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

April 24, 2024

Christine Melton-Lopez
[via Email]

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

Signatory Institution: **University of Arizona**

Dear Christine Melton-Lopez,

On April 22, 2024, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for University of Arizona received on April 22, 2024. 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:

- UACC – BH Letterhead

University of Arizona
Cancer Center

- UA Yuma Letterhead

ARIZONA
YUMA REGIONAL MEDICAL CENTER
INSTITUTIONAL RESEARCH

- Boilerplate Language – 12 Adult (v12-17-2019)

Question 12: Provide the boilerplate language that is added to the CIRB-approved informed consent document. This is standard language required by the institution that is inserted into the existing CIRB-approved informed consent document:

Our intent is to completely replace the boilerplate language that was previously submitted as part of our Annual Institution Worksheet about Local Context, Question 12. As such, the following previously submitted language should be deleted and replaced with the new language referenced in this attachment:

****Please note that if the language in the CIRB-approved consent form is similar enough to the language sited below, our site may opt not to use the boilerplate language, or may only need to use parts of it based on the site specific language referenced below****

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.

- Boilerplate language – 12 Adult: Yuma (v 03-04-2024)

Question 12: Provide the boilerplate language that is added to the CIRB-approved informed consent document. This is standard language required by the institution that is inserted into the existing CIRB-approved informed consent document:

Our intent is to completely replace the boilerplate language that was previously submitted as part of our Annual Institution Worksheet about Local Context, Question 12. As such, the following previously submitted language should be deleted and replaced with the new language referenced in this attachment:

****Please note that if the language in the CIRB-approved consent form is similar enough to the language sited below, our site may opt not to use the boilerplate language, or may only need to use parts of it based on the site-specific language referenced below****

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

Site will insert PI-specific information.

4. 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 928-317-2518.

If you are injured or become ill as a result of your participation in this study, contact the study doctor immediately. If you are in need of emergency treatment, get treatment right away.

All medical expenses incurred as the result of a research-related injury or illness will be billed to you and/or your insurance in the usual way. You will be responsible for co-payments and deductibles in the same way you would outside of a clinical trial. You will be responsible for any costs that your insurance does not cover. You should check with your health benefit plan to find out if the costs of care from being in this study are covered. The term "research-related injury" describes an injury or illness directly caused by the product or procedures required by the study that are different from the medical treatment you would have received if you had not participated in the study. No other compensation of any type (for example, payment for lost wages, disability, or discomfort) will be provided. You do not give up your legal rights by signing this consent form.

The University of Arizona and Yuma Regional 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.

- Boilerplate Language – 12 Child (v10/11/2019)

Question 12: Provide the boilerplate language that is added to the CIRB-approved informed consent document. This is standard language required by the institution that is inserted into the existing CIRB-approved informed consent document:

Our intent is to completely replace the boilerplate language that was previously submitted as part of our Annual Institution Worksheet about Local Context, Question 12. As such, the following previously submitted language should be deleted and replaced with the new language referenced in this attachment:

****Please note that if the language in the CIRB-approved consent form is similar enough to the language sited below, our site may opt not to use the boilerplate language, or may only need to use parts of it based on the site-specific language referenced below****

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.

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 – 12 Adult (v12/17/2019)

Pregunta 12: proporcione el lenguaje modelo que se agrega al documento de consentimiento informado aprobado por el CIRB. Este es el lenguaje estándar exigido por la institución, que se inserta en el actual documento de consentimiento informado aprobado por el CIRB:

Nuestro propósito es reemplazar por completo el lenguaje modelo presentado anteriormente como parte de nuestro Borrador institucional anual sobre el contexto local, pregunta 12. Como tal, el siguiente lenguaje presentado anteriormente se debe borrar y reemplazar con el nuevo lenguaje al que se hace referencia en este anexo:

****Tome en cuenta que si el lenguaje en el formulario del consentimiento aprobado por el CIRB es suficientemente similar al lenguaje citado a continuación, nuestro sitio puede optar por no utilizar el lenguaje modelo, o quizá sólo necesite utilizar partes del mismo con base en el lenguaje específico al sitio referido a continuación****

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.

- Spanish Boilerplate Language – 12 Adult: Yuma (v03-04-2024)

Pregunta 12: proporcione el lenguaje modelo que se agrega al documento de consentimiento informado aprobado por el CIRB. Este es el lenguaje estándar exigido por la institución, que se inserta en el documento de consentimiento informado actual aprobado por el CIRB:

Nuestro propósito es reemplazar por completo el lenguaje modelo presentado anteriormente como parte de nuestro Borrador institucional anual sobre el contexto local, pregunta 12. Como tal, el siguiente lenguaje presentado anteriormente se debe borrar y reemplazar con el nuevo lenguaje al que se hace referencia en este anexo:

****Tome en cuenta que si el lenguaje en el formulario del consentimiento aprobado por el CIRB es suficientemente similar al lenguaje citado a continuación, nuestro centro puede optar por no utilizar el**

lenguaje modelo, o quizá solo necesite utilizar partes de este con base en el lenguaje específico al centro referido a continuación**

5. Lenguaje específico al centro para contactos, si el sujeto tiene preguntas:

El centro insertará la información específica del IP.

