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 , ***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 lines must be used, and the language may 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 format and the font type and size should match the model consent for consistency throughout the consent form.
- 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.

External IRB Header and Footer

The Office for Human Research Studies (OHRS) will add the administrative header during the facilitated review process. The Office for Data Quality (ODQ) will add the footer at the time of activation prior to it being posted to OncPro.

Header

[The header is added to the DF/HCC-specific consent form one (1) inch from the top of the page to ensure that the MRN box and time stamp do not overlap any of the consent language.]

Research Consent Form for External Reviewed Research
Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH OHRS 10.04.2018

Footer

[The footer is added at below the page numbers.]

DFCI Protocol:	Acknowledged by DFCI IRB:	Date Posted for Use:

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):

Local Institution Information

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

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.

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: (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

[The "Signature of Participant between the age of 10 to 18" language may be revised to the age range age range specified in your study. If you need to revise the age range, please do so by making this revision in the Study-Specific Worksheet.]

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 these signature lines at the 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: _____

Interpreter/Witness Signature:

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

Witness Signature:

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____