

April 15, 2020

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 PhD,

On April 14, 2020, the NCI Pediatric CIRB reviewed and approved the Annual Signatory Institution Worksheet About Local Context for Dana-Farber Cancer Institute received on April 8, 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: 04/7/2020



Dana-Farber
Cancer Institute

Operations – Single IRB

Office for Human Research Studies

DF/HCC Consent Local Context Language for Studies Relying on an External Single IRB (sIRB)

This document contains consent local context language that can be inserted into the External sIRB approved consent template document at the end of the model consent document, **before** the signature line.

- DF/HCC consent local context language **may not** be changed.
- Instructions are provided in blue text and should be removed from the final version of the consent
- The model consent template signature block must be used and the language may not be removed or revised.
- The format and the font type and size will match the model consent for consistency throughout the document

- Any additional changes to the consent document (e.g., addition of sharing language, risks, etc.) must be submitted to the NCI CIRB for review on the Study-Specific Worksheet.

ODQ will add the following administrative header and footer when the consent document is posted to OncPro.

Research Consent Form for External Reviewed Research
Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH

OHRs 10.04.2018

DFCI Protocol:	Acknowledged by DFCI IRB:	Date Posted for Use:
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[Please add the following box listing the DF/HCC PI and Site PI to Page 1, following the study title.]

DF/HCC Principal Research Doctor / Institution:

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

Local Institution Information:

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

[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.

DF/HCC Financial Information

[The following list should be edited to list only the sites included in the specific study. Include only the relevant institutional numbers]

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 Steward St. Elizabeth's Medical Center: (800) 664-3884
- Massachusetts General Hospital/North Shore Cancer Center: (978) 882-6319
- Massachusetts General Hospital at Newton Wellesley Hospital (617) 243-6392
- The Lawrence. & Memorial Cancer Center in affiliation with Dana-Farber Community Cancer Care: (860) 442-0711 ext. 4702
- Cape Cod Healthcare: (508) 862-7575
- New Hampshire Oncology-Hematology, P.A.: (603) 622-6484

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:

- Consent for Continued Participation in a Research Study by a Young Adult Who Has Reached Age 18 – Date of DFCI IRB approval: March 18, 2008
- English Short Form (01/04/2016): translations: Bengali, Hebrew, and Romanian
- English Short form (01/15/2016): Albanian, Amharic, Arabic, Armenian, Brazilian Portuguese, Bulgarian, Cambodian-Khmer, Chinese – Simplified, Brazilian Portuguese, European Portuguese, Farsi, French, Greek, Haitian Creole, Hindi, Italian, Japanese, Korean, Nepali, Polish, Russian, Serbo-Croatian, Somali, Tagalog, Spanish, Thai, Turkish, and Vietnamese
- English Addendum to Short Form (12/31/2012) translations: Arabic, Amharic, Albanian, Armenian, Bulgarian, Cambodian (Khmer), Simplified Chinese, Farsi, European French, Greek, Haitian, Hindi, Italian, Japanese, Korean, Polish, Brazilian Portuguese, European Portuguese, Russian, Serbo-Croatian, Somali, Spanish, Thai, Turkish, Vietnamese, Nepali, Hebrew (5/20/2013), German (9/16/2016), Bengali (2/25/2014), Romanian (6/17/2015), Tagalog (1/13/2016)

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/Brigham and Women's Cancer Center at Milford Regional (MA188)
5	Dana-Farber/Brigham and Women's Cancer Center at South Shore (MA185)
6	Dana-Farber/Harvard Cancer Center (MA036)
7	Mass General/North Shore Cancer Center (MA093)
8	Massachusetts General Hospital Cancer Center (MA034)
9	Steward Saint Elizabeth's Medical Center (MA049)
10	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	Cape Cod Hospital (MA078)
2	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 ncicirbcontact@emmes.com.

Sincerely,

NCI Pediatric CIRB

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

