

Dear DF/HCC Research Community,

1) Announcement of new DF/HCC PI-Initiated Multi-Center Procedures

Over the past year, several issues have been identified with DF/HCC PI-Initiated multi-center trials through several components of DF/HCC's protocol review and monitoring process (internal audit system, DSMC, SRC and IRB review). In an effort to strengthen our internal systems to ensure the safety of subjects and provide support to DF/HCC investigators, new procedures for DF/HCC PI-Initiated Multi-Center Trials have been developed and will be effective as of **November 1, 2007** for new submissions or trials adding new sites to existing single center protocols.

To access the new procedures on the Clinical Trials Portal, click on Quality Assurance Office for Clinical Trials, and hit the Multi-Center Tab on the right-side of the screen.

To access this site directly from the DF/HCC intranet: <http://www.dfhcc.harvard.edu/clinical-research-support/quality-assurance-office-for-clinical-trials-qact/multi-center-trials/>

2) Revised Policy

The DF/HCC SOP: PM-402: Conducting PI-Initiated Multi-Center Trials at DF/HCC has been revised to reflect the requirements and new process for conducting multi-center trials.

To access this site from the Clinical Trials Portal, click on Clinical Research Unit which is located just below OPRS on the Portal Menu.

To access this site directly from the DF/HCC intranet: <http://www.dfhcc.harvard.edu/clinical-research-support/clinical-research-operations-cro/policies-and-procedures/>

Training sessions will be held at each of the DF/HCC sites over the next month. Announcements will be sent regarding the trainings as applicable.

We strongly encourage all research staff to review the new procedures and provide any feedback to any us.

Thank you,

Jane E. Russell, Quality Assurance Officer for Clinical Trials, (617) 632-3764

Alyssa K. DellaCroce, Assistant Director, QACT (617) 632-3731

Nancy M. Antonino, Clinical Research Operations, (617) 632-5188

Michele Copersino, Director, Clinical Trials Education Office, (617) 582-8422