

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

TITLE: Procedure for Non-Patient Volunteers on Clinical Trials	
SOP #: SM-505	Page: 1 of 1

**Applicable Regulations
& Guidelines:**

Other References: SOP # QA-712: Subject Protocol Registration, The Guide to Human Research Activities, Quality Assurance Office for Clinical Trials (QACT) Policies and Procedures Manual

Responsible Personnel: Principal Investigator (PI) and/or DF/HCC study staff designee, QACT Protocol Registrar

Policy Statement: Clinical research procedures are the same for patient and non-patient volunteers on clinical trials at DF/HCC to ensure safety.

Procedure:

- 1) Non-patient volunteers participating in research must be recruited according to a DFCI IRB approved clinical protocol.
- 2) Non-patient volunteers undergoing invasive procedures, such as bone marrow aspirates or administration of pharmacologically active substances, must be registered with the QACT as outlined in the Subject Protocol Registration SOP noted above. Blood draws are exempt from QACT registration, unless specified in the protocol. A copy of the consent form and all clinical documentation will be filed in the volunteer's medical record or research file.
- 3) Non-patient volunteers undergoing invasive procedures will be managed as per standard patient care.
- 4) Individuals performing any procedure on a non-patient volunteer must be appropriately credentialed to perform that procedure.

Original Approval Date: CLINPOC 9/01/05
Revision Dates: