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

TITLE: Eligibility ~~Checklist~~Checklists		
POLICY #: REGIST-100	**Page:** 1 of 5	**Effective Date:** ~~8~~1/**31**/~~16~~19

1. POLICY STATEMENT~~:~~:

The DF/HCC eligibility checklist is used ~~for~~when protocols ~~that~~ have inclusion and/or exclusion criteria and ~~require~~the study participants are to be registered in the OnCore Clinical Trials Management System (CTMS). This ~~could include~~policy applies to both treatment or non-treatment studies. ~~Every DF/HCC~~The protocol-specific eligibility checklist must be ~~created using the DF/HCC~~ used for eligibility ~~checklist template~~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~~3.4 Research Nurse
~~3.3~~3.5 Study Coordinator
~~3.4~~3.6 Office of Data Quality (ODQ) Clinical Research Systems Specialists
~~3.5~~3.7 ODQ Director
~~3.6~~3.8 Office for Human Research Studies (OHRS) Human Research Coordinators
~~3.7~~3.9 OHRS Online Communications Team

4. DEFINITIONS:

~~None~~
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 ~~that has~~with eligibility criteria~~, and requires participant registration~~ where participants are to be registered in the OnCore CTMS~~,~~ must have a ~~DF/HCC~~protocol-specific eligibility checklist ~~created using~~in the DF/HCC eligibility checklist template

Version: ~~7~~8
Effective Date: ~~8~~1/31/~~16~~19
Last Reviewed Date: ~~6/30/16~~11/13/18

Commented [CC1]: Revised throughout to align with new eligibility checklist process.

format. Protocols that are designed to enroll only a single subject are exempt from this requirement.

5.2 **Checklist Development**

~~5.2.1.The lead study team is responsible for creating the~~The ODQ Clinical Research Systems Specialist will create the protocol-specific eligibility checklist using the ~~most up-to-date version of the~~final, IRB-approved protocol document~~ and the DF/HCC eligibility checklist template.~~

~~5.2.2~~5.2.1 ~~The~~. The protocol sections containing eligibility criteria ~~listed on the eligibility checklist must be consistent with the protocol. The inclusion and/or exclusion criteria~~ must be copied directly from the protocol document into the eligibility ~~Criteria section on the eligibility checklist. The inclusion and/or exclusion criteria must be formatted according to the instructions provided in the eligibility checklist template~~checklist.

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

5.3 **Using the Eligibility Checklist**

~~1.1.1.~~ The Overall PI~~ must review and approve the eligibility checklist as part of the initial submission to the IRB.~~

~~1.1.2.The Office of Data Quality (ODQ) will perform a quality check of the eligibility checklist and ensure that all eligibility criteria included in the protocol are accurately represented.~~

~~1.1.2.1.ODQ will inform the Overall PI or designated~~, or delegated research team member~~ if any discrepancies are identified between~~, must always obtain the most recent version of the protocol-specific eligibility checklist ~~and protocol eligibility criteria.~~

~~1.1.2.2.The study team is responsible for addressing discrepancies and, if necessary, providing an updated checklist to ODQ for re-review.~~

~~5.2.3~~5.3.1 ~~OHRS will add the Posted Date to~~from the ~~eligibility checklist and post the finalized version of the checklist to~~ Oncology Protocol System (OncPro~~ at the~~

~~time of new protocol activation. ~~).

~~1.2. **Checklist Revisions**~~

~~1.2.1.The lead study team is responsible for making any updates or revisions to the~~ Subject eligibility ~~checklist, including revisions to eligibility criteria due to protocol amendments~~will be determined and ~~opening/closing~~documented by a member of ~~treatment arms and/or dose levels.~~

~~5.2.4~~5.3.2 ~~If~~ the Screening Staff. That individual must sign the ~~changes are due to an amendment, or opening/closing of treatment arms and/or dose levels, the revised~~ checklist where indicated for Screening Staff. All fields on the eligibility checklist must be ~~submitted to OHRS~~completed, as ~~a part of the protocol amendment. The revised~~required. If applicable, the treatment arm/dose level assigned must be indicated on the subject's eligibility checklist ~~must be reviewed and approved by the Overall PI as part of the Amendment submission~~.

~~1.2.1.1.If the changes are administrative, and are not accompanying an amendment, the revised checklist is submitted directly to ODQ.~~

~~1.2.2.ODQ will perform a quality check on the revised checklist as in section 5.2.4. ODQ will confirm that any updates to the protocol or eligibility criteria are accurately reflected on the eligibility checklist.~~

~~1.2.2.1.ODQ will confirm that any updates to the protocol or eligibility criteria are accurately reflected on the eligibility checklist.~~

5.3.3 ~~OHRS will update the Posted Date and post the final revised eligibility checklist to OncPro.~~ 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 sub-investigator on the protocol. The checklist can only be considered source documentation when completed according to DOC-100 (e.g., notations must be initialed/signed and dated).

5.3.5.1 If a physician investigator or physician sub-investigator 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 RESOURCES:

~~Protocol Registration Form~~
~~DF/HCC Eligibility Checklist template~~