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:

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:

Person(s) Responsible	**Procedures**
Clinical Research Operations Committee (CLINOPS)	Create new Standard Operating Procedures (SOPs) for clinical research. Review the SOPs every three years, or as needed.
Clinical Investigations Leadership Committee (CLC)	CLINOPS may forward SOPs to CLC for opinion or comment.
DFCI IRB	CLINOPS 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 Retain archive copies of all outdated policies, whether revised or discontinued.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	Send email notifications of all new or revised SOPS through the research listserv. New SOPS will be emailed via the listserv for a 14-day comment period before the SOPS are approved and posted.

Original Approval Date: CLINPOC May 27, 2004
Last Reviewed Date: 11/10/10
Revision Dates: CLINPOC 5/02/06, 5/08/07, 6/29/09, 11/10/10
Effective Date: 6/08/07, 6/29/09, 11/10/10