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

July 03, 2024

Lara Sloboda PhD
[via Email]

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

Signatory Institution: **Dana-Farber Cancer Institute**

Dear Lara Sloboda,

On July 01, 2024, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for Dana-Farber Cancer Institute received on June 26, 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:

- Boilerplate Language (Version Date: 21DEC2023)

Header:

Dana-Farber Cancer Institute

Operations – NCI CIRB
Office for Human Research Studies

DF/HCC Consent Local Context Language for Studies Relying on the NCI CIRB

This document contains local context language that can be inserted into the NCI CIRB model consent template.

- Instructions are provided in *blue text* and should be removed from the final version of the consent.
- The format and the font type and size should match the model consent for consistency throughout the consent form.
- DF/HCC consent local context language ***must not*** be changed.
- The model consent template signature lines must be used, and the language ***must not*** be removed or revised.
- The DF/HCC signature and date lines must also be used and placed ***after*** the model consent signature lines.

- The DF/HCC Local Institutional and Financial Information should be inserted under the "What are the costs of taking part in this study?" section of the consent form.
- Any additional local context language should be inserted ***before*** the signature line.
- Any additional changes to the consent form (e.g., addition of sharing language, risks, etc.) must be submitted to the NCI CIRB for review on the Study-Specific Worksheet.

DF/HCC Principal and Site Investigator Box

*[DF/HCC research teams are required to include the following DF/HCC principal and site investigator box to the DF/HCC-specific consent form. This box must be included **after** the study title on the first page of the document.]*

DF/HCC Principal Research Doctor / Institution:

DF/HCC Site-Responsible Research Doctor(s) / Institution(s):

[Please insert both local and financial information sections under "What are the costs of taking part in this study?." The following list should be edited to list only the sites included in the specific study. Include only the relevant institutional numbers.]

Local Institution Information

The following is information specific to the local Dana-Farber/Harvard Cancer Center (DF/HCC) institutions.

DF/HCC Financial Information

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services are:

- Beth Israel Deaconess Medical Center: (617) 667-5661
- Boston Children's Hospital: (617) 355-7188
- Brigham and Women's Hospital: (617) 732-5524 or (617) 732-7485
- Brigham and Women's Hospital/Faulkner Hospital: (617) 632-3455
- Dana-Farber Cancer Institute: (617) 632-3455
- Massachusetts General Hospital: (617) 726-2191
- Dana-Farber/Brigham and Women's Cancer Center (DF/BWCC) in clinical affiliation with South Shore Hospital: (781) 624-4329
- Dana-Farber/Brigham and Women's Cancer Center (DF/BWCC) at Milford Regional Medical Center: (508) 422-2970
- Dana-Farber Cancer Institute at Foxborough: (617) 632-3455
- Dana-Farber Cancer Institute at Merrimack Valley: (978) 620-2020
- Dana-Farber Cancer Institute at Steward St. Elizabeth's Medical Center: (800) 664-3884
- Massachusetts General Hospital/North Shore Cancer Center: (617) 726-2191
- Massachusetts General Hospital at Newton Wellesley Hospital (617) 726-3884
- Massachusetts General Hospital/Emerson (978) 287-3432
- Cape Cod Healthcare: (508) 862-7575
- Dana-Farber/New Hampshire Oncology-Hematology, P.A.: (603) 622-6484

Emergency Contact Information

[For pediatric studies only, please include the following emergency contact information in the section labeled, "Where can I get more information]

Dana-Farber Cancer Institute – weekdays 8am – 5pm: Call 617-632-3270 and ask for the on-call pediatric [insert ONCOLOGY FOR ONCOLOGY TRIALS / STEM CELL TRANSPLANT FOR HSCT OR CART TRIALS] provider.

Dana-Farber Cancer Institute – weekdays after 5pm, weekends and holidays: Call 617-632-3352 and ask for the on-call pediatric [insert ONCOLOGY FOR ONCOLOGY TRIALS / STEM CELL TRANSPLANT FOR HSCT OR CART TRIALS] provider.

Institutional Conflict of Interest (ICOI) Language

[*If ICOI disclosure language has been mandated by the Office for Research Integrity (ORI), please insert into the model consent document at the end of the body of the consent and before the signature block.]*

Any ICOI documents and consent disclosure language must be submitted to the NCI CIRB for review on the Study-Specific Worksheet.

Documentation of Consent and Assent

[Please insert the following "Documentation of Assent" after the COG Model Signature Lines. The "Signature of Participant between the age of 10 to 18" language may be revised to the age range specified in your study.]

Documentation of Assent:

_____ _____

Signature of Participant between the age of 10 to 18. Date

To be completed by person obtaining assent:

The assent discussion was initiated on _____ (date).

Signature of individual obtaining assent: _____

Printed name of above: _____

Date: _____

[Include the following signature lines following the NCI CIRB model consent signature lines.]

