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

August 21, 2025

Kristi DeHaai MS
[via Email]

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

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

Dear Kristi DeHaai,

On August 20, 2025, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for University of Nebraska Medical Center received on August 14, 2025. 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:

- NCI Adult letterhead NM 04-01-24

Nebraska Medicine **CONSENT FORM**

PT NAME
MR #

IRB PROTOCOL # **Page X of total pages**

Footer:
Protocol Version Date: **CONSENT FORM** **CONSENT**

- NCI Adult letterhead UNMC 04-01-24

UNMC

PT NAME
MR #

CONSENT FORM

IRB PROTOCOL # **Page X of total pages**

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- NCI Peds letterhead UNMC 04-01-24

UNMC Children's NEBRASKA

PT NAME
MR #

CONSENT FORM

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- Boilerplate Language, Version Date: 8/14/25

University of Nebraska Medical Center

PT NAME
MR #

CONSENT FORM

IRB PROTOCOL # **Page X of total pages**

Costs
You will have to pay any insurance deductibles and co-payments. If you want to speak with someone about your insurance, just tell us.

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

COI
[Only add separate COI section with required language if applicable]

Signature Lines
Signature of Subject _____
Date _____

Signature of Parent _____
Date _____

Signature of Person Obtaining Consent _____
Date _____

If informed consent is performed remotely, list the method of remote consent, the date of the informed consent discussion, and the date the signed consent form was received:

_____

Authorized Study Personnel

Footer:
Protocol Version Date: **CONSENT FORM** **CONSENT**

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

- None

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

- The child should be given a copy of the Child Information Sheet which includes a description of the research written at the appropriate language level, or a copy of the Informed Consent Form.
  The investigator should engage the child in an appropriate discussion about participation in the research to the extent possible in consideration of the child's age and cognitive ability. The child's parent(s) should be included in this discussion.
  If the child agrees to participate, the investigator should document the child's assent in the research record. Child assent may also be documented on an appropriate signature blank on the informed consent form.
- Children who reach the age of majority while actively participating in an study must give their consent to continue participation in the research, at the first visit after reaching the legal age of majority in the

manner described in IRB application. Subjects must then sign the informed consent document as "subject" without parental co signature.

- We require specific research injury language, require phone numbers for the study doctor, and identification of who can be contacted with questions or concerns about the study. We also require signature by the person obtaining consent and a list of authorized study personnel at the end of the consent forms.

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	Fred and Pamela Buffett Cancer Center - Kearney (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)

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