

October 16, 2019

Mariette Marsh
[via Email]

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

Signatory Institution: **University of Arizona**

Dear Mariette Marsh,

On October 15, 2019, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for University of Arizona received on October 11, 2019. 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:

Pediatric boilerplate: Version 10/11/2019



University of Arizona
Cancer Center

1. Site specific language for Contacts, should the subject have questions:

Site will insert PI-specific information.

2. Site specific language for study related injuries:

If your child is injured as a result of taking part in this study or for questions about a study-related injury, you and/or your child may contact the Principal Investigator, _____ (name of PI). You and/or your child can tell the doctor in person or call him/her at _____ (number of the PI).

The University of Arizona and Banner-University Medical Center have no funds set aside to pay for treatment expenses for a research-related injury, added medical costs, loss of a job, or other costs to your child or your family.

Adult boilerplate: Version 9/25/2018



University of Arizona
Cancer Center

1. Site specific language for Contacts, should the subject have questions:

Site will insert PI-specific information.

2. Site specific language for study related injuries:

If you are injured as a result of taking part in this study or for questions about a study-related injury, you may contact the Principal Investigator, _____ (name of PI). You can tell the doctor in person or call him/her at _____ (number of the PI).

The University of Arizona and Banner-University Medical Center have no funds set aside to pay for treatment expenses for a research-related injury, added medical costs, loss of a job, or other costs to you or your family.

UACC ADULT Q12 - v09/25/2018

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

Pediatric boilerplate:



University of Arizona
Cancer Center

1. Lenguaje específico al sitio para Contactos, si el sujeto tiene preguntas:

El sitio insertará la información específica del IP.

2. Lenguaje específico al sitio para lesiones relacionadas con el estudio:

Si su hijo sufre lesiones como resultado de participar en este estudio, o si tiene preguntas acerca de una lesión relacionada con el estudio, usted y/o su hijo pueden comunicarse con el investigador principal, _____ (nombre del IP). Usted y/o su hijo pueden hablar con el médico en persona o llamarlo al _____ (número del IP).

La Universidad de Arizona (University of Arizona) y Banner-Centro Médico Universitario (Banner-University Medical Center) no tienen fondos reservados para pagar gastos de tratamiento para una lesión relacionada con la investigación, costos médicos adicionales, pérdida de un empleo u otros costos para su hijo o su familia.

UACC CHILD Q12 - v02/01/2019

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Adult boilerplate:



University of Arizona
Cancer Center

1. Lenguaje específico al sitio para Contactos, si el sujeto tiene preguntas:

El sitio insertará la información específica del IP.

2. Lenguaje específico al sitio para lesiones relacionadas con el estudio:

Si usted sufre lesiones como resultado de participar en este estudio, o si tiene preguntas acerca de una lesión relacionada con el estudio, puede comunicarse con el investigador principal, _____ (nombre del IP). Usted puede hablar con el médico en persona o llamarlo al _____ (número del IP).

La Universidad de Arizona (University of Arizona) y Banner-Centro Médico Universitario (Banner-University Medical Center) no tienen fondos reservados para pagar gastos de tratamiento para una lesión relacionada con la investigación, costos médicos adicionales, pérdida de un empleo u otros costos para usted o su familia.

UACC ADULT Q13 - v09/25/2018

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

- NRG Follow-up Letter (Version Date: 01/04/2017)
- SWOG Follow-up Letter (Version Date: 01/04/2017)
- SWOG Follow-up Letter (Version Date: 01/04/2017) - Spanish
- COG Follow-up Letter (Version Date: 01/04/2017)
- COG Follow-up Letter (Version Date: 01/04/2017) - Spanish
- CIRB Attachment Question 14 Child (Version Date: 02/01/2019)
- CIRB Attachment Question 14 Child (Version Date: 02/01/2019) - Spanish
- CIRB Attachment Question 14 Adult (Version Date: 08/12/2017)
- CIRB Attachment Question 14 Adult (Version Date: 08/12/2017) - Spanish
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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 | Banner University Medical Center - Tucson (AZ017) |
| 2 | University of Arizona Cancer Center at Saint Joseph's (AZ151) |
| 3 | University of Arizona Cancer Center-North Campus (AZ110) |
| 4 | University of Arizona Cancer Center-Orange Grove Campus (AZ128) |
| 5 | University of Arizona College of Medicine Phoenix (AZ162) |

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 | Saint Joseph's Hospital and Medical Center (AZ009) |
| 2 | Yuma Regional Medical Center (AZ081) |

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