

Model Consent Language for PI-Initiated Multi-Center Protocols

Note: Informed consent authors should avoid changing DF/HCC recommended text except where it is not relevant or appropriate to a specific protocol. Specific requirements for retaining DF/HCC consent form language are noted below.

A. Introduction - External sites may change this language. It is recommended that the sponsor of the trial be identified in this section or elsewhere within the consent document. The sponsor should be identified as the lead DF/HCC institution (i.e. MGH, DFCI, BIDMC) on behalf of DF/HCC.

B. Why Is This Research Study Being Done? - External sites may change this language as long as information about phases is included.

C. 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.

D. 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, but CANNOT delete procedures.

E. How Long Will I Be In This Research Study? - External sites may change this language as long as it remains consistent with the protocol document.

F. 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 but 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.

Contact OHRS at 617-632-3029 with any questions regarding language in this section.

G. What Are The Benefits of The Research Study? - External sites can edit this language. Overall Site designee must ensure this section is reviewed for exculpatory language.

Contact OHRS at 617-632-3029 with any questions regarding language in this section.

H. Can I Stop Being In The Research Study and What Are My Rights? - External sites may change this language.

I. What Are The Costs? External sites may change language but cannot have any language that suggests the DF/HCC PI or any DF/HCC institution has any responsibility for covering costs.

Contact the Clinical Trials Business Office (CTBO) at 617-632-7645 with any questions regarding language in this section..

J. What Happens If I Am Injured or Sick Because I Took Part In This Research Study? – External sites may add language but 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 DFHCC. 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.

Contact Mary Melloni at 617-632-4192 with any questions regarding language in this section..

K. What About Confidentiality? – External Sites may change this language.

Contact OHRS at 617-632-3029 with any questions regarding language in this section..

L. Certificate of Confidentiality – External sites may change this language and it should only be included if a Certificate of Confidentiality is obtained from the government.

M. Whom Do I Contact If I Have Questions About The Research Study – External sites may change this language.

N. Privacy of Protected Health Information – External sites may change this language; however the research consent document must include a statement that private health information (PHI) data will be shared with the sponsor or its agents which may include an outside CRO, medical monitor, and DF/HCC. 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 stand alone authorization form, if applicable.

Contact OHRS at 617-632-3029 with any questions regarding language in this section..