VPR Services Fact Sheet

Contents

Institution's Legal Name & Address

University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900
Other names by which the institution is known by: UT Health San Antonio

Office of Sponsored Programs (OSP)

Official Authorized to Sign Agreements (i.e., CDA or CTA):

Chris G. Green, CPA, Senior Director
Office of Sponsored Programs (OSP)
7703 Floyd Curl Drive, Mail Code 7828
San Antonio, Texas 78229-3900

OSP phone: (210) 567-2340
OSP mailstop code 7828
OSP zip code 78229-3900

OSP Contracts and Agreements Contacts

e-mail: Contracts@uthscsa.edu
Rachel (Rae) Schofield, Schofield@uthscsa.edu, (210) 567-2332
Elizabeth (Beth) Hooks, HooksE@uthscsa.edu, (210) 567-2333

Clinical Trials Office (CTO)

VPRCTO@uthscsa.edu

- The CTO reviews all clinical trials and is responsible for the Medicare Coverage Analysis, budget negotiation, participant payments and administering the Clinical Trial Management System (Velos eResearch).
- CTO coordinates review of agreements (e.g., CDA or CTA) between the sponsor and the Office of Sponsored Programs (OSP)

The Clinical Trials Office review will require the following steps to be completed before submission to the Local Review Board.

Clinical Trials Process Flow	Step 1:	Step 2:	Step 3:	Step 4:	Step 5:	Step 6:
	Protocol and Preliminary Budget Review	Sponsor Survey (Required to clarify study details)	Coverage Analysis	Affiliate Pricing Requests	Sponsor Budget Negotiation	Initial Release to Submit to IRB/OCR

CTO Director

Jason Bates, BatesJR@uthscsa.edu, (210) 562-6818

Navigator and Protocol Development Services

Karen Nijland

- ClinicalTrials@uthscsa.edu

Budget Service

Patricia Miranda

- VPRCTO@uthscsa.edu

Office of Clinical Research (OCR)

Manager: Brandie Otten, otten@uthscsa.edu, (210) 567-8251

- OCR provides institutional approval of research
- Coordinates use of external IRBs

Institutional Review Board (IRB)

Director: Wanda Quezada, CIP, quezadaw@uthscsa.edu, (210) 567-8252
Associate Director: Jeannette Watterson, Ph.D., watterson@uthscsa.edu, (210) 567-8205
Office of the IRB: Email: irb@uthscsa.edu, Phone: 210-567-8250
IRB Official Address: 7703 Floyd Curl Dr., MC7830, San Antonio, TX 78229-3900

- The UT Health San Antonio IRB has obtained a federalwide assurance (FWA) from the Department of Health and Human Services:
  - FWA00005928 – FWA Expiration: September 13, 2027

- The IRB review is guided by the ethical principles in the Belmont Report and will be reviewed and implemented in compliance with DHHS human subjects regulations, 45 CFR 46, Subparts A-D, FDA human subjects regulations under 21 CFR 50 and 56 and with good clinical practice (GCP) as adopted by FDA. See IRB Assurance Letter for more information.

- UT Health San Antonio's IRBs have been continuously accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2009. In order to maintain accreditation standards, AAHRPP conducts annual assessments and on-site reviews every 5 years of the human research protection program.

- UT Health San Antonio operates three internal IRBs that meet every three weeks. The IRB provides oversight for human research on behalf of UT Health San Antonio, University Health and STVHCS (VA).

  Each IRB is registered with the DHHS Office for Human Research Protections:
  - IRB00000553 (IRB1)
  - IRB00002691 (IRB2)
  - IRB00009608 (IRB4)

- The IRB provides oversight for approximately 1,200 active human research studies with a target turnaround time (submission to approval) of 21 calendar days for clinical trials and 15 calendar days for non-clinical trials.
  See the IRB meeting dates here: https://www.uthscsa.edu/vpr/services/events

IRB FAQs

Does your institution use (rely on) external IRBs?

