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

August 13, 2020

Michael Bingham
[via Email]

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

Signatory Institution: **University of Wisconsin - Madison**

Dear Michael Bingham,

On August 5, 2020, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for University of Wisconsin - Madison received on August 3, 2020. 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:

UW-Madison-Required Language for National Cancer Institute Central Institutional Review Board (NCI CIRB) Consent Documents

Text in black should be included verbatim in the consent document. Blue text is for guidance and should **not** be included in the consent form. **This guidance assumes that the CIRB consent form template follows the CTEP Informed Consent Template, version date 11/27/2018.**

Cover page header:

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

UNIVERSITY OF WISCONSIN
CARBONE CANCER CENTER, 600 HIGHLAND AVENUE, MADISON, WI 53792

- The header should also name other UW or affiliate sites participating on the study:
  - **UW Health Oncology at 1 South Park – Madison, Wisconsin 53715** [adult studies only]
  - **UW Cancer Center – Johnson Creek, Johnson Creek, Wisconsin 53038** [adult studies only]
  - **American Family Children's Hospital – 1675 Highland Avenue, Madison, WI 53792** [pediatric studies only]
  - **Gundersen Lutheran Medical Center, Inc – LaCrosse, Wisconsin 54601** [pediatric studies only]

- **What exams, tests, and procedures are involved in this study?**

- **What happens if I am injured because I took part in this study?**
  UW-required compensation for research-related injury language:
  - If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.
  - If it is an emergency, call 911 right away or go to the emergency room.
  - For non-emergency medical problems, [specify what subjects should do, e.g. contact the study team for instructions, contact your regular health care provider].
  - Call the Lead Researcher, [name], at [phone number] to report your sickness or injury.

  - If Johnson Creek affiliate is participating, add:
    If you are a UW Cancer Center Johnson Creek patient, please contact your study doctor, **[name]**, at **[phone number]**.

  - If Gundersen Lutheran Medical Center is participating, add:
    Gundersen Lutheran Medical Center, Inc. subjects may contact **[name]** at **[phone number]**.

- **Who will see my medical information?**

  In the list of organizations that may look at study records, insert:

  - Research oversight and research support offices at the University of Wisconsin-Madison **[if applicable, add the following general statement only:** "and applicable affiliate sites"**]** may view study records.

- **Where can I get more information?**

  [General Questions]

  - All UW-Madison sites should insert the contact information embedded within the template.

  - If Johnson Creek affiliate is participating, add:
    If you are a UW Cancer Center Johnson Creek patient, please contact your study doctor, **[name]**, at **[phone number]**.

  - If Gundersen Lutheran Medical Center is participating, add:
    Gundersen Lutheran Medical Center, Inc. subjects may contact **[name]** at **[phone number]**.

[Questions regarding Rights]

- For all UW-Madison studies,
  If you have any questions about your rights as a research subject or complaints about the research study that you could not resolve with the study team contact UWHC Patient Relations Representative at 608-263-8009.
- If Johnson Creek affiliate is participating, add:
  If you are a UW Cancer Center Johnson Creek patient, call Cancer Connect at 1-800-622-8922.
- If Gundersen Lutheran Medical Center affiliate site is participating, add:
  Subjects enrolled at Gundersen Lutheran Medical Center should contact Bernard J. Hammes, Ph.D., Chairperson of the Gundersen Clinic, Ltd. HSC/IRB at (608) 782-7300 or 1-800-362-9567

If a consent template does not include a signature line for the person conducting the consent discussion, please include the following language underneath the signature line of the subject.

Signature of person(s) conducting the informed consent discussion

_____

Date of signature_____

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:

- None

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 Wisconsin Hospital and Clinics (WI020)

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	Aspirus UW Cancer Center (WI093)
2	Gundersen Lutheran Medical Center (WI029)
3	UW Cancer Center Johnson Creek (WI151)

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