

INSTITUTIONAL PROFILE

SECTION 1: *This information should be provided to **potential reviewing IRBs** during the ceding process.*

1. Name of Institution: **UT Health San Antonio**
2. List all other names by which the institution is known by:
The University of Texas Health Science Center at San Antonio
UT Health San Antonio Cancer Center
3. Organizations that are considered components under UT Health San Antonio's FWA: **None**
4. Is UT Health San Antonio a covered entity under HIPAA for research activities? **Yes**
5. Any components under UT Health San Antonio's FWA that are covered entities under HPAA for research activities. **None**
6. What are the HIPAA authorization/informed consent document requirements for UT Health San Antonio? **Combined or stand-alone HIPAA Authorization acceptable.**
7. What is UT Health San Antonio's policy on use of short form consent for non-English speaking individuals? **Our institution allows the use of a short form consent.**
8. Age of Majority in Texas: **18**

UT Health San Antonio's interpretation of state law regarding when minors can consent for themselves:

There is no state law in Texas for research consent regarding legally authorized representatives. We rely on the Texas State Order used for medical consent.

Title 4, Tex. Health & Safety Code § 313.002(1), <http://www.statutes.legis.state.tx.us/Docs/HS/htm/HS.313.htm>

LAR Guidance Document:

<https://www.uthscsa.edu/sites/default/files/Services/forms/irbconsentpolicyattachment1.pdf>

9. **Texas research laws**

This information was obtained from SMART IRB Institutional Profile form as part of SMART IRB, which is funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number UL1TR001102-04S1.

Texas Department of Family and Protective Services

Approval must be obtained from the Texas Department of Family and Protective Services) to conduct research involving DFPS client data or contact with DFPS clients or staff **unless** it involves de-identified retrospective data of children currently or formerly in conservatorship if the de-identified data is obtained from health system or hospital records and consent would not be required under an IRB approved protocol. Study team should be reminded to submit after obtaining IRB approval. Research activities may not begin until DFPS approval has been obtained and submitted to OCRmail@uthscsa.edu for review, **and** an UT Health San Antonio (UTHSA) institutional activation letter is provided by the Office of Clinical Research (OCR).

- DFPS Website: https://www.dfps.state.tx.us/policies/research_requests.asp

Investigational Stem Cell Treatment

Requires additional IRB documentation and reporting. Deferral to an external IRB is not allowed due to these additional requirements. Unapproved FDA stem cell therapy for use in a clinical trial will require an IND.

- FDA approved treatments:
<https://www.fda.gov/biologicsbloodvaccines/cellulargenetherapyproducts/approvedproducts/default.htm>
- HB810, <https://legiscan.com/TX/text/HB810/id/1625428/Texas-2017-HB810-Enrolled.html>

10. Does UT Health San Antonio have broad laws or institutional requirements that would be applicable to all protocols: **Witness signature on the informed consent document**

11. Did UT Health San Antonio “uncheck the box” **Yes** Does UT Health San Antonio implement flexible options with regard to review and approval of research at your institution? **No**

INSTITUTIONAL PROFILE

SECTION 2: This information should be provided to **potential relying IRBs** during the ceding process.

12. Is UT Health San Antonio willing to serve as an IRB of record (Reviewing IRB) for other institutions? **Yes**

13. Name of UT Health San Antonio IRBs:

Institutional Review Boards (IRB) #1, IRB00000553

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Institutional Review Boards (IRB) #2, IRB00002691

Institutional Review Boards (IRB) #3, IRB00002692

Institutional Review Boards (IRB) #4, IRB00009608

14. How are UT Health San Antonio IRB policies made available?:

Policies are made available on our website:

<https://www.uthscsa.edu/vpr/services/guidance-policies>

15. In the past five years, has UT Health San Antonio IRB had any letters of findings from OHRP or FDA as a result of investigations or inspections of the institution's IRB? **No**

16. Is UT Health San Antonio willing to serve as the Privacy Board for other institutions? **Yes**

17. Will UT Health San Antonio IRB require a listing, review, and/or approve of all study personnel from each Relying Institution? **No, training and qualification requirements are verified by the relying site.**

18. UT Health San Antonio IRB has assessed the quality of its IRB/HRPP through: **AAHRPP accreditation**