

**Multi-Center Coordinating Committee (MCC)
PI-Initiated Multi-Center Protocol
Information for External Sites**

Version: April 2009

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DFCI Institutional Review Board Adverse Event Reporting Policy

The DFCI IRB requires the following events be reported:

- **Grade 2 (moderate) and Grade 3 (severe) Events** – Only events that are Unexpected and Possibly, Probably or Definitely Related/Associated with the Intervention.
- **ALL Grade 4 (life threatening or disabling) Events** – Unless expected AND specifically listed in protocol as not requiring reporting.
- **ALL Grade 5 (fatal) Events** – When subject is enrolled and actively participating in the trial OR when event occurs within 30 days of the last study intervention.

Notes:

- If subject is in Long Term Follow Up, death is reported at continuing review.
- See protocol for additional reporting requirements (to sponsor, FDA, etc.).

DFCI IRB Reporting Forms:

When reporting adverse events to the DFCI IRB, one of the following forms MUST be used.

1. Serious Adverse Event Reporting Form:

http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/OPRS/Forms_Instructions/Post_Activation/SAE_Reporting.doc

The SAE Reporting Form must be used to report SAEs experienced by DF/HCC participants enrolled in a DF/HCC study including any serious adverse events on DF/HCC led Multi-Center trials where the event occurs at a non-DF/HCC site.

Full written SAE report must be submitted to OHRS as soon as possible, but no later than **10 working days** from notification of event. Reports must be submitted via OHRS Submit. No interoffice submissions, faxes or e-mail notifications of SAEs will be accepted.

a. Follow Up SAE Reports:

When submitting follow up reports to previously reported SAEs, **attach a copy of the original report and any prior IRB determinations to the follow up report.** This gives the reviewer all the information required to conduct a thorough review and eliminates questions that might otherwise be raised.

2. AdEERS Reporting Form:

[https://webapps.ctep.nci.nih.gov/openapps/plsql/gadeers_main\\$.startup](https://webapps.ctep.nci.nih.gov/openapps/plsql/gadeers_main$.startup)

The NCI AdEERS form may be used in place of the DFCI IRB SAE Reporting Form for NCI or Cooperative Group studies only. AdEERS will automatically file the report with the respective cooperative group. If the AdEERS form is used, the OHRS must be included on the e-mail (ohrs@dfci.harvard.edu) to the NCI. AdEERS reports must be submitted to OHRS as soon as possible, but no later than 10 working days from notification of event.

The following information **MUST** be included in the e-mail and within the description section of the AdEERS form:

1. DF/HCC Protocol Number
2. DF/HCC Overall Principal Investigator's Full Name

If the PI determines that the adverse event warrants a change to the protocol and/or consent form document(s) the completed AdEERS report must be submitted via OHRS Submit along with an amendment form. The AdEERS report must be attached to the amendment form as supporting documentation for the IRB to review.

a. Follow Up AdEERS Reports:

When submitting follow up reports to previously reported AdEERS, **attach a copy of the original report and any prior IRB determinations to the follow up report.** This gives the reviewer all the information required to conduct a thorough review and eliminates questions that might otherwise be raised.

Other Reporting Requirements:

PI-Initiated/Sponsor holds IND

The sponsor-investigator, as the holder of the IND/IDE, is responsible for reporting serious adverse events directly to the FDA. In addition to the FDA Form #3500a (Mandatory Medwatch Form), the DF/HCC PI may also be required to complete a form supplied by the sponsor. The DFCI IRB reporting requirements may differ from the sponsors. DF/HCC investigators must comply with both.

Industry Sponsored (Investigational)

In addition to the DFCI IRB SAE reporting form, the DF/HCC PI may also be required to complete a form supplied by the sponsor. The DFCI IRB reporting requirements may differ from the sponsor. DF/HCC investigators must comply with both.

Industry Sponsored (Commercial)

The FDA's MedWatch Online form, #3500, may be used to voluntarily report serious adverse events, potential and actual medical product errors, and product quality problems associated with the use of FDA-regulated drugs, biologics, devices and dietary supplements. The sponsor of the trial, however, may have its own form.

