Completion of Form FDA 1572

1. BACKGROUND:

All Food and Drug Administration (FDA) regulated research conducted under an Investigational New Drug (IND) requires a protocol-specific Form FDA 1572. The Form FDA 1572 is the investigator's commitment and agreement on how the protocol will be conducted. This agreement, to follow the legal commitments on the form, is implied upon submission to the sponsor.

DF/HCC requirements for completion of the Form FDA 1572 can be found in policy RCO-203: Regulatory Documentation. This operation provides procedures for completing the Form FDA 1572 for research managed within the DF/HCC and does not pertain to the Form FDA 1572 completed as part of the National Cancer Institute (NCI) Investigator Registration process, or those forms completed at institutions external to DF/HCC.

2. ASSOCIATED DF/HCC POLICIES:

2.1. RCO-203

3. PROCEDURE:

3.1. The ~~Overall~~ Principal Investigator (PI) or designated research team member at each participating DF/HCC site will obtain a copy of the Form FDA 1572 document. Generally, the form will be provided by the sponsor or sponsor's representative. If not, copies may be obtained from the FDA's website at: http://www.fda.gov/opacom/morechoices/fdaforms/cder.html.

3.2. The ~~Overall~~ PI or designated research team member completes all sections of the form per the following instructions:

3.2.1. **Section 1:** Type or print the full legal name (e.g. first name, middle name or initial, last name, and any suffix) of the ~~Overall~~ PI. The complete physical address should be provided.

3.2.2. **Section 2:** Check the box marked "Curriculum Vitae."

3.2.3. **Section 3:** List the name and address of each location where research activities will be conducted and research data will be generated or collected. Include locations where subjects will be seen and research procedures performed (e.g. where the test article will be shipped and/or administered, or where physical exams will be performed).

3.2.4. **Section 4:** List the name and address of clinical laboratory facilities and testing facilities (e.g., diagnostic labs performing blood work, imaging centers, etc.) where any protocol required testing will be done. This may also include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for studies under an IND.

3.2.4.1. Studies conducted at Dana-Farber Cancer Institute (DFCI) must list the Brigham and Women's Hospital (BWH), DFCI and any applicable DF/HCC Satellite site's clinical laboratories. DFCI Pediatric Oncology studies must list both DFCI and Boston Children's Hospital clinical laboratories.

3.2.5. **Section 5:** Enter the name and address of the Institutional Review Board (IRB) that is responsible for review and approval of the study. For oncology related research ~~, the IRB of record is the~~using the DFCI IRB as the IRB of record, ~~.t T~~he business address is:

Institutional Review Board
Dana-Farber Cancer Institute
450 Brookline Avenue~~, OS-229~~
Boston, MA 02215

3.2.6. **Section 6:** Insert the names of all subinvestigators at the PI's institution who, as part of the investigative team, will assist the ~~Overall~~ PI in the conduct of the research and make a direct and significant contribution to the reporting of research data (e.g. recruiting subjects, administering the informed consent document, determining subject eligibility, collecting study data, assessing primary endpoints, evaluating efficacy data, etc.). Their names must match their C.V.

3.2.6.1. List the physicians, physician assistants, nurse practitioners, and research nurses (as applicable) for each DF/HCC site.

3.2.6.1.1. Research nurses may be ~~excluded~~ included ~~from~~ on the Form FDA 1572 if the ~~Overall~~ PI ~~believes~~ determines they will ~~not~~ be making a direct and significant contribution to the data for a particular study. ~~The decision to add/exclude research nurses will reside with the Overall PI and if excluded this decision must be documented in the Lead-Site regulatory binder.~~

3.2.6.2. Research pharmacists, pharmacy technicians, study coordinators, infusion or inpatient nurses, radiologists, surgeons, pathologists, radiation oncologists, radiation nurses, residents, fellows and office staff are not generally included because they provide ancillary or intermittent care but do not make a direct and significant contribution to the data.

3.2.6.3. Individuals listed in ~~5.4.6.2~~above may be included on the Form FDA 1572 if the ~~Overall~~ PI ~~believes~~ determines they are involved in protocol mandated research or activities which go beyond routine clinical care and which significantly contribute to the research data in the IND application.

3.2.6.4. If a question arises as to whether an individual is to be included in section 6, contact the respective institutional clinical trials office for guidance.

3.2.6.5. All subinvestigators must provide financial disclosure and be listed on the Delegation of Authority Log. C.V.'s with supporting medical licenses (as applicable) will be present in the essential regulatory documents to support the education, training, experience, and qualifications for each individual. C.V.'s will not routinely be provided for individuals who are not listed on the Form FDA 1572.

3.2.7. **Section 7:** List the full protocol title. Add the IND number if required by the sponsor.

3.2.8. **Section 8:** Check one or both of the boxes if applicable.

3.3. It is permissible to attach additional pages to the Form FDA 1572 if you run out of space to type or print the required information.

3.4. It is recommended that the Form FDA 1572 be double-sided prior to obtaining the ~~Overall~~ PI's signature. If this is not done or the form is comprised of multiple pages, the pages must be stapled together.

3.5. The ~~Overall~~ PI must personally sign and date the Form FDA 1572 and any additional pages. Stamped signatures and typed dates are not acceptable.

3.6. Attach a signed and dated C.V. or other statement of qualifications for the ~~Overall~~ PI.

3.7. Make a photocopy of the Form FDA 1572 and file it with the essential regulatory documents ~~at the lead institution~~.

3.8. Forward the original signed Form FDA 1572 to the sponsor or government agency as applicable.

3.9. Revisions to the Form FDA 1572 may be made whenever there is a change to the information for any section. The process for completion and submission is the same as for the first Form FDA 1572.

3.9.1. The Form FDA 1572 does not need to be updated to show a laboratory or testing facility that is used just once to obtain standard of care results. However, the form needs to be updated when a laboratory or testing facility performs protocol-specific procedures for collection of significant endpoint safety or efficacy data.

3.10. Copies of Form FDA 1572 (original version or revisions) are not sent to the IRB.