Required Informed Consent Language for External Sites Participating in DF/HCC Multi-Center Protocols Under a local IRB

This document describes Health and Human Services (HHS) Revised Final Common Rule consent form requirements for research reviewed by the DFCI IRB on or after January 21, 2019 and led by the Dana-Farber Harvard Cancer Center (DF/HCC). External sites participating in DF/HCC investigator-sponsored, multi-center human subject research under their own IRB are expected to include this language in their local consent forms as described below. The DF/HCC Sponsor is ultimately responsible for ensuring that external participating sites meet the DF/HCC requirements for informed consent language, as described below and in accordance with MULTI-100.

In general, participating site informed consent authors should avoid changing DF/HCC consent form text except where it is not relevant or appropriate to a specific site.

External participating sites (e.g. non-DF/HCC and Dana-Farber/Partners CancerCare affiliates) are required to retain the consent form language as described below in red.

Header and Footer. External sites may change the Header and Footer as applicable to their site.

Title Box. External sites may change the Title Box as applicable to their site.

INTRODUCTION AND KEY INFORMATION - External sites may change this language, but it is strongly recommended to keep the general language and formatting as written. If the language and/or formatting is edited, please ensure that this section presents a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative (LAR) in understanding the reasons why one might or might not want to participate in the research. The information must be presented in a way that facilitates comprehension and is consistent with the protocol document.

A. WHY IS THIS RESEARCH STUDY BEING DONE? - External sites may change this language as long as information about phases is included and the information remains consistent with the protocol document.

B. WHAT OTHER OPTIONS ARE THERE? - External sites may NOT change this language unless a treatment is not available at the institution. External sites may ADD language, if necessary.

C. WHAT IS INVOLVED IN THIS RESEARCH STUDY? – External sites may add, edit or reorganize the content, as long as it remains consistent with the protocol document. External sites CANNOT delete procedures.

D. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY? – External sites may add risks, combine risks together, make risks more frequent (not less) or add more descriptive language. External sites CANNOT delete risks without local IRB justification. External sites must include a section that informs participants that they will be notified of newly discovered side effects or significant findings.

External Sites must contact their DF/HCC sponsor contact with any questions regarding language in this section. DF/HCC Sponsors may Contact OHRS for further assistance with this section.

E. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH? External sites may edit this language as needed, but the information regarding the FDA and what will happen to samples and data in the case of withdrawal must be accounted for and consistent with the protocol.

F. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY? External sites may NOT change this language.

External Sites must contact the DF/HCC sponsor contact with any questions regarding language in this section. DF/HCC Sponsor may contact OHRS for further assistance with this section.

G. WHO IS SUPPORTING THIS RESEARCH? External sites may NOT change this language, with the exception of any conflict of interest language that is either applicable or not applicable. For studies that receive any industry funding, the sponsor should be identified as "*Dana Farber/Partners CancerCare on behalf of Dana Farber/Harvard Cancer Center"*.
For studies receiving funding from other groups, the sponsor should be identified as the lead DF/HCC institution (i.e. MGH, DFCI, BIDMC) on behalf of DF/HCC.

External Sites must contact their DF/HCC sponsor contact with any questions regarding language in this section. DF/HCC Sponsor may contact their contracts office for further assistance with this section.

H. WHAT ARE YOUR COSTS? External sites may change language. External sites must not have any language that suggests the DF/HCC Investigator-sponsor or any DF/HCC institution has any responsibility for covering costs.

External Sites must contact their DF/HCC sponsor contact with any questions regarding language in this section. DF/HCC Sponsor may contact their Clinical Trials Business Office for further assistance this section.

I. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY? External sites may add language. External sites CANNOT delete the DFCI IRB language regarding no plan or policy. The language in this section must be consistent with the terms of the subcontract with the multi-center institution. The subcontract states: in the event of physical injury resulting from study participation no form of compensation is available from Dana-Farber Partners Cancer Care. Medical treatment may be provided at the patient's own expense, or at the expense of the health care insurer which may or may not provide coverage.

External Sites must contact their DF/HCC sponsor contact with any questions regarding language in this section. DF/HCC Sponsor may contact their contracts office for further assistance with this section.

J. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY? External sites may change this language to include local contact information for the site investigators and the reviewing IRB.

K. RETURN OF RESEARCH RESULTS. External sites may change this language, but the information must be accounted for and consistent with the protocol.

L. CLINICALTRIALS.GOV (CT.GOV). For all Clinical Trials registered on clinicaltrials.gov the following language must NOT be revised and must be included in the participating site's consent document: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

M. FUTURE USE OF DATA AND SPECIMENS. External sites may edit this language, but the information must be accounted for and consistent with the protocol.

N. CONFIDENTIALITY. External Sites may change this language, but the information regarding the sharing of de-identified data with collaborators must be accounted for and consistent with the protocol if applicable.

O. CERTIFICATE OF CONFIDENTIALITY (COC). External sites may not change this language. It must be included if a Certificate of Confidentiality has been automatically issued by the NIH or if one has been otherwise obtained from the government.

P. GENETIC RESEARCH. External sites may change the language if it does not pertain to their site. The information must be accounted for and consistent with the protocol. External sites may not change the language about Genetic Information Nondiscrimination Act of 2008 when included. External sites may not change the language about sharing data with the NIH Database for Genotypes and Phenotypes (dbGaP) when included.

Q. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION). External sites may change this language to match local HIPAA Authorization language. The HIPAA authorization for research, whether added to the consent form or provided to subjects separately, must include a statement that protected health information (PHI) data will be shared with the DF/HCC Investigator-sponsor or its agents which may include an outside CRO, medical monitor, and collaborators. This section must also identify what types of PHI will be shared and a timeline for retaining PHI. State laws vary on timeline requirements, so the Lead site designee must ensure that inclusion of an expiration date won't restrict DF/HCC access to the data. Note: This also applies to a standalone authorization form, if applicable.

R. CONSENT TO OPTIONAL RESEARCH STUDIES. External sites may change this language when it does not apply to their site. As applicable, optional study procedures should be briefly described, and participants should have an option to agree to participate (Opt In) or decline participation (Opt Out) in these optional procedures/studies.

Signature Page. External sites may change the signature page as applicable to their site.