

September 9, 2022

Natasha Willms, BA, BS
[via Email]

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

Signatory Institution: **University of Nebraska Medical Center**

Dear Natasha Willms,

On September 7, 2022, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for University of Nebraska Medical Center received on August 9, 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:

- Letterhead: Adult Consent Form- Neb. Med.

Header:	
	PT NAME MR #
CONSENT FORM	
IRB PROTOCOL #	Page X of total pages

- Boilerplate Language (Version Date: 11/16/2021) and Letterhead

	
	PT NAME MR #
CONSENT FORM	
IRB PROTOCOL #	Page X of total pages

Costs

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 or you can contact _____.

Injury Language

Your health and safety is our main concern. If you are injured or have a medical problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at Nebraska Medicine. You can also go to your doctor, the nearest emergency room or call 9-1-1.

[Insert the sponsor language]

We have no plans to pay for your treatment or give you any other money or compensation.

Signing this does not mean you have given up any of your legal rights.

Contact Information

- The investigator or other study personnel
- Institutional Review Board (IRB)
 - Telephone: (402) 559-6463
 - Email: IRBORA@unmc.edu
 - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
 - Telephone: (402) 559-6941
 - Email: unmcrsa@unmc.edu

Signature Lines

Signature of Subject _____

Date _____

Signature of Parent _____

Date _____

Signature of Person Obtaining Consent _____




Date _____

Authorized Study Personnel

Footer:



Protocol Version Date:

- Pediatric Letterhead (Version Date: 8/21/2019)

  	<input type="text" value="PT NAME"/> <input type="text" value="MR #"/>
CONSENT FORM	
IRB PROTOCOL #	Page X of total pages

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: 11/16/2021) and Letterhead

 	<input type="text" value="PT NAME"/>
CONSENT FORM	
IRB PROTOCOL #	Page X of total pages
Costos Pida ayuda a su médico o enfermera para encontrar la persona adecuada con quien hablar si no está seguro cuales costos se le facturarán a usted o su proveedor de seguros médicos o puede comunicarse con _____.	
Lenguaje de lesiones Su salud y seguridad son nuestra principal preocupación. Si se lesiona o tiene un problema médico debido a este estudio llame a alguien que figura al final de este documento de consentimiento. Puede obtener tratamiento médico de emergencia en Nebraska Medicine. También puede acudir a su médico, a la sala de urgencias más cercana o llamar al 9-1-1.	
[Insert the sponsor language]	
Nosotros no tenemos plan de pagar su tratamiento o darle ningún otro dinero o compensación.	
Firmar esto no significa que haya renunciado a ninguno de sus derechos legales	
Información de Contacto <ul style="list-style-type: none">• El investigador u otro personal del estudio• Junta de Revisión Institucional (IRB)<ul style="list-style-type: none">○ Teléfono: (402) 559-6463○ Correo electrónico: IRBORA@unmc.edu○ Correo: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830	

- Defensor de sujetos de investigación
 - Teléfono: (402) 559-6941
 - Correo electrónico: unmcrsa@unmc.edu

Signature Lines

Firma del sujeto _____

Fecha _____

Firma del padre o madre _____

Fecha _____

Signature of Person Obtaining Consent _____

Date _____

Authorized Study Personnel

Footer:

Protocol Version Date:

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

- Youth (ages 12-18) must sign the parental consent form.
- The child and youth information sheets are not signed.

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	Nebraska Medicine Heartland Hematology Oncology (NE048)
2	Nebraska Medicine-Bellevue (NE072)
3	Nebraska Medicine-Village Pointe (NE071)
4	University of Nebraska Medical Center (NE003)

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	Children's Hospital and Medical Center of Omaha (NE006)
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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