C›I›R›B
FOR THE NATIONAL CANCER INSTITUTE

October 19, 2023

Kimberly Hawkins BA
[via Email]

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

Signatory Institution: **University of Texas Southwestern Medical Center**

Dear Kimberly Hawkins,

On October 18, 2023, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for University of Texas Southwestern Medical Center received on October 12, 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: 12/18/2020 Updated: 09/08/2023

Required Consent Document elements:

CONSENT TO PARTICIPATE IN RESEARCH
To be conducted at *revise as applicable*
The University of Texas Southwestern Medical Center
Parkland Health
Children's Health and any of its affiliated entities

1. *Under section,* "What are the costs of taking part in this study?" *add if:*
   - *the following is not part of the NCI CIRB informed consent template:*
     Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.
   - *the "Experimental Therapeutics Program (ETP) Travel Assistance" applies to the study:*
     You may be eligible to receive help from Children's Health for some travel expenses to and from the hospital while on this research study. Please ask the study team for more details.

2. *After the paragraph giving contact information for questions, you are required to refer to UTSW as the UT Southwestern Human Research Protection Program Department not the Institutional Review Board.*

3. *Signature:*

If consent provided by adults (without a surrogate), include this signature section:

Adult Signature Section

			AM PM
Printed Name of Participant	Signature of Participant	Date	Time
			AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

*If consent provided by a surrogate, include this signature section for studies enrolling **adults unable to provide consent**. Add also to studies enrolling children, If NCI CIRB approval specify that **ONE PARENT** signature ONLY is required (greater than minimal risk with prospect of direct benefit or minimal risk)*

Surrogate Signature Section

			AM PM
Printed Name of Participant	Signature of Participant Giving Assent (10-17) (*If incapable of signing, person obtaining consent should initial here*)	Date	Time
			AM PM
Printed Name of Person Giving Consent for Participant (If applicable)	Signature of Person Giving Consent Parent/Guardian/Legally Authorized Representative	Date	Time
			AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

*If NCI CIRB approval specify that consent must be provided by **BOTH PARENTS** (greater than minimal risk with no prospect of direct benefit), include this signature section:*

Surrogate Signature Section

			AM PM
Printed Name of Participant	Signature of Participant giving Assent (10-17) (*If incapable of signing, person obtaining consent should initial here*)	Date	Time
			AM PM
Printed Name of Parent 1 Giving Consent for Child	Signature of Parent 1 Giving Consent	Date	Time
			AM PM
Printed Name of Parent 2 Giving Consent for Child	Signature of Parent 2 Giving Consent (***Required unless:*** *deceased, unknown, incompetent, not readily available, or no longer has legal parental rights)*	Date	Time
			AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time

KEEP THIS SECTION

Also, complete this section if IRB approves a non-English short form to be used.

Interpreter:

			AM PM
Printed Name of Interpreter	Signature of Interpreter	Date	Time

Witness [*Needed when the interpreter is not physically present, e.g., a language line is used*]:

			AM PM
Printed Name of witness	Signature of witness	Date	Time

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: 12/18/2020 Updated: 09/08/2023

Required Consent Document elements:

CONSENTIMIENTO PARA PARTICIPAR EN UNA INVESTIGACIÓN
que se realizará en *revise as applicable*
The University of Texas Southwestern Medical Center
Parkland Health
Children's Health y cualquiera de sus entidades afiliadas

1. *Under section,* "¿Cuáles son los costos de participar en este estudio?" *add if:*

- *the following is not part of the NCI CIRB informed consent template:*
  "Pídale ayuda a su médico o al personal de enfermería para encontrar a la persona más adecuada con quien hablar si no está seguro sobre qué costos se le facturarán a usted o a su proveedor de seguros".
- *the "Experimental Therapeutics Program (ETP) Travel Assistance" applies to the study:*
  "Usted puede ser elegible para recibir ayuda de Children's Medical Center para cubrir algunos gastos de traslado hacia y desde el hospital mientras participa en este estudio de investigación. Pídale al equipo del estudio que le dé más detalles".

2. *After the paragraph giving contact information for questions, you are required to refer to UTSW as the UT Southwestern Human Research Protection Program Office not the Institutional Review Board.*

3. *Signature:*

If consent provided by adults (without a surrogate), include this signature section:

Sección de firmas para adultos

			a. m. p. m.
Nombre del participante, en letra de imprenta	Firma del participante	Fecha	Hora
			a. m. p. m.
Nombre de la persona que obtiene el consentimiento, en letra de imprenta	Firma de la persona que obtiene el consentimiento	Fecha	Hora

If consent provided by a surrogate, include this signature section for studies enrolling ***adults unable to provide consent****. Add also to studies enrolling children, If NCI CIRB approval specify that* ***ONE PARENT*** *signature ONLY is required (greater than minimal risk with prospect of direct benefit or minimal risk)*

