

Office of Clinical Research (OCR)

Effective: December 31, 2014	Revised: September 24, 2020	Revision: 12
Responsibility: OCR		Page 1 of 6
Policy 1.4.1		

INSTITUTIONAL REVIEW POLICY AND PROCEDURE

1. **PURPOSE:** This policy establishes the process and procedures for institutional review for human subject research engaging UT Health San Antonio (also known as The University of Texas Health Science Center at San Antonio).
2. **POLICY:**
 - A. An institutional activation letter is required from UT Health San Antonio (UTHSA) prior to conducting research activities when UT Health San Antonio is [engaged](#) in human subjects research whether the research is under UTHSA IRB review or external IRB review. A record is created and maintained for all submissions to UT Health San Antonio regardless of whether the research is under local IRB review or external IRB review (see [Recordkeeping Policy and Procedure](#)).
 - B. All personnel changes must be reviewed and accepted by OCR for appropriate credentialing, experience and training as described in 4.A.(2)a.-c. below. Changes to affiliate personnel are routed through the affiliate research office(s) prior to approval (see [Coordination Policy and Procedure](#)).
 - C. All changes affecting any institutional requirements for external IRB studies must be reviewed and accepted by OCR using the [Modification Request Form](#) as applicable (see [Modifications and Amendments Policy and Procedure](#)).
 - D. The Office of Clinical Research (OCR) does not review non-human, non-regulated research, HUD/HDEs or emergency use 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

Office of Clinical Research (OCR)

Effective: December 31, 2014	Revised: September 24, 2020	Revision: 12
Responsibility: OCR		Page 2 of 6
Policy 1.4.1		

affiliate institutions consistent with the [Receiving, Routing, and Administrative Review of IRB Submissions Policy and Procedure](#).

(1) Coordination with appropriate departments and affiliate institutions:

- 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.
- c. If UT Health San Antonio is not [engaged](#) in human subjects research, institutional activation is not required. The OCR review is complete after all coordination activities with appropriate departments and affiliate institutions are finalized.

(2) Initial Review of institutional requirements:

- a. The OCR relies on UT medicine and department processes to ensure appropriate credentialing for licensed UT Health 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 UT Health San Antonio 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. 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. All UT employees are required by the university to complete initial and continuing education for HIPAA privacy and security regulations. The Institution has policies and practices in place to enforce and ensure that this training is completed. Training for non-UT Health employees (e.g. students) is verified by the OCR staff.
- d. The OCR staff ensure all research personnel engaged in research at UT Health San Antonio complete appropriate education in human subjects training [see Research Ethics Education Policy and Procedure].

Office of Clinical Research (OCR)

Effective: December 31, 2014	Revised: September 24, 2020	Revision: 12
Responsibility: OCR		Page 3 of 6
Policy 1.4.1		

- e. The OCR staff review personnel for appropriate credentialing, experience and training as described in 4.A.(2)a.-d. 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.
- f. The OCR staff ensures appropriate documentation from all institutional committees [i.e. the Radiation Safety Committee, Radioactive Drug Research Committee, Institutional Biosafety Committee, Mays Cancer Center Protocol Review Committee (PRC), Texas Dept. of Family and Protective Services, or Patient Data Governance Committee (PDGC)] or agencies (e.g. NIH for Genomic Data Sharing Policy or Certificates of Confidentiality), as applicable (see [Coordination with other Committees or Offices Policy and Procedure](#)).
- g. The OCR staff ensures that research projects with drug or device storage outside a hospital, commercial or Investigational Drug Section of the Mays Cancer Center have an OCR approved storage location (see [Storage and Control of Investigational Drugs and Devices for Clinical Research Policy](#)).
- h. The OCR staff identifies clinical trials 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 and posting of clinical trial consent form, where applicable (see [ClinicalTrials.gov Policy](#)).
- i. 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](#)).
- j. For studies in which UT Health San Antonio relies on another IRB through an existing or new IRB reliance agreement (see [Cooperative Research Policy and Procedure](#)), OCR staff provide pre-submission consultation for the relying investigator and/or their research staff ensuring that the relying investigator understands his/her responsibilities. 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

Office of Clinical Research (OCR)

Effective: December 31, 2014	Revised: September 24, 2020	Revision: 12
Responsibility: OCR		Page 4 of 6
Policy 1.4.1		

other authorities for counsel and resolution, where possible. Institutional and protocol specific information is provided to the IRB on the Single IRB Protocol Specific Form or UT Health San Antonio Institutional Profile form (or similar). An IRB approved communication plan will be obtained for investigator initiated multi-site studies and any other studies, where applicable.

