

Eligibility Checklist FAQs

Please see policy REGIST-100: Eligibility Checklists in the [Policy and Operation Library](#) for additional information.

Eligibility Checklist Development

What protocols have an eligibility checklist?

A protocol-specific eligibility checklist is required for any protocol with eligibility criteria where subjects are registered in OnCore. Protocols that are designed to enroll only a single subject are exempt from this requirement.

Where do I obtain the current eligibility checklist for a protocol?

Study teams should always use the current eligibility checklist available on OncPro. For more information on OncPro access, please see the [OHRIS Systems Access page](#).

How are eligibility checklists created?

Briefly, ODQ will create the eligibility checklist for each protocol by extracting the eligibility criteria pages from the protocol document itself and attaching a “coversheet”. If the protocol document does not contain checkboxes, ODQ will add them to facilitate completion of the checklist.

Please note that ODQ is only able to extract full pages from the protocol document as approved by the IRB. This means that the checklist may include some language from other protocol sections that occur on the same page as the start/end of the eligibility criteria. Pages cannot be re-numbered.

What does the eligibility checklist look like?

The Eligibility Checklist will have a standard cover sheet followed by the pages from the IRB-approved protocol document that contain the eligibility criteria. No changes will be made to the pages extracted from the IRB-approved protocol, except for the addition of checkboxes if they are not already present. [Click here](#) to see an example.

How do I revise the posted eligibility checklist if there is an error? Do I need to submit an amendment?

All checklists undergo quality control review before they are posted to OncPro. Please contact us at ODQ@dfci.harvard.edu if corrections are needed.

Using the Eligibility Checklist

How do I register a subject if the protocol doesn't have an eligibility checklist?

If registration is performed centrally by ODQ, please submit a completed [Protocol Registration Form](#) and the signed consent form according to [REGIST-OP-1](#). Procedures for decentralized protocols are also outlined in this operation.

Who signs the checklist as Screening Staff and Enrollment Monitor?

Please see [REGIST-100](#) for a definition of Screening Staff and Enrollment Monitor, and information on when an Enrollment Monitor is required.

Note: Institutional policies may differ as to who can be the Enrollment Monitor and when an Enrollment Monitor is required. Please consult your institutional Clinical Trials Office for more information.

Is the completed eligibility checklist considered source documentation?

The DF/HCC requires a physician investigator to sign as the Screening Staff in order for the completed checklist to be considered source documentation for eligibility criteria that require clinical judgment and/or interpretation of a subject's medical history and screening results (e.g., performance status, life expectancy, clinical staging).

Note: Institutional policies may differ as to the use of the eligibility checklist as a source document. Please contact your institutional Clinical Trials Office for details.

How do I write in values and dates if there are no blank lines?

Screening Staff may choose to make notations in blank spaces or margins. If the eligibility checklist is being used as source documentation, the Screening Staff must comply with applicable DF/HCC policy ([DOC-100](#)) when completing the eligibility checklist.

How do I indicate that the subject doesn't meet the exclusion criteria?

Applicable boxes should always be checked in order to document each criterion was reviewed. Checking each box indicates that the subject is eligible (i.e., meets the inclusion criteria, does not meet the exclusion criterion).

What is the "Date on study / treatment scheduled to begin"?

This field captures the On Treatment date that will be entered into OnCore when the subject is registered. For Treatment studies, the On Treatment date is the date treatment is schedule to begin.

However, for non-treatment protocols, there is no separate start of treatment date. Therefore, the On Study date is entered in OnCore for these types of studies. For more information, please consult the [OnCore WIKI](#).

How is the eligibility checklist used for external site registrations on multi-center trials?

The standard DF/HCC cover sheet does not contain all of the information that external sites need to provide in order to facilitate registration in OnCore. Therefore, we suggest using an [External Site Subject Registration Form](#) for outside sites on any DF/HCC investigator-sponsored multi-center trial. This form can be used along with the DF/HCC internal eligibility checklist.

Please contact ODQ@dfci.harvard.edu with questions.