To be completed by person obtaining consent:

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

Signature of Interpreter: _____

Signature of Witness: _____
Interpreter may also serve as Witness if present

Printed name of Interpreter: _____

Printed name of Witness: _____

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:

- Boilerplate Language – Spanish (Version Date: 21DEC2023)

Header:

Dana-Farber Cancer Institute

Operaciones – CIRB de NCI
Oficina para Estudios de Investigación Humana

Lenguaje de contexto local de consentimiento de DF/HCC para estudios que dependen de CIRB de NCI

This document contains local context language that can be inserted into the NCI CIRB model consent template.

- Instructions are provided in *blue text* and should be removed from the final version of the consent.
- The format and the font type and size should match the model consent for consistency throughout the consent form.
- DF/HCC consent local context language ***must not*** be changed.
- The model consent template signature lines must be used, and the language ***must not*** be removed or revised.
- The DF/HCC signature and date lines must also be used and placed ***after*** the model consent signature lines.
- The DF/HCC Local Institutional and Financial Information should be inserted under the “What are the costs of taking part in this study?” section of the consent form.
- Any additional local context language should be inserted ***before*** the signature line.
- Any additional changes to the consent form (e.g., addition of sharing language, risks, etc.) must be

submitted to the NCI CIRB for review on the Study-Specific Worksheet.

DF/HCC Principal and Site Investigator Box

*[DF/HCC research teams are required to include the following DF/HCC principal and site investigator box to the DF/HCC-specific consent form. This box must be included **after** the study title on the first page of the document.]*

Médico investigador principal de DF/HCC / Institución:

Médico(s) investigador(es) responsable(s) en el centro de DF/HCC / Institución(es):

[Please insert both local and financial information sections under "What are the costs of taking part in this study?." The following list should be edited to list only the sites included in the specific study. Include only the relevant institutional numbers.]

Información de la institución local

La siguiente es información específica de las instituciones locales de Dana-Farber/Harvard Cancer Center (DF/HCC).

Información financiera DE DF/HCC

Si tiene preguntas sobre la cobertura de su seguro o sobre los artículos por los que posiblemente deba pagar, llame a servicios financieros para obtener información. Información de contacto de servicios financieros:

- Beth Israel Deaconess Medical Center: (617) 667-5661
- Boston Children's Hospital: (617) 355-7188
- Brigham and Women's Hospital: (617) 732-5524 o (617) 732-7485
- Brigham and Women's Hospital/Faulkner Hospital: (617) 632-3455
- Dana-Farber Cancer Institute: (617) 632-3455
- Massachusetts General Hospital: (617) 726-2191
- Dana-Farber/Brigham and Women's Cancer Center (DF/BWCC) en asociación clínica con South Shore Hospital: (781) 624-4329
- Dana-Farber/Brigham and Women's Cancer Center (DF/BWCC) en Milford Regional Medical Center: (508) 422-2970
- Dana-Farber Cancer Institute en Foxborough: (617) 632-3455
- Dana-Farber Cancer Institute en Merrimack Valley: (978) 620-2020
- Dana-Farber Cancer Institute en Steward St. Elizabeth's Medical Center: (800) 664-3884
- Massachusetts General Hospital/North Shore Cancer Center: (617) 726-2191
- Massachusetts General Hospital en Newton Wellesley Hospital (617) 726-3884
- Massachusetts General Hospital/Emerson (978) 287-3432
- Cape Cod Healthcare: (508) 862-7575
- Dana-Farber/New Hampshire Oncology-Hematology, P.A.: (603) 622-6484

Emergency Contact Information
[For pediatric studies only, please include the following emergency contact information in the section labeled, "Where can I get more information]

Dana-Farber Cancer Institute, de lunes a viernes de 8 a. m. a 5 p. m.: Llame al 617-632-3270 y pregunte por el proveedor pediátrico de guardia [insertar ONCOLOGÍA PARA ENSAYOS DE ONCOLOGÍA / TRASPLANTE DE CÉLULAS MADRE PARA ENSAYOS DE HSCT O CART].

Dana-Farber Cancer Institute, de lunes a viernes después de las 5 p. m., fines de semana y feriados: Llame al 617-632-3352 y pregunte por el proveedor pediátrico de guardia [insertar ONCOLOGÍA PARA ENSAYOS DE ONCOLOGÍA / TRASPLANTE DE CÉLULAS MADRE PARA ENSAYOS DE HSCT O CART].

Lenguaje de Conflicto de intereses institucional (ICOI)

[If ICOI disclosure language has been mandated by the Office for Research Integrity (ORI), please insert into the model consent document at the end of the body of the consent and before the signature block.]

Any ICOI documents and consent disclosure language must be submitted to the NCI CIRB for review on the Study-Specific Worksheet.