Human Gene-Transfer Studies

The PI must report all applicable adverse events to the NIH/OBA per the OBA Guidelines outlined in Appendix M-I-C-4:

http://www4.od.nih.gov/oba/RAC/guidelines_02/Appendix_M.htm

Additional information about Human Gene-Transfer Reporting requirements can be found in section 25.9 of the DF/HCC Guide to Human Research Activities (Revised August 2006).

Additional Resources:

Common Toxicity Criteria for Adverse Events v.3.0 (CTCAE):

<http://safetyprofiler-ctep.nci.nih.gov/CTC/CTC.aspx>

OHRs Policy & Procedure for DEVIATION/VIOLATION/EXCEPTION REPORTING TO DFCI IRB

During the conduct of the study, changes to the protocol may be proposed or unintentional changes in the conduct of the study may be discovered. Changes to the IRB-approved protocol, planned or otherwise, are governed by:

- Federal and state regulations
- Dana-Farber/Harvard Cancer Center (DF/HCC) Standard Operating Procedures (SOPs) for Clinical Research

Federal regulations specifically require the IRB of record to review proposed changes in a **research activity**, and to ensure that such changes in approved research are not initiated without prospective IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject [45 CFR Part 46.103(b)(4)(iii) and 21 CFR Part 56.108(a)(4)]. Investigators are also responsible for conducting human subjects research in accordance with:

- Dana-Farber Cancer Institute (DFCI) Institutional Review Board (IRB) reviews and determinations
- DFCI IRB Policies and Procedures for the Protection of Human Subjects in Research
- Quality Assurance Office for Clinical Trials (QACT) requirements
- All applicable Regulatory Sponsor requirements

Non-compliance with IRB reviews and determinations, DFCI IRB policies and procedures, QACT requirements, DF/HCC SOPs or sponsor requirements during the conduct of a research study results in a **protocol deviation, violation or exception** and as such must be reported to the DFCI IRB.

The following reference information is provided below:

- Definitions of key terms
- Overview of specific reporting requirements
- Examples of major and minor deviations, violations and exceptions

Note: Planned ongoing protocol changes (amendments) to an IRB-approved protocol must be submitted as a formal protocol amendment and not as a protocol deviation.

DEFINITIONS

The following definitions apply throughout this guidance document:

Research Activity: All aspects of the conduct of the research study outlined in the protocol submission and reviewed and approved by the IRB, e.g., recruitment methods, consent process, treatment plan, data collection, procedures used to protect privacy and confidentiality, etc.

Protocol Deviation: Any departure from the defined procedures set forth in the IRB-approved protocol.

Protocol Exception: Any protocol deviation that relates to the eligibility criteria, e.g., enrollment of a subject who does not meet all inclusion/exclusion criteria.

Protocol Violation: Any protocol deviation that was not prospectively approved by the IRB prior to its initiation or implementation.

- **Major Deviation/Violation:** a deviation or violation that impacts the risks and benefits of the study; may impact subject safety, affect the integrity of study data and/or affect subject's willingness to participate in the study.
- **Minor Deviation/Violation:** a deviation or violation that does not impact subject safety, compromise the integrity of study data and/or affect subject's willingness to participate in the study.

REPORTING REQUIREMENTS

It is the responsibility of the Principal Investigator (PI) to determine whether a deviation or violation is major or minor and to ensure proper reporting to the IRB. Reports of protocol deviations, violations and exceptions should be submitted to the sponsor as outlined in the sponsor's protocol.

All **protocol exceptions** must be requested of the IRB prior to subject enrollment using the **DFCI IRB - MAJOR DEVIATION/VIOLATION/EXCEPTION FORM** found on the OHRS website.

All **major violations** must be reported to the IRB within ten (10) working days of discovery using the **DFCI IRB - MAJOR DEVIATION/VIOLATION/EXCEPTION FORM** found on the OHRS website.

All **major deviations** must be reported to the IRB within five (5) working days of when it is known that a deviation from the protocol is anticipated using the **DFCI IRB - MAJOR DEVIATION/VIOLATION/EXCEPTION FORM** found on the OHRS website. Whenever possible, major deviations should be reported two to three (2-3) days before the event date so that the IRB has sufficient time to review and take action.

All **minor deviations** need not be submitted to the IRB for prospective review. Rather, they should be documented using the **DFCI IRB – DEVIATION/VIOLATION LOG**. The log can be found on the OHRS website.