6. Lenguaje específico al centro 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). Puede informarle al médico en persona, o llamarle al 928-317-2518.

Si usted sufre una lesión o se enferma como resultado de su participación en este estudio, comuníquese de inmediato con el médico del estudio. Si necesita tratamiento urgente, obténgalo de inmediato.

Todos los gastos médicos en que se incurra como resultado de una lesión o enfermedad relacionada con la investigación se le facturarán a usted y/o a su compañía de seguros de la manera habitual. Usted será responsable de los copagos y deducibles, de la misma manera que lo haría fuera de un ensayo clínico. Usted será responsable de cualquier costo que su seguro no cubra. Usted debe preguntar al representante de su plan de beneficios de salud si este cubre los costos de la atención por participar en este estudio. El término "lesión relacionada con la investigación" describe una lesión o enfermedad causada directamente por el producto o por los procedimientos requeridos por el estudio que difieren del tratamiento médico que usted habría recibido si no hubiera participado en el estudio. No se proporcionará ninguna otra compensación de ningún tipo (por ejemplo, pago por salarios perdidos, incapacidad o molestias). Al firmar este formulario de consentimiento usted no renuncia a sus derechos legales.

La Universidad de Arizona (University of Arizona) y el Yuma Regional Medical Center no tienen fondos reservados para pagar los gastos de tratamiento de una lesión, costos médicos adicionales, pérdida de un empleo u otros costos para usted o su familia, relacionados con la investigación.

- Spanish Boilerplate Language – 12 Child (v10/11/2019)

Pregunta 12: proporcione el lenguaje modelo que se agrega al documento de consentimiento informado aprobado por el CIRB. Este es el lenguaje estándar exigido por la institución, que se inserta en el actual documento de consentimiento informado aprobado por el CIRB:

Nuestro propósito es reemplazar por completo el lenguaje modelo presentado anteriormente como parte de nuestro Borrador institucional anual sobre el contexto local, pregunta 12. Como tal, el siguiente lenguaje presentado anteriormente se debe borrar y reemplazar con el nuevo lenguaje al que se hace referencia en este anexo:

****Tome en cuenta que si el lenguaje en el formulario del consentimiento aprobado por el CIRB es suficientemente similar al lenguaje citado a continuación, nuestro sitio puede optar por no utilizar el**

lenguaje modelo, o quizá sólo necesite utilizar partes del mismo con base en el lenguaje específico al sitio referido a continuación**

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.

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

- Boilerplate Language – 14 Child (v09/27/2022)

Question 14: Provide any other institutional requirements for informed consent documents, if applicable:

- Our site will list the accruing center(s) on the front page, e.g. Banner University Medical Center - Tucson (AZ017), University of Arizona Cancer Center-North Campus (AZ110), University of Arizona Cancer Center-Orange Grove Campus (AZ128)

- Our site will include our institution's required logos and barcodes in the headers and footers of our consents.

- Our site will make any formatting changes necessary due to adding our boilerplate language (to ensure that the consent flows easily, i.e. there are no blank pages, no site instructions left in the consent, etc.).

- Our site will add a local version date to the header of the CIRB-approved consent form. It will be denoted as "UACC Version Date: ____"

- Our site attempts to maintain standard signature lines on all of our consent forms and will incorporate some form of the following template signature section, depending on the type of study.

Printed Name of Subject's Parent/Legal Guardian
Signature of Subject's Parent/Legal Guardian
Person Obtaining Consent and Assent printed name
Person Obtaining Consent and Assent signature line
LAR printed name – if applicable
LAR signature line – if applicable

- Spanish Boilerplate Language – 14 Child (v09/27/2022)

Pregunta 14: proporcione cualquier otro requisito institucional para documentos de consentimiento informado, como corresponda:

- Nuestro sitio listará el (los) centro(s) de acopio en la portada, por ejemplo Banner University Medical Center - Tucson (AZ017), University of Arizona Cancer Center-North Campus (AZ110), University of Arizona Cancer Center-Orange Grove Campus (AZ128)

- Nuestro sitio incluirá los logotipos y los códigos de barras requeridos de nuestra institución en los encabezados y pies de página de nuestros consentimientos.

