.

- 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 non-research patient care setting. Unlicensed research personnel may not be trained to do procedures that require a medical license.
- Non-licensed research personnel, including individuals who have an MD, DO, BSN, MSN, degree without licensure, are not allowed to perform duties and procedures that would require licensure and/or consent of the patient in a standard (non-research) patient care setting.

New Health Science Center research personnel may not participate in a research protocol until all requirements of this policy are met, including an

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approved [Scope of Practice for Research Personnel](#) form.

Health Science Center personnel listed below are expected to comply with this policy:

- Research fellows (non-ACGME) working as research coordinators, project coordinators, or research assistants.
- Research coordinators, project coordinators and other unlicensed personnel.
- Research nurses, nurse practitioners, physician assistants, psychologists, podiatrists, optometrists, etc.

Unlicensed research personnel working as research coordinators or research fellows (excluding those in an ACGME approved program) may obtain informed consent if competency is verified on the [Scope of Practice for Research Personnel](#) form. However, they may not use their educational degree after their signature on Institutional Review Board (IRB) approved consent forms or on research staff contact lists. Unlicensed research personnel also may not display their educational degree (e.g. MD, RN, etc. on a name badge) in any way that would convey to the research participant or staff that he/she is a licensed practicing clinician.

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## **Responsibility**

The Office of Clinical Research will provide required forms and instructions for completing the [Scope of Practice for Research Personnel](#) form, provide the employee and the respective Principal Investigator (PI) a copy of the approved [Scope of Practice for Research Personnel](#) form or notification if the scope is not approved, maintain a copy, and notify the PI when the two-year review is required.

The research employee/staff and PI will complete the [Scope of Practice for Research Personnel](#) form. The PI must verify the employee's competency to perform the roles and responsibilities identified on the [Scope of Practice for Research Personnel](#) form.

The [Scope of Practice for Research Personnel](#) form must be reviewed and approved by the Assistant Vice President for Research Operations

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and the appropriate Dean of Associate Dean for Research of the appropriate School.

The IRB will require the PI to verify that all of the research staff on a protocol have a current approved [Scope of Practice for Research Personnel](#) form at initial approval and on the continuing review progress report for each protocol.

**Educational Requirements**

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All individuals involved in human subjects research at Health Science Center complete the human subject protection education requirement of the IRB using the Collaborative IRB Training Initiative (CITI) course.

All individuals engaged in research with human subjects (clinical trials, epidemiologic research, socio-behavioral research) must also complete the “Conducting Clinical Research” course offered by the Office of Clinical Research, or an alternate course approved by the Office of Clinical Research. (Society of Clinical Research Associates (SOCRA), Association of Clinical Research Professionals (ACRP), Food and Drug Administration (FDA) sponsored Good Clinical Practice (GCP)) within six months of the [Scope of Practice for Research Personnel](#) form approval.

**Procedure**

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PIs must complete and submit the [Scope of Practice for Research Personnel](#) form to the Office of Clinical Research when the individual is first employed by the Health Science Center, whenever the duties must be modified, and when notified that the two-year review is required. PIs adding a current Health Science Center employee to their research protocol must review and retain a copy of the employee’s [Scope of Practice for Research Personnel](#) form. A revised [Scope of Practice for Research Personnel](#) form should be submitted if modifications are needed to cover duties on a new protocol.

The Assistant Vice President for Research Operations and the Dean or Associate Dean for Research of the respective school will review the [Scope of Practice for Research Personnel](#) form and concur if the requested roles and responsibilities are appropriate.

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The Office of Clinical Research will provide the employee and the respective PI with a copy of the approved [Scope of Practice for Research Personnel](#) form or notification of disapproval if the scope could not be approved as submitted.

Research personnel engaged in research at the Health Science Center should submit the [Scope of Practice for Research Personnel](#) form to the Office of Clinical Research and the respective clinical research office of an affiliate institution if required by that institution (e.g., South Texas Veterans Health Care System, University Healthcare System).

**Applicability**

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This policy applies to the School of Medicine, School of Nursing, and School of Health Professions.

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