

Dear DF/HCC Research Community, the following two SOPs have been posted to the clinical research support with an effective date of 2/21/2008.

SM-506 Documentation of Informed Consent: This is a new SOP which includes changes in the storage of the signed original research consent forms for BWH/DFCI.

Please note: A research listserv was sent out in August 2007 stating a change in practice for DFCI and BWH study teams to maintain original signed research consent documents in the research files with a copy sent to Health Information Services (HIS) to be scanned in the medical record. At BWH, the original signed informed consent document must be obtained from the floor before discharge. After scanning, BWH does not maintain the hardcopies once documents are uploaded into the electronic LMR. DFCI HIS will eventually do the same. For research purposes it is critical that the original signed consent document remain available in the research files.

PM-413 Case Report Forms Compliance: This new SOP was created to specifically prevent enrollment of more than 3 participants without appropriate CRFs.

To access this site from the Clinical Trials Portal, click on Clinical Research Support which is located just below OPRS on the Portal Menu. Next, click DF/HCC Clinical Research Policies and Procedures in the Quick Links box.

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

Please contact Jane or Nancy below with any questions.

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