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

April 07, 2023

Mara Levy B.A.
[via Email]

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

Signatory Institution: **Children's Hospital Los Angeles**

Dear Mara Levy,

On April 06, 2023, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for Children's Hospital Los Angeles received on October 17, 2022. 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 version 3-21-2022

1. The following box should be added to the first page of the consent form:

Subject's Name:	_____	**Birth Date:**	_____
CHLA MRN#:	_____		

2. "The CHLA Institutional Review Board and authorized representatives of CHLA" should be added to the list of organizations in the consent form that may look at or receive copies of some of the information in the subject's study records.

3. The following statements should be added to the consent form with the contact information of the CHLA Investigator inserted:

"If you have questions, concerns, or complaints about the study, or think this research has harmed you, talk to the CHLA research team at (XXX)-XXX-XXXX."

"You may also call Children's Hospital Los Angeles, Human Subjects Protection Program office at (323) 361-2265."

4. Lines for individuals to print their names may be added to the consent form.
For Example Only:

Printed Name of Participant

5. Any signature and date lines for special subject populations (e.g. parental permission for minors, legally authorized representatives consenting for adults lacking consent capacity, witnesses for enrolling non-English speaking populations, etc.) that are not included in the CIRB approved consent template may be added:

For Example Only:

Parent/Legal Guardian **Date**

Parent/Legal Guardian **Date**

Printed Name(s) of Parent(s)/Legal Guardian(s)

Legally Authorized Representative **Date**

Printed Name of Legally Authorized Representative

Witness **Date**

Printed Name of Witness

6. Per CA Family Code (Sections 111515-111545), minor consent is required prior to administering an experimental drug. Parental or legal guardian consent (permission) is required and minor consent (assent) is required for children 7 years of age or older. When an assent information sheet is available from the NCI CIRB, and the research involves children ages 7 to 13 and/or adults lacking consent capacity, a signature section may be added to the assent information sheet to document assent from these populations:

Example:

Signature of Participant (if able to sign) **Date**

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

- Boilerplate version 3-21-2022 (Spanish)

1. The following box should be added to the first page of the consent form:

Nombre del sujeto:	**Fecha de nacimiento:**
N.º DE EXPEDIENTE MÉDICO (MRN) DEL CHILDREN'S HOSPITAL LOS ÁNGELES (CHLA):	

2. "La Junta de Revisión Institucional del CHLA y los representantes autorizados del CHLA" should be added

to the list of organizations in the consent form that may look at or receive copies of some of the information in the subject's study records.

3. The following statements should be added to the consent form with the contact information of the CHLA Investigator inserted:

"Si tiene preguntas, preocupaciones o quejas sobre el estudio, o si cree que esta investigación lo dañó, comuníquese con el equipo de investigación del CHLA al (XXX)-XXX-XXXX".

"También puede llamar a la oficina del Programa de Protección de Sujetos Humanos (Human Subjects Protection Program) del Children's Hospital Los Angeles al (323) 361-2265".

4. Lines for individuals to print their names may be added to the consent form.
For Example Only:

_____
Nombre en letra de molde del participante

5. Any signature and date lines for special subject populations (e.g. parental permission for minors, legally authorized representatives consenting for adults lacking consent capacity, witnesses for enrolling non-English speaking populations, etc.) that are not included in the CIRB approved consent template may be added:

For Example Only:

_____ _____
Padre/tutor legal **Fecha**

_____ _____
Padre/tutor legal **Fecha**

_____ _____
Nombres en letra de molde de los padres/tutores legales

_____ _____
Representante legalmente autorizado **Fecha**

_____
Nombre en letra de molde del representante legalmente autorizado

_____ _____
Testigo **Fecha**

_____
Nombre en letra de molde del testigo

6. Per CA Family Code (Sections 111515-111545), minor consent is required prior to administering an experimental drug. Parental or legal guardian consent (permission) is required and minor consent (assent) is required for children 7 years of age or older. When an assent information sheet is available from the NCI CIRB, and the research involves children ages 7 to 13 and/or adults lacking consent capacity, a signature section may be added to the assent information sheet to document assent from these populations:

Example:

_____ _____
Firma del participante (si puede firmar) **Fecha**

Footer:
v.03.21.2022

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

- CHLA Experimental Subject's Bill of Rights
- Assent to Participate in Research Study, Revision Date: 09-22-2020* (CHLA Template Simplified Assent Children and Adults 09-22-2020.docx) *Must be submitted for approval before use

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	Children's Hospital Los Angeles (CA009)

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:

None

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