

Dear Research Community:

The attached policy went into effect on 2/21/08. For DFCI and BWH adult protocols you must maintain original signed research consent documents in the research files maintained by the study teams. Send copies of the research consent to Health Information Services to be scanned in the medical record. At BWH, the original signed informed consent document must be obtained from the floor before discharge. Pediatric protocols will continue to maintain the originals in the medical record.

BWH has been shredding hardcopies once documents are uploaded into the electronic LMR for about a year now.

Effective immediately, DFCI Health Information Systems has decided to shred documents once they are scanned and go through a Quality Control review. If an original consent is identified during the QC review, it will not be shredded and Nancy Antonino will be contacted for follow-up.

For research purposes it is critical that the original signed consent document remain available.

To access the policies 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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**DANA-FARBER / HARVARD CANCER CENTER
STANDARD OPERATING PROCEDURES FOR CLINICAL RESEARCH**

TITLE: Documentation of Informed Consent	
SOP #: SM-506	Page: 1 of 1

Applicable Regulations

& Guidelines:

45 CFR 46.116, 21 CFR 56.116, 21 CFR Sec.312.53, 21 CFR part 50, 21 CFR part 56

Other References:

The Guide to Human Research Activities
SOP QA-713 Centralized NCI Annual Registration
SOP ET-204 Human Subjects Protection Training Requirements
SOP SM-501 Obtaining Informed Consent in Human Research Studies

Responsible Personnel:

Study staff obtaining signed informed consent and study team members responsible for managing the files.

Policy Statement: The process of informed consent must be documented in the medical record.

Definitions:

Treatment Protocols: Protocols that involve a drug, device, surgery, or radiation.

Procedure:

Treatment Protocols

- 1) The process of informed consent must be documented either by a copy of the informed consent form or in a note.

- 2) It is Good Clinical Practice (GCP) to document that the informed consent process has taken place.

Non-treatment Protocols

- 1) Documentation of consent will be as determined by the IRB.

Note: With the exception of DFCI/CHB pediatric protocols, the original informed consent form must be retained in the research subject file. A copy of the informed consent form must also be sent to Health Information Services (Medical Records). DFCI/CHB pediatric protocols retain the original informed consent document in the medical record and a copy is kept in the research subject file.

Original Approval Date: CLINPOC 2/21/08
Revision Dates:
Effective Date: 2/21/08