DANA-FARBER / HARVARD CANCER CENTER
POLICIES FOR HUMAN SUBJECT RESEARCH

TITLE: Eligibility Checklists		
POLICY #: REGIST-100	**Page:** 1 of 3	**Effective Date:** 1/31/~~19~~2020

1. POLICY STATEMENT:

The DF/HCC eligibility checklist is used when protocols have inclusion and/or exclusion criteria and the study participants are to be registered in the OnCore Clinical Trials Management System (CTMS). This policy applies to both treatment or non-treatment studies. The protocol-specific eligibility checklist must be used for eligibility confirmation as part of the registration process.

2. BACKGROUND:

None

3. RESPONSIBLE PERSONNEL:

3.1 ~~Overall~~ Principal Investigator (PI)
~~3.2 Site Responsible Investigator~~
~~3.3 Sub-investigator~~
3.2 Subinvestigator
~~3.4~~3.3 Research Nurse
~~3.5~~3.4 Study Coordinator
~~3.6~~3.5 Office of Data Quality (ODQ) Protocol Systems Coordinators
~~3.7~~3.6 Office for Human Research Studies (OHRS) Human Research Coordinators
~~3.8~~3.7 OHRS Online Communications Team

4. DEFINITIONS:

4.1 **Screening Staff:** Appropriately qualified members of the study team who have been trained on the protocol and are responsible for determining and documenting subject eligibility on the checklist in accordance with institutional policies.

4.2 **Enrollment Monitor**: Staff responsible for reviewing the eligibility checklist filled out by the Screening Staff for completeness and accuracy based on any source data or source documentation used to establish subject eligibility. The Enrollment Monitor is selected from within each study team, in accordance with institutional policies.

5. POLICY:

5.1 Any protocol with eligibility criteria where participants are to be registered in the OnCore CTMS must have a protocol-specific eligibility checklist in the DF/HCC eligibility checklist template format. Protocols that are designed to enroll only a single subject are exempt from this requirement.

Version: 9
Effective Date: 1/31/20
Last Reviewed Date: 11/12/19

Commented [SC1]: Minor updates to responsible personnel and to remove old terminology

5.2 **Checklist Development**

5.2.1 The Office of Data Quality Protocol Systems Coordinators will create the protocol-specific eligibility checklist using the final, IRB-approved protocol document. The protocol sections containing eligibility criteria must be copied directly from the protocol document into the eligibility checklist.

5.2.1.1 In cases where an external sponsor (e.g., cooperative group) provides an eligibility checklist, the sponsor checklist can be inserted into the DF/HCC template in lieu of the actual protocol pages.

5.3 **Using the Eligibility Checklist**

5.3.1 The ~~Overall~~ PI, or delegated research team member, must always obtain the most recent version of the protocol-specific eligibility checklist from the Oncology Protocol System (OncPro).

5.3.2 Subject eligibility will be determined and documented by a member of the screening staff. That individual must sign the checklist where indicated for screening staff. All fields on the eligibility checklist must be completed, as required. If applicable, the treatment arm/dose level assigned must be indicated on the subject's eligibility checklist.

5.3.3 If not otherwise specified in the protocol, all screening laboratory tests must be completed within 14 days prior to the date of registration and all screening diagnostic tests, such as MRIs and CT scans, must be performed within 30 days of the date of registration. For BMT protocols, if not otherwise specified in the protocol, all eligibility tests must be completed within 42 days of registration.

5.3.4 For all clinical trials that are deemed by the IRB to be greater than minimal risk that also involve a drug, device, surgery, or radiation, an enrollment monitor must review, sign and date the checklist. Minimal risk trials do not require enrollment monitor review. Greater than minimal risk trials that do not involve a drug, device, surgery or radiation, may be excluded from enrollment monitor review with the approval of the ODQ Director.

5.3.4.1 Enrollment monitor review must occur after the checklist is completed and signed by the screening staff. The enrollment monitor must be a different

member of the study team than the screening staff and selected per institutional guidelines. If enrollment monitor review is not required, the enrollment monitor section must be lined through and marked as "N/A".

5.3.5 If allowable per institution, the completed checklist may be considered source documentation for eligibility criteria that require clinical judgement and/or interpretation of a subject's medical history and screening results (e.g., performance status, life expectancy, clinical staging) if the Screening Staff is a physician investigator or physician subinvestigator on the protocol. The checklist can only be considered source documentation when completed according to DOC-101 (e.g., notations must be initialed/signed and dated).

5.3.5.1 If a physician investigator or physician subinvestigator does not act as the screening staff, separate source documentation of subject eligibility must be available for every inclusion and exclusion criterion in accordance with DOC-101.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 - Investigational Device Exemptions
45 CFR 46 – Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811

7. RELATED REFERENCES:

International Conference on Harmonization – E6
Protocol Document
Sponsor Provided Eligibility Checklist

8. RELATED FORMS & TOOLS:

DF/HCC Eligibility Checklist template