Research Procedures at External Sites

In general, all DF/HCC protocol-specified research procedures must be performed at a Dana-Farber Cancer Institute (DFCI) Institutional Review Board (IRB) approved site participating in the study. This Information Sheet describes the circumstances under which procedures may be performed at External (non-DFCI IRB approved) sites.

External sites are defined as institutions not covered by the DFCI IRB approval and oversight of the research.

I. Procedures Done at a External Site with Local IRB Approval

If there is Local IRB approval and oversight of the protocol at the external site, then any protocol-specific procedures may be done at that site as long as the protocol states that they will be done there. The specific sites must be identified by name both in the Protocol (or Alert Page) and on the Front Sheet. IRB Approval memos from the external sites will be required both at the time of Add/Remove Site Amendment Submission and on an ongoing basis at each Continuing Review.

II. Routine Procedures and Standard of Care Interventions without Local IRB Approval

The following three categories of procedures may be done at external sites without local IRB approval. The Protocol (or Alert Page) must specifically indicate that this is permissible (though the sites do not need to be identified by name). The DF/HCC Overall Principal Investigator retains responsibility for overseeing the protocol-related activities and ensuring that appropriate arrangements are made for receiving protocol-related data from the non-DF/HCC institution.

1) ***Routine services*** if all of the following conditions are met:

a. The services performed do not merit professional recognition or publication privileges;
b. The services performed are typically performed by the external institution for non-research purposes; and
c. The institution's employees do not administer any study intervention being tested or evaluated under the protocol.

- Examples of such services include:
  - An appropriately qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service.
  - A hospital whose employees obtain blood through a blood draw or collect urine and provide such specimens to investigators as a service.
  - A radiology clinic whose employees perform chest x-rays and send the results to investigators as a service.

2) ***Routine clinical monitoring and follow up procedures*** if all of the following conditions are met:

a. The clinical trial-related medical services are typically provided by the external site for clinical purposes;
b. The institution's employees do not administer the study interventions being tested or evaluated under the protocol; and
c. The institution's employees do not enroll subjects or obtain the informed consent of any subject for participation in the research.

- Examples of such services include:
  - Obtaining medical history
  - Performing physical examinations
  - Assessing adverse events
  - Performing blood tests
  - Performing chest x-rays or CT scans

3) ***Administration of approved "standard of care" interventions*** that are not specifically dictated in the protocol or under evaluation (i.e., the protocol does not specifically dictate the doses, dose modifications, etc.)

- Examples of "standard of care" interventions include:
  - Any chemotherapy where the doses being administered and dose modifications are per the pharmaceutical drug label.
  - Any radiation therapy where the schedule of fractions are typically given by those institutions for non-research purposes.
  - Any surgical procedure where the procedure itself is not an intervention done for research purposes.
- Examples of interventions which are **NOT** considered "standard of care" include:
  - The administration of any approved drug regimen where the regimen (which could be standard of care) is being compared with an investigational intervention (e.g., Phase 3 studies).
  - An approved drug is being administered off label and per protocol.
  - Radiation therapy where the schedule of fractions are specifically defined by the protocol for research purposes and evaluation.

Note: In order to administer interventions which are NOT standard of care at external sites, please see the options described below.

III. One-Time or Short Term Administration of Non-Standard of Care Study Interventions

The study team may request DFCI IRB approval for a study intervention being tested or evaluated under the protocol to be administered at an external site on a one-time or short term basis. This exception is intended to be used when, for example, an oncologist at a non-DF/HCC institution administers chemotherapy to a participant as part of a study because the participant unexpectedly goes out of town.

In order to obtain IRB approval for administration of the study intervention, the study team must submit a Deviation Request to OHRS.

The study team must verify that all of the following conditions are met:

a. The DF/HCC investigator determines that it would be in the participant's best interest to receive the study intervention;
b. The non-DF/HCC institution's employees do not enroll subjects or obtain the informed consent of any subject for participation in the research;
c. The DF/HCC investigator will retain responsibility for:
   i. Overseeing protocol-related activities;
   ii. Ensuring the study interventions are administered in accordance with the IRB-approved protocol; and
   iii. Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at DF/HCC, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.

IV. Procedures Done at an External Site Relying on the DFCI IRB

For procedures which do not meet the requirements above, in limited cases the DFCI IRB may consider entering into an IRB Reliance Agreement with the external site. Under the Agreement, the external site's institution would rely on the DFCI IRB for review and oversight of the research. The IRB Reliance Agreement must be facilitated by the OHRS Senior Director. Please contact OHRS for further guidance regarding this option.

If you have any questions or need more information, please contact the OHRS at (617) 632-3029.

References:

DF/HCC Policy RCO-207, "Performance of Protocol Specified Procedures at non-DF/HCC Sites"

OHRP Guidance on Engagement of Institutions in Human Subjects Research:
http://www.hhs.gov/ohrp/policy/engage08.html