

## Use of Informed Consent Documents Posted to OncPro

### General Information

Upon activation of a research study, the IRB-approved protocol documents and consent form will be posted to the Oncology Protocol System (OncPro). IRB-approved consent forms are not available until the submission is activated and posted to OncPro. This is to prevent the initiation of research procedures prior to activation. Investigators must ensure that the most current, IRB-approved version of the protocol is followed and the consent form from OncPro is used when obtaining informed consent.

For details on obtaining informed consent please see 1) [DFCI IRB Policy and Procedure Manual](#); 2) DF/HCC Policy [CON-100 Informed Consent Process](#); 3) DF/HCC Policy [CON-101 Obtaining Informed Consent for Non-English Speakers](#); and 4) DF/HCC [CON-OP-01 Reconsent/Patient Notification Guidance](#).



For information regarding the use of IRB-approved consents posted to OncPro, please see below.

- **Official IRB-Approved PDF Versions:** The most current version of the consent is posted to OncPro by ODQ at the time of activation. Study teams are notified of activation via a system-generated iRIS email. Study teams should review the consent form posted to OncPro as soon as possible to make sure that the correct version is posted.
  - If the IRB waives the requirement for documentation of informed consent but requires that an information sheet or script be used, the information sheet or script will be posted to OncPro.
  - If the IRB requires a separate HIPAA Authorization form, the form will be posted to OncPro.
- **Print, Do Not Save:** Study team members should always download the most current version of the consent from OncPro before obtaining the informed consent of a new study participant. Saving the consent form to a desktop, or printing numerous copies for future use, could result in a participant signing an outdated version.
- **Unofficial “Not For Subject Use” Versions:** Study teams will submit proposed consent forms for review with a “Not for Subject Use” watermark. The IRB approved versions with the same “Not for Subject Use” watermark are also available to study teams within iRIS. These versions are provided solely for reference and to facilitate editing when submitting future amendments and must not be used to consent study participants.
  - The watermark is removed only at the time of activation and posting to OncPro.
- **Expired Protocols:** If a continuing review submission is not approved and IRB approval expires, the protocol will be put on hold. No research activities may occur, and no new subjects can be consented or enrolled while IRB approval has lapsed.
- **Header and Footer:** For studies relying on the DFCI IRB, ODQ adds required header and footer elements to the approved consent document at the time of posting. Study teams are advised to use the DFCI IRB consent form templates for all research under the DFCI IRB, and NOT TO EDIT the consent form header or footer information.

# Info Sheet - Operations

## Consent Header Information

For research reviewed and approved by the DFCI IRB, ODQ adds elements A and C in the consent header prior to posting. For research reviewed and approved by an outside IRB, ODQ will add elements A and C when there is adequate space to do so. Please see below for details.

<b>A</b> 9/26/2016 11:13 am	<b>C</b> <input type="text"/> <input type="text"/>	
<b>B</b> <b>Research Consent Form for Biomedical Research</b> Dana-Farber/ Harvard Cancer Center BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates		<b>D</b> 
		<b>E</b> OHRS 10.02.15

- A. Added by ODQ at posting. The date/time stamp that updates each time the document is opened and captures when the consent document was printed for use.
- B. Included in the consent template. The document includes the name of the Consent template in the header.
- C. Added by ODQ at posting to assist researchers in complying with CON-100 documentation requirements.
  - a. The top box is for the subject's name or initials
  - b. The bottom box is for the subject's Medical Record Number (MRN).
- D. The consent form templates include a QR code in the upper right-hand corner used by sites to identify the document as Research Consent Form in the EMR. This must be part of the submitted and approved consent form and is not added by ODQ after the fact.
- E. The consent form template also includes a version date indicating which template version was used to create the consent form.

## Consent Form Footer Information

The DFCI IRB consent form template includes page numbers in "Page X of Y" format within the footer. These should be included in the submitted consent. To ensure version control, additional footer information is added by ODQ before the consent form is posted to OncPro.

**Note:** Consent forms posted prior to July 8, 2019 may appear in a different format.

DFCI Protocol Number: 19-000	Approved Date (DFCI IRB Approval): 01/10/2019
Date Posted for Use: 01/25/2019	

For research reviewed and approved by the NCI CIRB and NMDP IRB, ODQ will only add the footer above to the HIPAA form approved by the DFCI IRB.

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- **DFCI Protocol Number:** This number is assigned by OHRS and is used by both the DF/HCC SRC and DFCI IRB to identify research protocols submitted for their review and approval.
- **Approved Date (DFCI IRB Approval):** The date the IRB granted final approval of the consent form. This is the same date as the "Version Date" listed in OnCore.
- **Date Posted for Use:** The date the consent form was posted to OncPro and first became available for subject use.

For consent documents reviewed and approved by an external IRB, no local footer will be added.

## Log Sheet Information

The Log Sheet is a document posted to OncPro to summarize changes with each submission. The Log Sheet is only updated after a submission has been activated and the revised documents have been posted to OncPro.

The log sheet will include the following information:

- **Date Posted:** The date that ODQ posted any revised documents to OncPro.
- **Revised Documents:** A brief description of which documents have been posted / updated on OncPro.
- **Approved Date:** The final date the DFCI IRB approved the submission, when applicable. For studies under an external IRB, this will be the date the DFCI IRB acknowledged and accepted the submission. This is also the version date that appears for the consent form version(s) in OnCore and is generally the same as the Approved Date.

Date Posted	Revised Sections	Approved Date
01/16/2020	Consent Form replaced due to AM #012345	01/15/2020

**Note:** Some older protocols also have a column for Version Date (OnCore). This is being maintained to capture legacy information that is no longer necessary under current procedures. This was used to capture the consent version date in OnCore if different from the IRB approval date.

## Consent Form Addendums

Consent Addendums should only be used when a limited amount of new information or changes that need to be communicated to subjects. Please reference DF/HCC [CON-OP-01 Reconsent / Patient Notification Guide](#) for examples and further guidance on when a Consent Form Addendum may be used.

Consent Addendums should be created using the current OHRS Consent Addendum Template and submitted to OHRS as an amendment. In most cases, the main consent form must also be revised with the new information and posted to OncPro alongside the addendum.

Multiple addendums for the same study may be active simultaneously. Each addendum must be given a unique title (or unique number) referencing the new information to be communicated to subjects (e.g. Safety Update 1, Safety Update 2).

## **Info Sheet - Operations**

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Study teams are responsible implementing the consenting plan as approved by the IRB of Record. Study teams are also responsible for knowing which addendum needs to be used when and with what subject(s). Study teams are also responsible for submitting an amendment to remove addendums from OncPro that are no longer needed. This should only occur once all affected subjects have been reconsented using the addendum.