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

October 23, 2020

Judy Murray C.C.R.C.,B.S.
[via Email]

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

Signatory Institution: **Johns Hopkins University School of Medicine**

Dear Judy Murray C.C.R.C.,B.S.,

On October 23, 2020, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for Johns Hopkins University School of Medicine received on October 21, 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:

- Boilerplate, Version date: 10/20/2020

*****REMINDER TO THE STUDY TEAM: ATTACH THE SEPARATE HIPAA FORM WHEN CREATING A PDF VERSION OF THE CONSENT FORM FOR LOCAL USE*****

INSTRUCTIONS TO THE STUDY TEAM: MAINTAIN ALL HEADERS AND TEXT FROM THE SPONSOR'S TEMPLATE AND ADD THE INFORMATION PROVIDED BELOW. INCORPORATE ANY STUDY-SPECIFIC ADDITIONS APPROVED SEPARATELY BY THE CIRB.

COPY THE FOLLOWING MRN BOX ONTO THE SPONSOR'S APPROVED TEMPLATE *BEFORE* THE SPONSOR'S STUDY TITLES:

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's EPIC/EMR record.

Patient I.D. Plate

INSERT THE FOLLOWING *AFTER* THE SPONSOR'S STUDY TITLE HEADER:

JHM IRB Application No.: <<IRB00xxxx>>

Sponsor/Supporter/Funded By: *<<Please choose the most appropriate header. It is required that entities providing monetary or material support be listed here. If there are multiple supporters, please list them and identify the type of support. Delete this line if not applicable>>*

Principal Investigator: *<<Name>>*
<<Mailing address>>
<<Email address>>
<<Phone information>>

INSERT THE FOLLOWING *IN* THE 'If Injured' SECTION:

Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people. The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you. By signing this form you will not give up any rights you have to seek compensation for injury.

INSERT THE FOLLOWING SECTIONS *AFTER* THE 'More Information' SECTION:

What should you do if you have questions about being in the study at Johns Hopkins?

Contact the Johns Hopkins Principal Investigator at the phone number or address provided on the first page of this consent form.

For more information about the costs of taking part in this study, you may contact the study doctor or research nurse. Contact information is provided on the first page of this consent form. You may also find more information in the "Information and Research Participant Financial Responsibility Information Sheet" provided to you with this consent form.

If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at https://www.cancer.gov/about-cancer/treatment/clinical-trials/paying. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What should you do if you are injured or ill as a result of being in this study at Johns Hopkins?

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call ***<<Insert the name of the Principal Investigator, or if the Principal Investigator is not a medical doctor, include designated physician>>*** at ***<<insert telephone number>>*** during regular office hours and at ***<<insert phone or pager number available 24 hours >>*** after hours and on weekends.

<<If this study may include participants at another Johns Hopkins site include the following language for each site: >>
If you are taking part at ***<<Site Name, i.e.: Johns Hopkins All Children's Hospital, Howard County General Hospital, Sibley Memorial Hospital, Suburban Hospital>>*** and have questions or you have a medical problem related to your taking part in this study, call ***<<insert PI name>>*** at ***<<insert telephone number>>*** during regular office hours and at ***<<insert phone or pager number available 24 hours >>*** after hours and on weekends.

ADD '**Printed Name**' AND '**Time**' TO THE CIRB's SIGNATURE LINES. For example:

_____

Signature of Participant Printed Name Date/Time

_____

Signature of Person Obtaining Consent Printed Name Date/Time

ADD ANY OF THE FOLLOWING THAT ARE APPLICABLE FOR THIS STUDY AND DELETE ANY THAT DO NOT APPLY:

_____

Signature of Parent/Legal Guardian/Court-Appointed Representative FOR CHILD PARTICIPANT Printed Name Date/Time

_____

Description of relationship to child research participant (for example: parent, legal guardian, court-appointed representative)

_____

Signature of Parent #2 Printed Name Date/Time
(Required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

_____

Signature of Child Participant (optional unless IRB required) Printed Name Date/Time

_____

Signature of Interpreter/ Witness to Consent Procedures Printed Name Date/Time
(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

ADD THE FOLLOWING SECTION AT THE END, AS APPLICABLE:

Physician/mid-level provider consent discussion

_____

Signature of Participant Printed Name Date/Time

ADD ANY OF THE FOLLOWING SIGNATURE LINES THAT ARE APPLICABLE FOR THIS STUDY AND DELETE ANY THAT DO NOT APPLY:

_____

Signature of Parent/Legal Guardian/Court-Appointed Representative Printed Name Date/Time
FOR CHILD PARTICIPANT

_____

Description of relationship to child research participant (for example: parent, legal guardian, court-appointed representative)

_____

Signature of Parent #2 Printed Name Date/Time
(Required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

_____

Signature of Child Participant (optional unless IRB required) Printed Name Date/Time

_____

Signature of Interpreter/ Witness to Consent Procedures Printed Name Date/Time
(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

END WITH THE FOLLOWING:

My signature below indicates that I have discussed the risks, benefits, and alternatives.

_____

Signature of Physician/Mid-Level Provider Printed Name Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

Footer:

JH <<insert local revision 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:

- None

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

- A study-specific "Insurance and Research Participant Financial Responsibility Information Sheet" will be provided to potential subjects
- MD017 Age of Consent Template v02-2015

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	Johns Hopkins University/Sidney Kimmel Cancer Center (MD017)

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	Howard County General Hospital (MD046)
2	Johns Hopkins All Children's Hospital (FL068)
3	Johns Hopkins Bayview Medical Center (MD043)
4	Sibley Memorial Hospital (DC018)
5	Suburban Hospital (MD007)

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