Sección de firmas del representante

			a. m. p. m.
Nombre del participante, en letra de imprenta	Firma del participante que otorga el asentimiento (10-17) (*Si no es capaz de firmar, la persona que obtiene el consentimiento debe escribir sus iniciales aquí*)	Fecha	Hora a. m. p. m.
Nombre de la persona que otorga el consentimiento por el participante, en letra de imprenta (Si corresponde)	Firma de la persona que otorga el consentimiento Padre/madre/tutor/representante legalmente autorizado	Fecha	Hora a. m. p. m.
Nombre de la persona que obtiene el consentimiento, en letra de imprenta	Firma de la persona que obtiene el consentimiento	Fecha	Hora

*If NCI CIRB approval specify that consent must be provided by **BOTH PARENTS** (greater than minimal risk with no prospect of direct benefit), include this signature section:*

Sección de firmas del representante

			a. m. p. m.
Nombre del participante, en letra de imprenta	Firma del participante que otorga el asentimiento (10-17) (*Si no es capaz de firmar, la persona que obtiene el consentimiento debe escribir sus iniciales aquí*)	Fecha	Hora a. m. p. m.
Nombre del padre o la madre 1 que otorga el consentimiento por el menor, en letra de imprenta	Firma del padre o la madre 1 que otorga el consentimiento	Fecha	Hora a. m. p. m.
Nombre del padre o la madre 2 que otorga el consentimiento por el menor, en letra de imprenta	Firma del padre o la madre 2 que otorga el consentimiento (***Es obligatorio a no ser que:*** *haya fallecido, sea desconocido, sea incompetente, no esté disponible de momento o ya no tenga derechos parentales legales)*	Fecha	Hora

Nombre de la persona que obtiene el consentimiento, en letra de imprenta	Firma de la persona que obtiene el consentimiento	Fecha	Hora a. m. p. m.

KEEP THIS SECTION

Además, complete esta sección si la Junta de Revisión Institucional (Institutional Review Board, IRB) aprueba el uso de un formulario breve que no sea inglés.

Intérprete:

Nombre del intérprete, en letra de imprenta	Firma del intérprete	Fecha	Hora a. m. p. m.

Testigo [*necesario cuando el intérprete no está físicamente presente, es decir, se usa un intérprete telefónico*]:

Nombre del testigo, en letra de imprenta	Firma del testigo	Fecha	Hora a. m. p. m.

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

- The IRB reviews the proposed process and, if applicable, the assent process to ensure compliance with IRB guidance and federal requirements. In general in determining whether assent of children is required in all, some or none of the children in a study the IRB is guided by the following age ranges:
  - i. Ages 0-6 – The capability of children of this age group is so limited that they cannot reasonably be consulted. Assent is not required.
  - ii. Ages 7-10 – Children of this age group may be capable of providing assent depending on the maturity and psychological state of the children involved in the research. Verbal or written assent may be required but must not be waived by the IRB if the child is unable to provide assent. The PI is responsible for determining the plan for documenting assent (i.e., verbal assent documented within the participant's research record, written assent documented via the consent form, etc.).
  - iii. Ages 10 – 17 – Children of this age group are expected to be capable of providing assent. Written assent is usually required unless waived by the IRB. Written assent is documented in the Surrogate Signature Section that will be included in the consent form unless a separate assent form is provided by the Sponsor.
- Consent to Participate in Research (v3 July 2020) [forms_form_e.s_short_form_consent_english_v3_07_2020.docx] translated into the following languages: Albanian, Amharic, Arabic, Armenian, Bengali, Bosnian, Brazilian Portuguese, Burmese,

Creole, Dari, Edo, European Portuguese, Farsi, French, German, Greek, Gujarati, Hebrew, Hindi, Hungarian, Igbo, Italian, Japanese, Karen, Khmer, Korean, Nepali, Pashto, Polish, Punjabi, Russian, Simplified Chinese, Sinhalese, Somali, Tagalog, Thai, Traditional Chinese, Turkish, Urdu, Vietnamese, Wolof, and Yiddish.

- Long-term follow-up letter template will be sent to participants of all UTSW cancer studies.
    - CC1 DT 10 30 20 - Entering LTFU Letter Template_FINAL_102320.docx
    - CC1 DT 10 30 20 - Entering LTFU Letter Template_FINAL_102320_ES.doc
- Experimental Therapeutics Program (ETP) Travel Assistance Family Letter
    - ETP Travel Fund Letter v2 20181120_ENG_CC.docx
    - ETP Travel Fund Letter v2 20181120_SPA_CC.docx

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	Clements University Hospital (TX427)
2	UT Southwestern Clinical Center at Richardson/Plano (TX425)
3	UT Southwestern Simmons Cancer Center - RedBird (TX465)
4	UT Southwestern/Simmons Cancer Center-Dallas (TX011)
5	UT Southwestern/Simmons Cancer Center-Fort Worth (TX150)

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	Childrens Medical Center (TX009)
2	Parkland Memorial Hospital (TX006)

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 support@ncicirbcontact.zendesk.com.

Sincerely,

NCI Pediatric CIRB

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