TITLE: Eligibility Checklist	
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Applicable Regulations & Guidelines:

Other References:
QA-712 Subject Protocol Registration
SM-501 Qualifications for Who Can Consent Participants in Human Research Studies
QACT Policies and Procedures Manual
DF/HCC Guide to Human Research Activities

Responsible Personnel: QACT, OHRS, Principal Investigator (PI) or study staff designee

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

Procedures:

A. Development

1) QACT develops eligibility checklists for all therapeutic protocols. The PI or study staff designee and QACT collectively determine when non-therapeutic trials require a checklist.

2) Once developed QACT 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) QACT sends the finalized checklist to OHRS for posting on OncPro.

B. Implementation

1) The PI or study staff designee prints out a copy of the current online checklist and completes it for every new participant being enrolled.

2) The PI or study staff designee faxes the completed checklist to QACT (617-632-2295) at the time of registration. QACT reviews the form for completeness, queries the PI or study staff designee when necessary, randomizes the participant when applicable, and registers the participant to the trial.

3) If a required checklist is missing, incomplete or inaccurate, QACT will not register the participant to the trial.

Original Approval Date: CLINPOC 11/16/04
Last Reviewed Date; 11/30/10
Revision Dates: 2/25/08, 6/29/09, 11/30/10
Effective Date: 3/25/08, 6/29/10, 11/30/10