

September 4, 2008

To Whom It May Concern:

The Dana-Farber Cancer Institute (DFCI) has an approved Federal Wide Assurance (FWA-FWA00001121 on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP). The Dana-Farber/Brigham and Women's Cancer Center at Faulkner Hospital is a component of the Dana-Farber Cancer Institute. This FWA expires on August 24, 2011.

The following IRBs are registered with OHRP and are designated in the DFCI FWA to conduct reviews of research involving human subjects for the Dana-Farber Cancer Institute: IRB00000052; IRB00000753; IRB00001186; IRB00003340; IRB00005504; and IRB00006224. The DFCI IRBs are the designated IRBs of record for all oncology protocols for institutions that comprise the Dana-Farber/Harvard Cancer Center (DF/HCC) consortium, including Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Children's Hospital Boston, Dana-Farber Cancer Institute, and Massachusetts General Hospital. Additionally, the DFCI IRBs serve as the IRBs of record for several affiliated institutions pursuant to cooperative agreements.

All research involving human subjects reviewed by the DFCI Institutional Review Boards (IRBs) is guided by the ethical principles in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The DFCI IRBs are duly constituted, fulfilling Federal requirements for membership; have written procedures for initial and continuing review for human subjects research; prepare written minutes of convened meetings; and retain records pertaining to the review and approval process all in compliance with the requirements for IRBs defined in DHHS 45 Code of Federal Regulations (CFR) Parts 46 and 164, Food and Drug Administration (FDA) 21 CFR Parts 50 and 56, and Guidelines of the International Conference on Harmonization relating to Good Clinical Practices (GCPs) to the extent required by the FDA.

The DFCI IRBs do not post membership rosters or release names of IRB members. Any IRB member who is an investigator, co-investigator or has any other conflict of interest with a protocol under review by the DFCI IRBs will not participate in the deliberation or vote of that protocol although he or she may be called upon to answer questions during the review.

The DFCI IRBs do not require the IRB Chairs or any other member of the IRB to sign approval memoranda. There is no regulatory requirement for such signatures. Final IRB approval occurs when the IRB votes to approve a research protocol and that approval is reflected in the minutes. With respect to a conditional approval, an IRB member signs off on a verification form that confirms that the investigator has met all of the IRB conditions.

Once that verification form has been signed, approval memoranda are generated by the staff of the Office for Human Research Studies (OHRS), which is the office charged with managing scientific and IRB review of oncology protocols for both the DFCI and the DF/HCC. (Please note: OHRS was formerly the Office for the Protection of Research Subjects. The change in name occurred in September of 2008.)

The DFCI IRB approval memoranda serve to document IRB approval of the entire submission including, but not limited to, the protocol, the informed consent document, and, if applicable, the Investigator Brochure.

Research protocols obtain SRC approval and IRB approval. No subject may be registered to a trial until it is 'activated.' This means that all steps are in place to ensure that once a subject is enrolled, research procedures may commence immediately. IRB approved consent documents are stamped "not for subject use" until the research is "activated."

The DFCI IRBs review events arising during the course of the research that may require a re-consenting of subjects. The DFCI IRB will determine the appropriate method of re-consenting based upon each individual situation. The DFCI IRB will take into account an investigator or sponsor determination to re-consent a subject. The DFCI IRB will also consider whether a new signed consent document is required or whether verbal re-consent with accompanying documentation in the medical or study record will be satisfactory given the circumstances.

The DFCI IRBs do not use version numbers on informed consent documents, but electronically stamps the document with the last IRB approval date and expiration date. When the institution conducting the research is ready to open the study, the informed consent form is electronically stamped with the date it is posted for use.

If you require additional information please contact our office at the number listed above.

Sincerely,

A handwritten signature in cursive script, appearing to read "Michele Russell-Einhorn".

Michele Russell-Einhorn, JD
Senior Director