

DF/HCC Operations for Human Research
Eligibility Checklist Development**1. BACKGROUND:**

The Office of Data Quality creates each protocol-specific eligibility checklist per REGIST-100.

2. ASSOCIATED DF/HCC POLICIES:2.1. [REGIST-100](#)**3. PROCEDURE:****3.1. General Procedures**

- 3.1.1. The ODQ Clinical Research Systems Specialist (CRSS) team will create protocol-specific eligibility checklists for new and amended protocols once the final IRB-approved protocol document is available.
- 3.1.2. For protocol amendments, the CRSS will only create a new version of the checklist when there are changes to the eligibility section of the protocol. The lead study team must indicate this on the amendment submission.
- 3.1.3. The assigned CRSS will identify and extract the pages of the protocol containing the eligibility criteria and append those pages to the DF/HCC Eligibility Checklist Coversheet. The standard coversheet will be used for all eligibility checklists, except in the limited situations noted below where the coversheet may need to be customized.
- 3.1.4. When the protocol document does not contain checkboxes, the CRSS will add checkboxes in the margin next to each major criterion in the protocol. All other information will be presented on the checklist exactly as in the protocol document. Other than the addition of checkboxes, the CRSS will make no alterations to the pages extracted from the protocol document.
- 3.1.5. The OHRS online posting team completes the eligibility checklist footer at the time of posting to OncPro.

3.2. Centrally Randomized Protocols

- 3.2.1. For investigator-sponsored protocols centrally randomized by ODQ, the CRSS will customize the coversheet as follows:
 - Add fields to capture additional subject information, as required to ensure accurate registration in OnCore.
 - Add fields to capture registering staff contact information in the event ODQ encounters questions when processing the randomization and registration.

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- Add fields to capture the protocol-specific stratification factors, as required per protocol.
- Add reminder that the protocol is blinded, when applicable.
- Add standard instructional language explaining when, where and how to submit the registration information to ODQ.

3.3. Multi-Step Registration

3.3.1. For protocols with multiple registration steps, the CRSS will customize the coversheet as follows:

- Clearly indicate on the first coversheet that it shall be used to capture the initial registration and assignment to a treatment arm in OnCore.
- Add abbreviated coversheet pages following the first to capture subsequent registration steps that may occur per protocol.

3.3.2. Eligibility Criteria for each registration step will be presented on the checklist exactly as in the protocol document. Other than the addition of checkboxes, the CRSS will make no alterations (e.g., splitting out, copying, separating) to the pages extracted from the protocol document.