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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.

|-----------------------------|-----------------------------------------------|--------------------------------------------------------|---------------------------|---------------------------------|----------------------------------------|------------------------------------------|

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

Navigator and Protocol Development Services
Brandi Weaver, WeaverB@uthscsa.edu, (210) 450-8827

Budget Service
Patricia Miranda, MirandaPR@uthscsa.edu, (210) 450-4057

Research Protection Programs
Director: Kimberly Summers, PharmD, summers@uthscsa.edu, (210) 567-8249

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)
Associate Director: Vacant

- UT Health San Antonio’s IRBs have been continuously accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2009.
- UTHealth San Antonio operates four IRBs and participates in the National IRB Reliance Initiative (SMART IRB) making it possible to defer approval or serve as the IRB of record to any of the 500+ participating IRBs
- The UT Health San Antonio’s IRB’s median “time to approval” is 28 calendar days.
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 behalf 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 any accreditations?
Yes - UT Health San Antonio’s IRBs have been continuously accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2009.

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

Does the site have an Institutional Review Board (IRB) or Ethics Committee?
Yes – operates four IRBs that oversee approximately 1,200 active human research studies on behalf of UT Health San Antonio, University Health and STVHCS (VA). The IRB meets every two weeks. The IRB turnaround time (submission to approval) is 21 calendar days for clinical trials and 15 calendar days for non-clinical trials (median). See the IRB dates here: https://www.uthscsa.edu/vpr/services/events

Does your institution use (rely on) external IRBs?
Yes, 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 IRB 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 the IRB constituted as per the ICH-GCP guidelines?
No – the IRB follows ICH-GCP as adopted by the US Food and Drug Administration (FDA).

Is there a public list of IRB members and their professions?
No – UT Health San Antonio does not provide that information. A letter documenting appropriate constitution of the IRB including the Federal Wide Assurance (FWA) number for the institution is available on the IRB website. https://www.uthscsa.edu/sites/default/files/Services/forms/assurance_letter.pdf

Is there a review fee?
Yes – 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
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

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

Only licensed copies of computer software may be used on University computers. Information Management & Services (IMS) approval 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

**RESEARCH APPROVAL PROCESS**

Is the study a clinical trial?

- **YES**
  - PI submits Clinical Trial Information to CTO Portal
  - Budget and Contract (UT Health CTO and OSP)
    - CDA, grants or contracts, conflict-of-interest (Form B)
    - Participant recruitment
    - CTO draft for submission to IRB/OCR
  - CTO coordinates budget negotiations with affiliates

- **NO**
  - PI submits Research Application to IRB/OCR
  - OR
  - UT Health IRB Submission
    - Institutional Research Application and UT Health IRB Application
    - OCR institutional activation based on the UT Health IRB submission
  - OR
  - External IRB Submission
    - Institutional Research Application
    - Submission to the external IRB occurs after OCR receives a local application and provides clearance for IRB submission

  - OCR coordinates institutional research application review with affiliates
  - IRB Approval
    - UT Health or External IRB
    - Human subjects protection following appropriate Federal requirements
  - OCR coordinates institutional research application review with affiliates

  - Institutional Activation
    - UT Health OCR
    - Institutional-specific policy (e.g., credentials, security, etc.)
    - OCR coordinates and institutional documents

  - Subject enrollment may begin