

March 02, 2023

Brandie Otten
[via Email]

Re: CIRB Approval of the Annual Signatory Institution Worksheet About Local Context

Signatory Institution: **University of Texas Health Science Center at San Antonio**

Dear Brandie Otten,

On March 01, 2023, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for University of Texas Health Science Center at San Antonio received on February 10, 2023. The information contained in this Worksheet contributes toward establishing the Institution's local context considerations for the CIRB. The review conducted by NCI Pediatric CIRB applies to all boards.

The CIRB reviewed and approved the consent form boilerplate language and institutional requirements. The CIRB understands that no consent form text is being deleted from the CIRB-approved consent form(s) without CIRB approval.

No changes to either the boilerplate language or institutional requirements may be implemented without prior CIRB approval. Any changes must be reported promptly to the CIRB for review and approval prior to implementation.

The CIRB-approved boilerplate language to be inserted into the CIRB-approved consent form(s) by the Investigator is as follows:

- Boilerplate Language, Version Date: 02/10/2023

Header:

Title of Study: *must match the title listed on the protocol EXACTLY*

Consent to be part of a Research Study

The University of Texas Health Science Center at San Antonio (UT Health San Antonio)

To be conducted at

Select appropriate Study sites

Mays Cancer Center

University Health

Principal Investigator Name:

[enter PIs name]

Daytime Telephone Number(s):

###-###-####

24-hour Contact Number(s):

###-###-####

UT Health San Antonio is the local Institutional Review Board committee that reviews research on human subjects (Institutional Review Board) and can also answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UT Health San Antonio, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Footer:

Cancer Center Version Date : ###/###/###
CIRB Version Date: ###/###/###

CTMS# : XX-XXXX
Main/Screening

Local Protocol # : HSC#####X
Page # of #

The translation of the CIRB-approved boilerplate language to be inserted into the CIRB-approved consent form(s) by the Investigator is as follows:

- Spanish Boilerplate Language, Version Date: 02/10/2023

Header:

Título del estudio: must match the title listed on the protocol EXACTLY

Consentimiento para ser parte de un estudio de investigación
University of Texas Health Science Center at San Antonio (UT Health San Antonio)
Para conducirse en
Select appropriate Study sites
Mays Cancer Center
University Health

Nombre del investigador principal: [enter PI's name]
Número (s) de teléfono durante el día: ###-###-####
Número (s) de contacto las 24 horas: ###-###-####

UT Health San Antonio es el comité local de la Junta de Revisión Institucional (Institutional Review Board o IRB) que revisa investigación en seres humanos y puede contestar cualquier pregunta sobre sus derechos como participante en investigación, y tomará las preocupaciones, comentarios, o quejas que usted pudiera querer ofrecer. Puede ponerse en contacto con el IRB llamando al 210-567-8250, o por correo a IRB, UT Health San Antonio, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Footer:

Cancer Center Version Date : ###/###/###
CIRB Version Date: ###/###/###

CTMS# : XX-XXXX
Main/Screening

Local Protocol # : HSC#####X
Página # of #

The CIRB agrees that Investigators conducting CIRB-approved studies must comply with the institutional requirements as follows:

- The parent, guardian, or representative signs and personally dates the consent form as the Person Giving Consent, and the assent of the child, when appropriate, is documented by having the child sign as the Subject [per section 5. a) Infants and Children of SOP Obtaining Informed Consent (Revision: 3, Revised: January 21, 2019)]. If an additional information sheet is developed for easier comprehension, it will be submitted on the Study Specific Worksheet for review.

The Signatory Institution Principal Investigator has the responsibility for ensuring that CIRB-approved boilerplate language is appropriately inserted into the CIRB-approved consent form(s) and institutional requirements are met.

The following institutions are included in this approval and future CIRB approvals will pertain to these institutions also, until the CIRB is notified of a change:

Component Institutions: Component Institutions are defined by the CIRB as meeting all of the following criteria:

- the Component Institution operates under a different name than the Signatory Institution, but the Signatory Institution has legal authority for the Component Institution;
- the FWA number for the Component Institution is the same as the Signatory Institution;
- the local context considerations of the Component Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Signatory Institution Worksheet About Local Context;
- the boilerplate language and institutional requirements of the Component Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Signatory Institution Worksheet About Local Context; and
- the conduct of research at the Component Institution and the Signatory Institution is monitored by the same office.

Component Institutions list:

| | |
|---|--|
| 1 | University of Texas Health Science Center at San Antonio (TX059) |
|---|--|

Affiliate Institutions: Affiliate Institutions are defined by the CIRB as meeting all of the following criteria:

- the local context considerations of the Affiliate Institution are the same as the Signatory Institution. Local context considerations are reported by the Signatory Institution in the Annual Signatory Institution Worksheet About Local Context;
- the boilerplate language and institutional requirements of the Affiliate Institution are the same as the Signatory Institution. The boilerplate language and institutional requirements are reported by the Signatory Institution in the Annual Signatory Institution Worksheet About Local Context; and
- the conduct of research at the Affiliate Institution and the Signatory Institution is monitored by the same office.

Affiliate Institutions list:

| | |
|---|---|
| 1 | Christus Santa Rosa Health Care (TX158) |
| 2 | STCC at DHR Health Institute for Research and Development (TX389) |
| 3 | University Hospital (TX182) |
| 4 | Valley Health / Winchester Medical Center (VA008) |

The CIRB reminds you that any additions or deletions of Component or Affiliate Institutions that change the approved local context considerations included in this letter must be reported to the CIRB in a timely manner.

If you have any questions regarding this review, contact the CIRB at ncicirbcontact@emmes.com.

Sincerely,

NCI Pediatric CIRB

cc: Signatory Institution Primary Contact(s)
Signatory Institution Principal Investigator(s)
NCI CIRB Operations Office