

Office of Clinical Research (OCR)

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INSTITUTIONAL REVIEW POLICY AND PROCEDURE

1. **PURPOSE:** This policy establishes the process and procedures for obtaining approval to activate research that engages the University of Texas Health Science Center at San Antonio (UTHSCSA) in human subjects research.
2. **POLICY:** The Office of Clinical Research (OCR) reviews all human subjects research projects submitted to Research Regulatory Programs for institutional requirements.
 - A. Research that meets **ANY** of the following criteria may not be conducted without obtaining approval to activate research at UTHSCSA:
 - (1) Research associated with a grant or contract administered by the Office of Sponsored Programs (OSP) at UTHSCSA; or
 - (2) Research conducted by or under the direction of any UTHSCSA salaried employees, volunteers, students, or those who have a signed Individual Investigator Agreement (IIA).
 - B. Research that meets **ALL** of the following criteria does not require UTHSCSA institutional review:
 - (1) Research in which UTHSCSA is not administering funding; and
 - (2) Research conducted solely by non-UTHSCSA employees.
 - C. The Office of Clinical Research (OCR) does not review non-human or non-regulated research submissions.
3. **RESPONSIBILITY:**
 - A. Principal Investigator (PI) – Ensures research is not conducted prior to receiving institutional approval from OCR.
 - B. Office of Clinical Research (OCR) – Reviews all research projects that involve human subjects for institutional requirements and coordination with appropriate departments and affiliates.
4. **PROCEDURES:**
 - A. The OCR reviews the institutional research application form and supporting documents for all initial research projects submitted to Research Regulatory Programs that involve human subjects for institutional requirements and coordination with appropriate departments and affiliate institutions.
 - (1) Coordination with appropriate departments and affiliate institutions:

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- a. Affiliate institutions (e.g. UHS, VA) and/or Clinical Research Units (i.e. FORU, BRU) are notified of research projects when their resources are being utilized.
 - b. The Clinical Trials Office (CTO) is notified of research projects identified with a possible billing risk or participant payments.
- (2) Initial review of institutional requirements:
- a. The OCR relies on UT medicine and department processes to ensure appropriate credentialing for licensed UTHSCSA personnel. Licensed Practitioner's, with a medical or other advanced degree, are verified by the UT medicine credentialing staff. Verification of credentials for nurses providing clinical care in a research setting are verified by the appropriate department.
 - b. The OCR staff review all UTHSCSA personnel listed on the Research Application, Inst M or B-2 form (or similar) and ensure that each individual has appropriate experience and training consistent with the roles/duties approved by the IRB and the Research Scope of Practice (RScOP), if required. Further details regarding training and RScOP requirements are listed on the OCR website: <http://research.uthscsa.edu/ocr/training.shtml>. When reviewing requests for changes in personnel, the change of personnel will be reviewed in conjunction with the IRB through the IRB amendment process if the roles/duties are modified or the change in personnel affect any of the IRB documents (e.g. informed consent document).
 - c. The OCR staff ensure all research personnel engaged in research at UTHSCSA complete appropriate education in human subjects training [see Research Ethics Education Policy and Procedure].
 - d. The OCR staff review personnel for appropriate credentialing, experience and training as described in 5.A.(2)a.-c. above. If personnel have not met all requirements at the time of a new submission, they will be removed from the study and added at a later date when completed. If the principal investigator or individual assigned to a specialized role have not met all requirements, institutional activation will not be granted until completed. If personnel have not met all requirements at the time of a personnel change request, they will not be added to the study and added at a later date when completed.
 - e. The OCR staff ensures appropriate documentation from all institutional committees [i.e. the Radiation Safety Committee, Radioactive Drug Research Committee, Institutional Biosafety Committee, CTRC Protocol Review Committee (PRC), or Texas Dept. of Family and Protective Services], as applicable.

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- f. The OCR staff ensures that research projects with drug or device storage outside a hospital or CTRC pharmacy have an OCR approved storage location according to the OCR policy “Storage and Control of Investigational Drugs and Devices for Clinical Research.”
 - g. The OCR staff identifies clinical trials under review which are subject to federal rules requiring registration and NCT ID numbers in clinicaltrials.gov. OCR staff additionally assists and assures compliance and ongoing maintenance of registrations, to include results reporting, where applicable. (see [ClinicalTrials.gov Policy](#))
 - h. The OCR staff identifies new research where the PI is acting as a sponsor-investigator in an FDA regulated study and works with the PI to ensure all applicable FDA requirements (record keeping, monitoring, storage, accountability, etc.) are met for investigators who hold an IND and/or IDE (see [Sponsor Investigator Policy](#)).
 - i. For studies in which UTHSCSA relies on another IRB through an existing or new IRB reliance agreement, OCR staff review the research protocol and informed consent document for local regulatory issues and state or local laws that must be addressed. When protocols present conflict with state or local laws, OCR staff will comply with those laws or coordinate with Compliance, Legal, or other authorities for counsel and resolution, where possible,
- B. The OCR can approve institutional activation of a research project when all institutional requirements have been met (see paragraph 5.A.(2)), IRB approval has been received, and CTO has cleared the project.
 - C. Changes affecting any institutional requirements for external IRB studies must be submitted for review and approval by the OCR.
5. REFERENCES:
- A. Definitions ([see Glossary](#))