DANA-FARBER / HARVARD CANCER CENTER
STANDARD OPERATING PROCEDURES FOR CLINICAL RESEARCH

TITLE: Procedure for the Review, Approval, and Updating of SOPS	
SOP #: GA-101	**Page:** 1 of 1

Applicable Regulations & Guidelines: All state and federal regulations pertaining to clinical research.

Other References:

Responsible Personnel: See table below

Policy Statement: There is a process for the approval and maintenance of all clinical research policies and procedures.

Procedures:

When an SOP is written or revised, an SOP Submission form will be completed and submitted along with the SOP to the QACT office.

Person(s) Responsible	**Procedures**
DF/HCC Clinical Research Operations Committee	Review the Standard Operating Procedures for clinical research every three years, and at other times as needed.
DF/HCC Clinical Investigations Leadership Committee (CLC)	The Clinical Research Operations Committee will forward SOPs to CLC for approval.
DFCI IRB	The Clinical Operations Committee will forward relevant SOPs to the DFCI IRB for approval, as needed.
QACT	Create pdf versions of the SOP and update the DF/HCC clinical research intranet with the revised sections. Retain paper copies of current SOP manual for business continuity purposes if the online versions are unavailable. Retain archive copies of all outdated policies, whether revised or discontinued.
QACT	The clinical research staff will receive email notifications of all new or revised SOPS. New SOPS will be emailed to the clinical research staff via the listserv for a 14-day comment period before the SOPS are approved and posted.

Original Approval Date: CLINPOC May 27, 2004
Revision Dates: CLINPOC 5/02/06, 5/08/07, 6/29/09
Effective Date: 6/08/07