- k. The OCR staff ensures that fully executed agreements (e.g. CTA, DUA) have been processed through the Office of Sponsored Programs. A clinical trial agreement (CTA) for clinical trials with a billing risk are verified by the Clinical Trials Office.

- B. The OCR can approve institutional activation of a research project when all institutional requirements have been met (see paragraph 4.A.(2)), IRB approval has been received, and CTO has cleared the project.

- C. Investigators may not initiate any changes in study personnel without prior OCR review and approval (see [Modifications and Amendments Policy](#)). When reviewing requests for changes in personnel, OCR reviews the change of personnel 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).

- D. Investigators may not initiate any institutional changes for external or UTHSA IRB studies without prior OCR review and approval (see [Modifications and Amendments Policy](#)).

- E. Prompt reports submitted for issues sensitive to the institution are reviewed by OCR for appropriate actions and coordination with applicable UTHSA offices. OCR also provides institutional follow-up as needed after an IRB determination for a possible noncompliance or a possible UPIRSO (see [Noncompliance Policy and Procedure](#) and [UPIRSO and UADE Policy and Procedure](#)). Reporting to AAHRPP will occur as soon as possible but generally within 48 hours after becoming aware of:
 - a) Any negative actions by a government oversight office including, but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions placed on IRBs or Investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
 - b) Any litigation, arbitration, or settlements initiated related to human research protections.
 - c) Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Organization's HRPP.

Office of Clinical Research (OCR)

Effective: December 31, 2014	Revised: September 24, 2020	Revision: 12
Responsibility: OCR		Page 5 of 6
Policy 1.4.1		

F. An unanticipated problem, a determination of serious or continuing non-compliance, or a suspension or termination reported by a lead IRB for an external IRB study is reviewed by the IRB/OCR Director or designee to determine if further action is required by the institution according to the [Reporting Policy and Procedure](#). The IRB authorization agreement or corresponding documentation (e.g. Agreement Implementation Checklist and Documentation Tool) specifies whether the lead IRB or relying institution is required to report to external parties (e.g., regulatory and funding agencies, sponsors, and other oversight authorities).

G. Institutional Update

(1) The following type of studies will require an institutional update every 3 years:

- a. External IRB studies;
- b. UT IRB exempt studies with identifiable information; or
- c. UT IRB expedited or full board studies for which continuing review is not required

The institutional expiration date is based on the IRB approval or determination date. The principal investigator is notified of the institutional expiration date through the IRB approval or determination letter. The institutional expiration date may be sooner than 3 years for extenuating circumstances (e.g. end of academic program).

(2) Years 1 and 2, the PI receives an email reminder for study team responsibilities (e.g. IRB reporting requirements). Year 3, the PI receives an email reminder requesting an Institutional Project Update form for review and approval by OCR to extend the study or an Institutional Inactivation form or IRB Inactivation form to close the study. The Year 3 email reminder is sent approximately eight weeks and then four weeks prior to expiration. The OCR analyst reviews the Institutional Project Update form for compliance with institutional requirements (e.g. COI, scope of practice, clinicaltrials.gov) and updates internal databases with study information.

(3) For exempt studies with identifiable information and external IRB studies, an Institutional Inactivation form is processed by the OCR which closes the study with the institution. Institutional inactivation can only occur for external IRB studies after receiving an IRB inactivation letter from an external IRB. Institutional inactivation can only occur for exempt studies if:

- a. The identifiable data (and original data set) and key to any codes are permanently stored (archived) in a secure location, and

Office of Clinical Research (OCR)

Effective: December 31, 2014	Revised: September 24, 2020	Revision: 12
Responsibility: OCR		Page 6 of 6
Policy 1.4.1		

- b. A copy of the original data set (called a secondary data set) or specimens actively being analyzed are permanently de-identified (and there are no identifying links or codes to the de-identified data).

6. REFERENCES:

- A. Definitions (see [Glossary](#))