UT Health San Antonio participates in the National IRB Reliance Initiative (SMART IRB), making it possible to defer approval to any of the 500+ participating IRBs (including commercial IRBs). Reliance on IRBs that do not participate in SMART IRB are handled on a case-by-case basis. Contact the Office of Clinical Research for more information.

Is there a public list of IRB members and their professions?

The IRB does not provide that information. The IRB procedures do not permit an IRB member with a conflicting interest in the research to participate in the discussion or vote. A copy of the IRB Assurance Letter can be provided to Sponsors.

Is there a review fee?

Initial and continuing review fees are charged to applicable studies.
See the current fee schedules here:
https://www.uthscsa.edu/sites/default/files/Services/forms/fees_pharma_forprofit.pdf

Has your institution been audited by a Regulatory Authority?

In 2020, the IRB was audited by the FDA, and the FDA found that the IRB adhered to the applicable FDA regulations governing the protection of human subjects.

Affiliate Hospitals

University Health (Bexar County Hospital)

Clinical Research Department, 210-743-6450, research@uhs-sa.com

- University Health is UT Health San Antonio's primary clinical and research partner. Research contracts and Clinical Trial Agreements are negotiated by UT Health San Antonio on behave of both institutions.

- University Health includes more than two dozen locations. University Health serves as the primary teaching facility for UT Health San Antonio and is a Level I trauma center and the region's only pediatric Level I trauma center. University Health is also home to the highest level neonatal intensive care unit and the region's only Joint Commission accredited Comprehensive Stroke Center. University Health offers advanced care for children and adults.
- University Health Pharmacy provides support for investigational drugs and is available 24/7.

Veterans Administration Audie Murphy Hospital

Also known as: South Texas Veteran's Health Care System (STVHCS)
R&D Service, (210) 617-5300 ext 18058

Foundation for Advancing Veteran's Health Research (FAVHR)

Coordinates all industry sponsored research on behalf of the STVHCS (VA)
FAVHR CEO, Michelle Trimble, (210) 617-5300 ext 15376, Michelle.Trimble@va.gov

Methodist Hospital

Clinical Trials Office, 210-575-4238
Sherri Shade
Sherri.shade@mhshealth.com

FAQs

What type of Institution is the site?

UT Health San Antonio is an academic health care institution.
UT Health Physicians is the faculty medical practice featuring more than 700 physicians and health care providers offering advanced services and technology. For a list of specialty practices go to:
https://www.uthscsa.edu/patient-care/physicians/specialty-practices

Does the site have Imaging Facility?

Yes – Clinical imaging can be performed at several locations of the UT Health San Antonio campus or University Health hospital and clinics.
In addition, UT Health San Antonio operates a research imaging facility (Research Imaging Institute – RII) capable of investigational and non-traditional imaging.

Does the site have a Clinical Laboratory?

Yes – The UT Health San Antonio Department of Pathology Laboratories is a CAP (College of American Pathologists) and CLIA (Clinical Laboratory Improvement Amendments) certified laboratory. Certificates of accreditation are renewed annually and available on the UT Health San Antonio Reference Laboratory website. The UT Health Clinical Laboratory offers a range of laboratory services, including multiple sites for blood draws. For a list of testing services offered, or to access the CAP and CLIA certificates, go to: https://pathology.uthscsa.edu/reference-labs/

Who reviews and approves clinical trial agreements (CTA), contracts, and confidentiality agreements (CDA)?

The Office of Sponsored Programs (OSP) negotiates agreements on behalf of UTHSCSA and UHS. Faculty and staff are not authorized to sign agreements unless they are first approved by OSP. Contracts@uthscsa.edu

Is the site affiliated with any Site Management Organizations (SMO)?

No

Do you have a Research Coordinator?

In addition to research staff working directly for the PI, UTHSCSA's FIRST Program manages a mobilized staffing pool of qualified workforce technicians, research assistants, and study coordinators who are trained in best practices for GCP and are credentialed in multiple institutions.