- For sponsored trials, proper documentation of sponsor acknowledgement and/or approval for each minor deviation is required and should be kept with the log.
- Three or more minor deviations of the same type are considered a major violation and must be submitted to the IRB via the Major Deviation Form.

All **minor violations** are to be documented using the **DFCI IRB – DEVIATION/VIOLATION LOG** and submitted to the DFCI IRB at continuing review. The log can be found on the OHRS website.

Minor Events Reported at Multiple DF/HCC institutions

The overall study team is responsible for maintaining the minor deviation/violation log for all DF/HCC sites participating in the study and **submitting it to the IRB with the continuing review form**. A protocol that is approved and taking place at more than one site is still considered one protocol.

Example: Protocol 09-999 is approved to be conducted BIDMC, DFCI and MGH. The overall PI is at MGH. At BIDMC, the study team failed to take the vital signs of subject x; at MGH the study team failed to take the vital signs of subject y; and at DFCI, the study team failed to take the vital signs of subject z. The latter missed vital sign is now the third minor violation of the same type for the study – missed vital signs. There is now one major violation that must be reported to the IRB by the overall PI with 10 working days of discovery.

Note: Any permanent change to the protocol constitutes an amendment that must be submitted to the IRB for approval prior to initiation.

EXAMPLES

Major Deviations and Violations

This list of examples is intended as a guide and is not all-inclusive:

- Failure to obtain informed consent, i.e., there is no documentation of informed consent
- Informed consent obtained after initiation of study procedures
- Inappropriate documentation of informed consent, including:
 - missing subject signature
 - missing investigator signature
 - copy not given to the person signing the form
 - someone other than the subject dated the consent form
 - Informed consent for therapeutic studies obtained by someone other than individuals authorized to obtain consent, e.g. someone other than a licensed physician investigator
 - Use of invalid consent form, i.e. consent form without IRB approval stamp, or outdated/expired consent form
- Enrollment of a subject who did not meet all inclusion/exclusion criteria
- Performance of a study procedure not approved by the IRB
- Failure to report serious adverse event to the IRB and/or sponsor
- Failure to perform a required study visit or procedure that, in the opinion of the PI, may affect subject safety or data integrity
- Study visit or procedure is conducted outside of required timeframe that, in the opinion of the PI, may affect subject safety or data integrity
- All drug/study medication dispensing or dosing errors
- Breaches of confidentiality
- Inappropriate destruction of study records
- Failure to follow safety monitoring plan

- Over-enrollment to a protocol
- Repeated or continued negligence in performance of study procedures
- Repeated or continued inability of a subject to comply with the research activity
- Dosing or treatment plan change with the potential for altered therapeutic efficacy and/or adequate evaluation of toxicity
- The number of missed oral medication doses indicates a problem with compliance with study procedures on the part of the subject, a problem with the ability of the study staff to monitor subject compliance, and/or the number of missed oral doses impacts the risk/benefit ratio.
- Enrollment of subjects after IRB-approval of study has expired
- Failure to submit continuing review application to the IRB before study expiration
- 3 or more minor deviations for the same subject
- 3 or more minor deviations of the same type

Examples of when to report a Major Deviation or Violation with **missed oral medications** or a **missed day of treatment** with a continuous therapy:

Type of Therapy:	Cycle or Tx Time Period:	Number of Missed doses or days of treatment
Daily Oral Medication	22-28 Days	More than 3 doses missed in that time period
	15-21 Days	More than 2 doses missed in that time period
	6-14 Days	More than 1 dose missed in that time period
	1-5 Days	Any doses are missed in that time period
Continuous Therapy	28-44 Days	More than 3 days of treatment missed
	15-27 Days	More than 2 days of treatment missed
	6-14 Days	More than 1 day of treatment missed
	5 Days or Less	Any Days of treatment are missed

Minor Deviations and Violations

This list of examples is intended as a guide and is not all-inclusive:

- Implementation of unapproved recruitment procedures
- Missing original signed and dated consent form (only a photocopy available)
- Missing pages of executed consent form
- Failure to follow the approved study procedure that, in the opinion of the PI, does not affect subject safety or data integrity:
 - Study procedure conducted out of sequence
 - Omitting a IRB approved research activity on a protocol (e.g. mailing out or collecting QOL surveys, evaluating and documenting performance status)
 - Failure to perform a required lab test
 - Missing lab results
 - Study visit conducted outside of required timeframe
- Failure of subject to return study medication

Examples of when to report a Minor Deviation or Violation with **missed oral medications** or a **missed day of treatment** with a continuous therapy:

Type of Therapy:	Cycle or Tx Time Period:	Number of Missed doses or days of treatment:
Daily Oral Medication	22-28 Days	3 or fewer doses missed in that time period
	15-21 Days	2 or fewer doses missed in that time period
	6-14 Days	1 dose is missed in that time period
Continuous Therapy	28-44 Days	3 or fewer days of treatment missed
	15-27 Days	2 or fewer days of treatment missed
	6-14 Days	1 day of treatment is missed

**DANA-FARBER / HARVARD CANCER CENTER
STANDARD OPERATING PROCEDURES FOR CLINICAL RESEARCH**

TITLE: Conducting PI-Initiated Multi-center Trials	
SOP #: PM-402	Page: Page 1 of 4

Applicable Regulations

& Guidelines:

21 CFR 312.60 General responsibilities of investigators;
21 CFR 312.62 Investigator record keeping and record retention;
21 CFR 312.64 Investigator Reporting Requirements;
21 CFR 312.68 Inspection of investigator's records and reports
ICH E6 GCP Consolidated Guidelines

Other References:

Policies and Procedures for Dana-Farber/Partner's CancerCare (DF/PCC) Affiliate Network Clinical Trials
QA-717 Data Management of DF/HCC PI-Initiated Therapeutic Protocols
QA-706 Notifying DF/HCC of External Audits
PM-407 Reporting Unexpected Events (Violations/Deviations/Exceptions) to the IRB for Approved Protocols
AE-601 Procedures for Identifying, Documenting, and Reporting Adverse Events
PM-409 Regulatory Binder Management
PM-408 Responsibilities of the Sponsor-investigator
DF/HCC Multi-center Data and Safety Monitoring Plan
SM-501 Obtaining Informed Consent in Human Research Studies
Forms and Templates posted on the DF/HCC Clinical Research Unit website

Responsible Personnel:

Members of the study team, the Dana-Farber Quality Assurance Office for Clinical Trials (QACT), Multi-Center Coordinating Committee (MCC), and the DFCI IRB office.

Policy Statement:

All DF/HCC Overall Principal Investigators conducting multi-center trials must follow the process outlined below to ensure compliance.

Definitions:

Multi-center: Refers to inclusion of at least one site external to DF/HCC and the DF/PCC Affiliate Network.

Overall PI: The Overall Principal Investigator has the ultimate responsibility for the conduct of the clinical trial to ensure subject safety and data integrity. This individual is the Principal Investigator named on the single DF/HCC Form FDA 1572..

Site PI: The Site Principal Investigators will be listed as a sub-investigator on the protocol specific Form FDA 1572 . There is one Site PI for each participating site of a multi-center trial.

Lead Site: This is the site of the Overall PI, which serves as the coordinating center for the trial.

Procedure:

NOTE: The Overall PI must have the necessary resources to adhere to these procedures. This may include but is not limited to a project manager, additional study coordinator(s) and/or a CRO. Additionally, if the proposed multi-center trial may include international site(s), you must contact the OHRS office for guidance.