Documentation of Consent and Assent

[Please insert the following "Documentation of Assent" after the COG Model Signature Lines. The "Signature of Participant between the age of 10 to 18" language may be revised to the age range specified in your study.]

Documentación de asentimiento:

_____ _____
Firma del participante que tiene entre 10 y 18 años. Fecha

Para ser completado por la persona que obtiene el asentimiento:

La conversación sobre el asentimiento se inició el _____ (fecha).

Firma de la persona que obtiene el asentimiento: _____

Nombre en letra de imprenta de la persona antedicha: _____

Fecha: _____

[Include the following signature lines following the NCI CIRB model consent signature lines.]

Para ser completado por la persona que obtiene el consentimiento:

La conversación sobre el consentimiento se inició el _____ (fecha).

Firma de la persona que obtiene el consentimiento: _____

Nombre en letra de imprenta de la persona antedicha: _____

Fecha: _____

Firma del intérprete: _____

Firma del testigo: _____
El intérprete también puede desempeñarse como testigo si está presente

Nombre en letra de imprenta del intérprete: _____

Nombre en letra de imprenta del testigo: _____
Fecha: _____

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

- Assent will be documented within the main consent document using the DF/HCC Assent template (included in the standard DF/HCC signature block for all pediatric studies) language which is included in the boilerplate language.
- CONSENT FOR CONTINUED PARTICIPATION IN A RESEARCH STUDY BY A YOUNG ADULT WHO HAS REACHED AGE 18, (Date DFCIRB Approved this Consent Form: March 18, 2008, Date Posted for Use: April 8, 2008) [Consent Form - Age of Majority - version 04.04.2008.doc] for participants who turn 18 years of age and are no longer in active treatment but enrolled in one (1) or more studies that require ongoing follow-up. When consenting to the Age of Majority consent, the participant is provided a copy of the originally signed consent form. However, it is not an institutional requirement for DF/HCC research teams to use the Age of Majority consent. The alternative is to use the original consent form to re-consent at the age of majority.
- Short Form Consent to Participate in a Research Study (version 1/21/2019) [Short Form Consent Form - English - version 01-21-2019.pdf] has been translated into the following languages: Albanian, Amharic, Arabic, Armenian, Bengali, Bulgarian, Cambodian (Khmer), Farsi, French European, German, Greek, Haitian, Hebrew, Hindi, Italian, Japanese, Korean, Nepali, Polish, Portuguese Brazilian, Portuguese European, Romanian, Russian, Serbo-Croatian, Simplified Chinese, Somali, Spanish, Tagalog, Thai, Turkish, and Vietnamese.
- English Addendum to the Short Form Consent to Participate in a Research Study, [Addendum - English - version 12-31-2012.doc] has been translated into the following languages: Albanian, Amharic, Arabic, Armenian, Brazilian Portuguese, Bulgarian, Cambodian (Khmer), European Portuguese, Farsi, French European, Greek, Haitian, Creole, Hindi, Italian, Japanese, Korean, Nepali, Polish, Russian, Somali, Spanish, Thai, Turkish, Vietnamese (translations certified 12/31/12), Bengali (translation certified 2/25/2014), German (translation certified 9/16/2016), Hebrew, (translation certified 5/20/2013), Romanian (translation certified 6/17/2015), Tagalog (translation certified 1/13/2016)
- As of January 31, 2020, any new DF/HCC studies or modifications to pre-existing studies to add a new DF/HCC participating site requires a separate Study-Specific Worksheet (SSW) and Form FDA 1572 for each DF/HCC participating institution. In addition, the principal investigator at each DF/HCC institution must sign a separate SSW and Form FDA 1572. Each investigator is responsible for the oversight and conduct of research at their respective institution.

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	Beth Israel Deaconess Medical Center (MA038)
2	Boston's Children's Hospital (MA052)
3	Brigham and Women's Hospital (MA037)
4	Dana Farber-Merrimack Valley (MA198)
5	Dana-Farber Cancer Institute - Chestnut Hill (MA201)
6	Dana-Farber Cancer Institute at Foxborough (MA202)
7	Dana-Farber/Brigham and Women's Cancer Center at Milford Regional (MA188)
8	Dana-Farber/Brigham and Women's Cancer Center at South Shore (MA185)
9	Dana-Farber/Harvard Cancer Center (MA036)
10	Mass General/North Shore Cancer Center (MA093)
11	Massachusetts General Hospital Cancer Center (MA034)
12	Steward Saint Elizabeth's Medical Center (MA049)
13	The Dana-Farber Cancer Institute at Londonderry (NH043)

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	Boston Children's Hospital (MA042)
2	Cape Cod Hospital (MA078)
3	Emerson Hospital/MGH Cancer Center (MA100)
4	Newton-Wellesley Hospital (MA056)

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