In addition, the VA's Foundation for Advancing Veteran's Health Research (FAVHR) operates a coordinator pool.

Do you have dedicated research space?

In addition to department or clinic space, UT Health San Antonio's FIRST Program also operates two Clinical Research Units (CRU) where research visits and procedures can be performed.

- Bartter Research Unit (BRU) is an Inpatient/Outpatient Adult unit located within the Bartter Center on Unit 7A in the STVHCS - VA hospital;
- FIRST-Outpatient Research Unit (FORU) is an Outpatient unit located on the first floor of the Medical Arts & Research Center (MARC).

Does your institution have an electronic (computerized) system used for collecting and storing Electronic Medical Records (EMR)?

Yes – insert Epic and Sunrise capability summary or information link; pending University Health and Epic Team responses

Does your institution have a 21 CFR Part 11 compliant system for e-signature?

Yes – UT Health San Antonio's DocuSign Enterprise License Agreement has CFR Part 11 Compliant Envelopes. There is a fee associated with the use of each envelope. DocuSign envelopes can be requested through UT Health San Antonio's My Service Center (Team Dynamix).

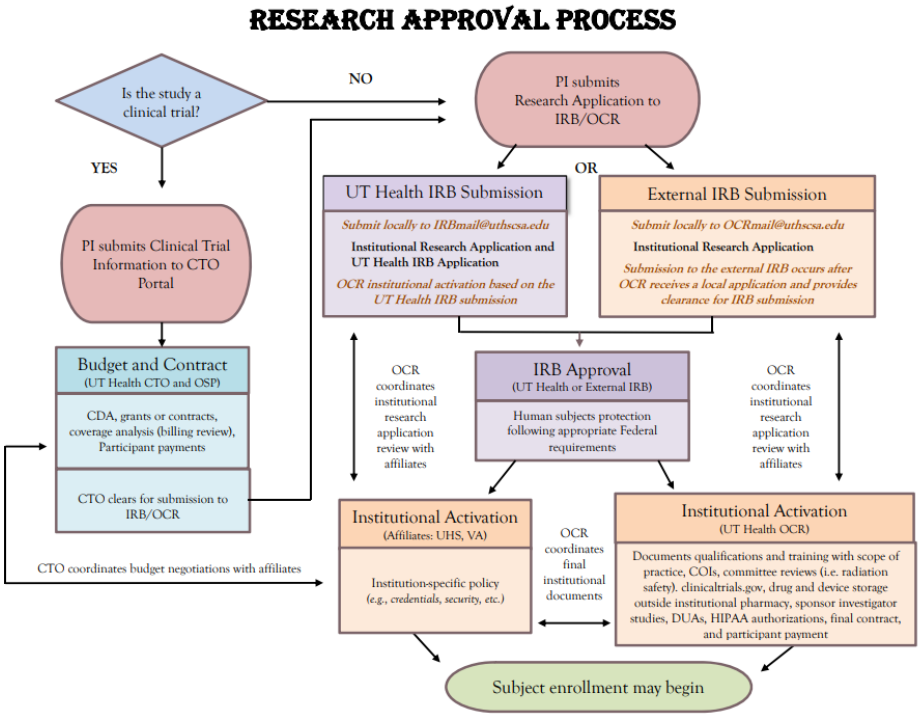
Are there additional approvals for using/installing computer applications or software?

Only licensed copies of computer software may be used on University computers. Information Technology approval through UT Health San Antonio's My Service Center (Team Dynamix) is required for electronic informed consent, use of a mobile application and for purchasing software applications.
https://www.uthscsa.edu/sites/default/files/Services/forms/infosec-faq.pdf

How are equipment rental/leases handled?

Equipment rental/leases are processed through the Purchasing Office unless under $5,000 and parts or supplies are not involved.

Research Approval Process



Clinical Trial Approval Process