ROLES AND RESPONSIBILITIES

1. Overall Principal Investigator (Overall PI)

- Act as single liaison with outside regulatory agencies, with DF/HCC internal review and oversight committees, and with participating sites, although this may be delegated as appropriate and necessary (e.g. when she/he is out of town).
- Coordination of the approval of the initial protocol as well as its subsequent amendments. It is the responsibility of the Overall PI to ensure that the sites are using the correct version of the protocol.
- Identify a Study Coordinator (CRC/CRA) or Research Nurse as a study contact.
- Select qualified sites for participation. The Overall PI must obtain the DFCI IRB approval and inform the study sponsor, if applicable, which non-DF/HCC institutions will be involved in the study.
- Ensure all participating site investigators and study staff are trained on the DF/HCC SOPs, the conduct of the protocol, study procedures, SAE reporting, and data collection.
- Monitor progress and oversee the overall conduct of the trial at all participating sites.
- Responsible for the analysis, reporting, integrity and accuracy of data.
- Sponsor-Investigator IND Holders have additional responsibilities as written in the Code of Federal Regulations. Refer to SOP PM-408, Responsibilities of the Sponsor-investigator.
- Inter-institutional agreement / contract, if applicable: This may be required in situations, (1) where patient information, patient samples, or both are sent by or between study teams and coordinating center(s), (2) where financial arrangements are made, or (3) where no other agreements, such as network affiliate agreements, exist between the institutions. The agreement must be reviewed and approved by the DF/HCC Research Administration Office.

2. Site Principal Investigators (Site PI)

- Responsible for the conduct of the trial at their individual site. The Site PI may delegate authority within the site for conduct of trial.
- Identify the physician members of the study team who will be obtaining consent and signing the consent form for therapeutic protocols. It is DF/HCC policy that Nurses and Fellows cannot obtain consent to greater than minimal risk trials. The Site PI may designate non-physician members of the study team to obtain consent and sign the consent form for participation in a study that has been deemed minimal risk.
- Identify a Study Coordinator (CRC/CRA) or Research Nurse as a study contact.

- Submit data in a timely fashion to the Overall PI.
- Timely reporting of all SAEs and unexpected problems involving research (violations/deviations/exceptions) to the IRB of record and to the Overall PI.
- Ensure that their study team members have the current version of protocol and informed consent documents.
- Ordering, storage and dispensing of the study drugs. Investigational agents should be supplied free of charge to each participating site by the sponsor or company that is supporting the trial.

3. Quality Assurance Office for Clinical Trials (QACT)

- QACT Central Patient Registration is required for all participating sites.
- The DF/HCC Data Safety Monitoring Committee/Board (DSMC/DSMB) reviews all PI-initiated multi-center trials at least twice a year.
- All external audit reports must be submitted to the QACT per SOP QA-706 referenced above.
- Coordination of data collection, QA and computerization

4. Multi-Center Coordinating Committee (MCC)

- Assist in Protocol review
- Assure Multi-center criteria defined in this SOP are met

COORDINATION

Protocol

There will be one protocol document and each participating site will utilize that document. The site of the Overall PI is designated as the overall coordinating center (Lead Site) for the study.

Protocol must include:

- 1) DFCI Protocol Front Sheet, and Title page, if applicable (e.g., NCI, CTEP sponsored trials), with name of each participating institution and the site PI.
- 2) *Outline of procedure for central registration
- 3) *Outline of data submission schedule and process
- 4) *Section describing how SAEs and Deviations/Violations/Exceptions will be reported from each participating site to the overall Lead Site and to regulatory agencies, if applicable
- 5) *Section describing on-site auditing/monitoring plan for each participating site. This plan must be consistent with DF/HCC standards (refer to Multi-center Auditing and Monitoring SOP).
*Refer to the DF/HCC Multi-center Data and Safety Monitoring Plan.

Informed Consent

The Lead Site study team develops the model research consent document that must include a statement that data will be shared with the sponsor or its agents (which may include an outside CRO, medical monitor, Lead Site (DF/HCC), DSMB/DSMC and Lead Site's study team. The consent form must state that data shared with the Lead Site may include subject identifiers (name, date of birth, medical record

number). The Overall PI or designee is responsible for obtaining copies of each site's IRB approved consent forms. Each consent form must be reviewed for compliance with the DF/HCC multi-center consent template. Per DF/HCC policy, nurses and fellows cannot obtain consent to greater than minimal risk trials.

Central Specimen Collection, if applicable

A detailed process for this must be clearly outlined in the protocol and a method for tracking the information. Signed informed consent must occur before specimens are collected and the consent form may include a separate area for the research subject to opt out of optional research samples. If the subject chooses not to participate in the collection of optional specimens there must be a well-defined process for tracking this to prevent the collection of specimens without informed consent.

Regulatory paperwork

Study initiation: The Overall PI must obtain documentation of IRB approval from each participating site prior to the first subject registration at that site. There will be a separate protocol specific FDA 1572 form for each of the non-DF/HCC participating sites. The Overall PI must obtain and review the Form FDA 1572 and CV. This applies to both IND and non-IND trials.

