

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

TITLE: Eligibility Checklist Development and Implementation	
SOP #: QA-711	Page: 1 of 1

**Applicable Regulations
& Guidelines:**

Other References: SOP # QA-712 Subject Protocol Registration, SOP # SM-501 Obtaining Informed Consent in Human Research Studies, Quality Assurance Office for Clinical Trials (QACT) Policies and Procedures Manual, The Guide to Human Research Activities

Responsible Personnel: QACT Protocol Registrar, QACT Protocol Systems Coordinator, Oncology Protocol System (OncPro) team in Office for the Protection of Research Subjects (OPRS), Principal Investigator (PI) or study staff designee

Policy Statement: Eligibility confirmation is a required part of the registration process for research subjects.

Procedure:

- 1) The QACT develops eligibility checklists for all therapeutic protocols. The PI or study staff designee and QACT together determine when non-therapeutic trials require a checklist.
- 2) Once developed the registrar sends the eligibility checklist to the PI or study staff designee for revision and/or approval. The PI or study staff designee reviews and revises the checklist.
- 3) The registrar sends the checklist to the OncPro team in the OPRS, who coordinates posting checklists on OncPro.
- 4) The PI or study staff designee prints out a copy of the current online checklist and completes it for every new subject being enrolled.
- 5) The PI or study staff designee faxes completed checklists to the QACT (617-632-2295) at the time of registration. The registrars check for completeness and accuracy and query the PI or study staff designee when necessary. The subject is randomized when applicable and registered to the trial.
- 6) If a required checklist is missing, incomplete or inaccurate, the subject will not be registered to the trial.

Original Approval Date: CLINPOC 11/16/04
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