- Nuestro sitio hará cualquier cambio de formato necesario debido a la adición de nuestro lenguaje modelo (para asegurar que el consentimiento fluya fácilmente, por ejemplo, que no haya páginas en blanco, que no se dejen instrucciones del sitio en el consentimiento, etc.).

- Nuestro sitio agregará una fecha de versión local al encabezado del formulario de consentimiento aprobado por el CIRB. Se indicará como "Fecha de versión del UACC: ____"

- Nuestro sitio intenta mantener líneas de firma estándar en todos los formularios de consentimiento e incorporará algún formulario con la siguiente plantilla de la sección de firmas, dependiendo del tipo de estudio.

Nombre del padre/tutor legal del sujeto, con letra de imprenta
Firma del padre/tutor legal del sujeto
Nombre en letra de imprenta de la persona que obtiene el consentimiento y asentimiento
Línea de firma de la persona que obtiene el consentimiento y el asentimiento
Nombre del LAR en letra de imprenta (si corresponde)
Línea para la firma del LAR (si corresponde)

- Boilerplate Language - 14 Adult (v12/17/2019_updated 11/3/2022)

Question 14: Provide any other institutional requirements for informed consent documents, if applicable:

- Our site will list the accruing center(s) on the front page, e.g. Banner University Medical Center - Tucson (AZ017), University of Arizona Cancer Center-North Campus (AZ110), University of Arizona Cancer Center-Orange Grove Campus (AZ128), etc.

- Our site will include our institution's required logos and barcodes in the headers and footers of our consents.

- Our site will make any formatting changes necessary due to adding our boilerplate language (to ensure

that the consent flows easily, i.e. there are no blank pages, no site instructions left in the consent, etc.).

- Our site will add a local version date to the header of the CIRB-approved consent form. It will be denoted as "UACC Version Date: ____"

- Our site attempts to maintain standard signature lines on all of our consent forms and will incorporate some form of the following template signature section, depending on the type of study.

  Subject's printed name
  Subject's signature line
  Person Obtaining Consent's printed name
  Person Obtaining Consent's signature line
  LAR printed name – if applicable
  LAR signature line – if applicable

- Spanish Boilerplate Language - 14 Adult (v12/17/2019_updated 11/3/2022)

Pregunta 14: proporcione cualquier otro requisito institucional para documentos de consentimiento informado, como corresponda:

- Nuestro sitio listará el (los) centro(s) de acopio en la portada, por ejemplo Banner University Medical Center - Tucson (AZ017), University of Arizona Cancer Center-North Campus (AZ110), University of Arizona Cancer Center-Orange Grove Campus (AZ128), Yuma Regional Medical Center (AZ081).

- Nuestro sitio incluirá los logotipos y los códigos de barras requeridos de nuestra institución en los encabezados y pies de página de nuestros consentimientos.

- Nuestro sitio hará cualquier cambio de formato necesario debido a la adición de nuestro lenguaje modelo (para asegurar que el consentimiento fluya fácilmente, por ejemplo, que no haya páginas en blanco, que no se dejen instrucciones del sitio en el consentimiento, etc.).

- Nuestro sitio agregará una fecha de versión local al encabezado del formulario de consentimiento aprobado por el CIRB. Se indicará como "Fecha de versión del UACC: ____"

- Nuestro sitio intenta mantener líneas de firma estándar en todos los formularios de consentimiento e incorporará algún formulario con la siguiente plantilla de la sección de firmas, dependiendo del tipo de estudio.

  Nombre del sujeto en letra de imprenta
  Línea para la firma del sujeto
  Nombre de la persona que obtiene el consentimiento, en letra de imprenta
  Línea para la firma de la persona que obtiene el consentimiento

- Boilerplate Language – 14 Adult: Yuma (v12/17/2019_updated11/03/2022)

Question 14: Provide any other institutional requirements for informed consent documents, if applicable:

- Our site will list the accruing center(s) on the front page, e.g. Banner University Medical Center - Tucson (AZ017), University of Arizona Cancer Center-North Campus (AZ110), University of Arizona Cancer Center-Orange Grove Campus (AZ128), Yuma Regional Medical Center (AZ081).

- Our site will include our institution's required logos and barcodes in the headers and footers of our consents.

- Our site will make any formatting changes necessary due to adding our boilerplate language (to ensure that the consent flows easily, i.e. there are no blank pages, no site instructions left in the consent, etc.).

- Our site may add a local version date to the header of the CIRB-approved consent form. It will be denoted as "UACC Version Date: ____" Site will keep the CIRB approval date on the header.

- Our site attempts to maintain standard signature lines on all of our consent forms and will incorporate some form of the following template signature section, depending on the type of study.

  Subject's printed name and date
  Subject's signature line
  Person Obtaining Consent's printed name and date
  Person Obtaining Consent's signature line
  LAR printed name and date– if applicable
  LAR signature line – if applicable

- Boilerplate Language – 14 Adult: Yuma (v12/17/2019_updated11/03/2022)

Pregunta 14: proporcione cualquier otro requisito institucional para documentos de consentimiento informado, como corresponda:

- Nuestro sitio listará el (los) centro(s) de acopio en la portada, por ejemplo Banner University Medical Center - Tucson (AZ017), University of Arizona Cancer Center-North Campus (AZ110), University of Arizona Cancer Center-Orange Grove Campus (AZ128), Yuma Regional Medical Center (AZ081).

- Nuestro sitio incluirá los logotipos y los códigos de barras requeridos de nuestra institución en los encabezados y pies de página de nuestros consentimientos.

- Nuestro sitio hará cualquier cambio de formato necesario debido a la adición de nuestro lenguaje modelo (para asegurar que el consentimiento fluya fácilmente, por ejemplo, que no haya páginas en blanco, que no se dejen instrucciones del sitio en el consentimiento, etc.).

- Nuestro sitio puede agregar una fecha de versión local al encabezado del formulario de consentimiento aprobado por el CIRB. Se denotará como "Fecha de la versión del UACC: ____" El sitio mantendrá la fecha de aprobación por el CIRB en el encabezado.

- Nuestro sitio intenta mantener líneas de firma estándar en todos los formularios de consentimiento e incorporará algún formulario con la siguiente plantilla de la sección de firmas, dependiendo del tipo de estudio.

  Nombre del sujeto en letra de imprenta
  Línea para la firma del sujeto
  Nombre de la persona que obtiene el consentimiento, en letra de imprenta
  Línea para la firma de la persona que obtiene el consentimiento
  Nombre del LAR en letra de imprenta (si corresponde)
  Línea para la firma del LAR (si corresponde)

- Minors are not able to consent to research activities for themselves. Therefore, the parent/legal guardian must give permission to participate in the research and the minor may give assent to participate. The investigator must provide an explanation of how parental permission and minor assent will be obtained. A statement of the proposed method of obtaining parental permission and minor assent along with protocol-specific discussions of the justification of the process must be included for complete IRB review. Minor Assent Assent of a minor participating in research is required, however depending on the age, level of maturity, etc. of each child participating in the study different consent/assent permissions may be approved by the IRB. The IRB does not require the signature of the minor be obtained. In general, the IRB follows these standards: For children under 8 years of age (0-7 years): Formal assent of the child is not a necessary condition for participating in a research protocol. • For children 8 - 13 years of age: Many children have limited capacity to understand what participation in a research protocol means. Nonetheless, the IRB expects that investigators provide to children in this age range developmentally appropriate information about the study. • For children 14 years of age or older: Formal assent is required for participating in a research study.
- If study procedures (including identifiable data analysis) are ongoing when a child turns the age of majority (18 in Arizona), then the child must be re-consented to continue participation in the study as an adult.
- Barcode required on page one of the consent for UACC site (see attachment to review barcode). Barcode not required for Yuma site.
- University of Arizona Cancer Center - COG Follow-up Letter (UACC Version Date: 01/14/2017) provided in English and Spanish [CIRB Attachment -COG FU Letter v1-4-17.doc and CIRB Attachment -COG FU Letter v1-4-17 Spanish.doc]
- University of Arizona Cancer Center - NRG Follow-up Letter (UACC Version Date: 01/14/2017) provided in English and Spanish [CIRB Attachment -NRG FU Letter_1-4-2017.doc and CIRB Attachment -COG FU Letter v1-4-17 Spanish.doc]
- Yuma Regional Medical Center Institutional Research – NRG Follow-up Letter (Version Date: 05/19/2022) [CIRB Attachment -NRG FU Letter_Yuma 5.19.2022.docx and CIRB Attachment -NRG FU Letter_Yuma 5.19.2022 Spanish.doc]
- University of Arizona Cancer Center - SWOG Follow-up Letter (UACC Version Date: 01/14/2017) provided in English and Spanish [CIRB Attachment -SWOG FU Letter v1-4-17.doc and CIRB Attachment -SWOG FU Letter v1-4-17 Spanish.doc]
- Yuma Regional Medical Center Institutional Research – SWOG Follow-up Letter (Version Date: 05/19/2022) [CIRB Attachment -SWOG FU Letter Yuma v5.19.2022.docx and CIRB Attachment -SWOG FU Letter Yuma v5.19.2022 Spanish.doc]

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 - Prevention Research Clinic (AZ163)
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	Southern Arizona Veterans Affairs Health Center (AZ016)
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 support@ncicirbcontact.zendesk.com.

Sincerely,

NCI Pediatric CIRB

cc: Signatory Institution Primary Contact(s)
Signatory Institution Principal Investigator(s)
NCI CIRB Operations Office