The Regulatory Binder for the study is kept at the Lead Site. It should be noted that the non-lead sites maintain a non-lead regulatory binder for their reference in managing the trial; however we do not keep duplicate regulatory binders at the sites.

The Overall PI or designee at the Lead Site will manage all regulatory documents. The Overall PI is responsible for obtaining the regulatory documents from each participating site during the conduct of the study.

Site Communication

There must be documentation of regular communication with all participating sites. Participation includes all appropriate research staff, including investigators, research nurses and study coordinators. Communication may be by convened meetings, teleconferences or email distributions with the participating sites to update and inform about progress of the trial in a manner that is consistent with safe conduct of the trial. Documentation of the study communication regarding protocol/research subject related issues must be filed in the Lead Site regulatory binder.

SAE Reporting

All participating sites report SAEs directly to the IRB of record and to the Overall PI. The Overall PI or designee will submit non-DF/HCC SAEs to the DFCI IRB if they meet the DFCI IRB SAE reporting requirements. SAEs from non-DF/HCC participating sites are reported to the DFCI IRB using the DFCI IRB SAE Safety Reporting Form.

Reporting unexpected problems involving research (violations/deviations/exceptions)

All participating sites report violations/deviations/exceptions directly to the IRB of record and to the Overall PI. The Overall PI or designee will submit violations/deviations/exceptions to the DFCI IRB per the DFCI OHRS Policy & Procedure for Deviation/Violation/Exception reporting requirements.

Original Approval Date: CLINPOC 6/07/05
Revision Dates: 10/02/07, CLINPOC 5/21/08, 6/22/2009
Effective Date: 7/21/2009

**DANA-FARBER / HARVARD CANCER CENTER
STANDARD OPERATING PROCEDURES FOR CLINICAL RESEARCH**

TITLE: Qualifications for Who Can Consent Participants in Human Research Studies	
SOP #: SM-501	Page: 1 of 2

Applicable Regulations

& Guidelines:

45 CFR 46.116, 21 CFR 56.116, 21 CFR Sec.312.53, 21 CFR part 50, 21 CFR part 56

Other References:

The Guide to Human Research Activities
SOP QA-713 Centralized NCI Annual Registration
SOP ET-204 Human Subjects Protection Training Requirements

Responsible Personnel:

All DF/HCC Investigators, Study Staff Designee, and Quality Assurance Office for Clinical Trials (QACT) Registrars

Policy Statement:

All physicians that obtain informed consent and sign the consent form in human research studies are required to have a current NCI 1572 (investigator registration) and current human subjects protection training.

Definitions:

Obtaining Informed Consent: The act(s) of presenting information to persons to enable them to decide voluntarily whether or not to participate in research as a participant, which will result, if the participant decides to enter into the research, in the participant signing an Informed Consent Form.

Reconsenting Participants: The act(s) of presenting new information about research to participants that might affect a participant's willingness to continue to participate in research, which will result, if the participant decides to continue with the research, in the participant signing a new Informed Consent Form.

Procedure:

- 1) The DF/HCC Principal Investigator (PI) must identify physician members of the study team who will be obtaining consent and signing the consent form when the study is submitted for IRB review. Fellows cannot obtain consent to greater than minimal risk trials.
- 2) At the time of QACT registration, the QACT registrar checks the protocol front sheet to verify the consenting physician is listed on the DF/HCC front sheet of the protocol. If the physician is not listed on the DF/HCC front sheet of the protocol, the QACT registrar will verify that the consenting physician has met the requirements of NCI registration and human subjects protection training. If these requirements are met, the physician may consent the participant and also order the study agents.
- 3) When obtaining consent for participation in a study that has been deemed minimal risk, the overall PI may designate non-physician members of the study team to obtain consent and sign the consent form. The overall PI must email the QACT director or designee in advance with the names of the designated study team members who may obtain consent.

Original Approval Date: CLINPOC 1/22/04
Revision Dates: CLINPOC 11/16/04, CLINPOC 5/02/06, CLINPOC 5/21/08; 6/9/09
Effective Date: 7/9/2009

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..