

Office for the Protection of Research Subjects

New Procedures for Communicating Changes in Study-wide and DF/HCC Accrual Figures to OPRS and the IRB.

As of April 1, 2008, the following information should be applied to protocols:

1. Single-Center Studies (i.e., DF/HCC is the only center participating). For studies where DF/HCC institutions are the only participating sites and **enrollment will only take place within the DF/HCC**, the study-wide accrual and local DF/HCC accrual figures should be equal on the front sheet. For these studies, any change in the accrual figures should continue to be submitted to OPRS as an Amendment for processing along with a revised Front Sheet and revised Informed Consent Document.

2. Multi-Center Studies. For studies **where enrollment will take place at the DF/HCC and at least one other center**, the study-wide accrual figure will be larger than the local DF/HCC accrual figure. (For example, Novartis is the sponsor of Protocol X. There is a global accrual of 100 and it is expected that 20 subjects will be enrolled at DF/HCC; 25 at Hopkins and 55 at Memorial Sloan.)

Initial Submission of Protocols:

- a. Local DF/HCC accrual numbers will be estimated on the Front Sheet when a protocol is initially submitted for review (e.g., the number 20 for DF/HCC).
- b. Local DF/HCC accrual numbers will be estimated in the New Project Application Form.
- c. Local DF/HCC accrual numbers should not be noted in the Informed Consent Document. However, the study-wide accrual number should continue to be noted in the Informed Consent Document.

Communicating Changes in Accrual Numbers:

- a. If the **study-wide target accrual numbers** change, a completed Amendment Form must be submitted to OPRS along with a revised Front Sheet and revised Informed Consent Document.
- b. If the **local DF/HCC estimated accrual numbers** change in a Multi-Center study, an amendment need not be filed with OPRS. Instead, the Principal Investigator should communicate via email the increase in local DF/HCC target accrual directly to the QACT protocol registrars.

Request for Changes to Currently Approved Informed Consent Documents:

- a. For Multi-Center studies where the estimated number of participants to be enrolled at the DF/HCC institutions (i.e., local DF/HCC target accrual figure) is noted in the Informed Consent Document, please delete this information and keep just the study-wide number of participants. Please note that the IRB will not require

- reconsenting of already enrolled subjects for this change.
- b. This informed consent document change should be submitted with your next amendment that revises the consent form.
 - c. If the informed consent document requires no other revisions before the next continuing review date, please submit an amendment to make this requested deletion of the local accrual figures no later than the continuing review of the protocol.

Please contact OPRS with any questions.

**The Office for the Protection of Research Subjects
Communications Group
20 Overland Street
2nd Floor
Boston, MA 02115**

DF/HCC
Member
Institutions

Beth Israel Deaconess Medical Center / Brigham and Women's Hospital / Children's Hospital Boston /
Dana-Farber Cancer Institute / Harvard Medical School / Harvard School of Public Health /
Massachusetts General Hospital



A Comprehensive Cancer
Center Designated by the
National Cancer Institute