

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 use of IRB-approved consents posted to OncPro, please see below.

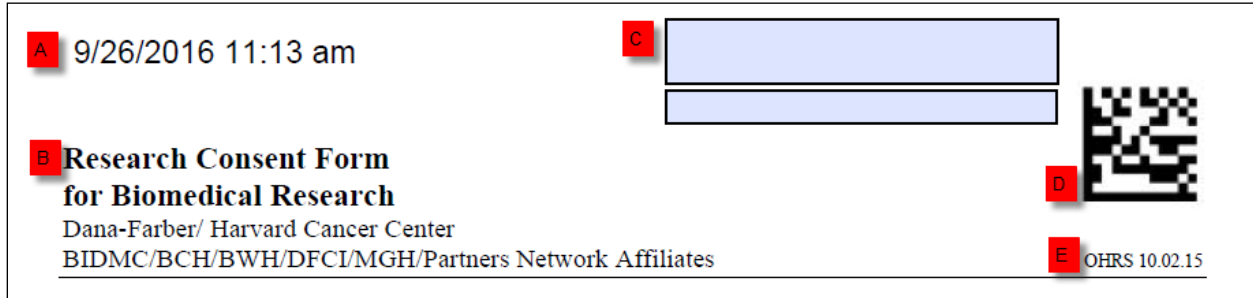
- **Official IRB-Approved PDF Versions:** The most current version of the consent is posted to OncPro by ODQ at the time of activation. Study teams are notified of activation via email. Study teams should review the consent form posted to OncPro as soon as possible to make sure that the correct version is posted.
 - If the IRB waives the requirement for informed consent or authorization, then a notice to that effect will be posted in lieu of the informed consent document.
 - If the IRB waives the requirement for documentation of informed consent/authorization, but requires that an information sheet or script be used, the information sheet or script will be posted to OncPro as an appendix to the protocol.
- **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the consent form to a desktop, or printing numerous copies for future use, could result in a participant signing an outdated version.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. These versions are provided solely for reference and to facilitate editing when submitting future amendments. It 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. The consent form will not be revised, and no new subjects can be consented or enrolled while IRB approval has lapsed.
- **Protocols in Data Analysis Only:** As of October 2, 2015, consent documents will be removed from OncPro at the time that the continuing review approval is posted.

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- **Header and Footer:** ODQ adds required header and footer elements to the approved consent document at the time of posting. Study teams are advised NOT TO EDIT the consent form header or footer information.

Consent Header Information

There are several items in the consent header that ODQ inserts prior to posting. Please see below for details.



- A. Prior to posting, ODQ inserts a date/time stamp that updates each time the document is opened.
- B. The document includes the name of the Consent template in the header.
- C. Prior to posting, ODQ adds two blue boxes:
 - a. The top box is for the subjects name
 - b. The bottom box is for the subjects Medical Record Number (MRN).
- D. The document includes a QR code in the upper right hand corner used by sites to identify the document as Research Consent Form in Epic.
- E. The document includes the version date of the template that was used to initially create the consent.

Consent Form Footer Information

Every consent form posted to OncPro has a footer enabling version control. The consent form footer is added by ODQ before it is posted to OncPro and different footer formats (versions) have been used historically. Explanation of these footer versions are explained below.

Note: Depending on the 'date posted for use', the consent form will fall within one of these three categories.

Starting with the current version, if the consent form was posted on or after (Please note that there may be a few exceptions around the transition date as a backlog of workflows are processed):

1) July 8, 2019 to Present

The current footer format was developed to minimize the required fields and streamline the posting process.

DFCI Protocol Number:	12-000	Approved Date (DFCI IRB Approval):	01/10/2015
Date Posted for Use:	01/25/2015		

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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.
Please Note: The "Approved Date" for Central IRB (CIRB) studies is the date the DFCI IRB acknowledged/Accepted the amendment.
- **Date Posted for Use:** The date the consent form was posted to OncPro and first became available for subject use.

When research is reviewed and approved by an outside IRB (e.g., a study under the CIRB or other sIRB), DF/HCC may add elements to the consent form consistent with the approved local context worksheet or boilerplate. For example, the consent footer may appear as follows:

DFCI Protocol:	Acknowledged by DFCI IRB:	Date Posted for Use:
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2) **October 11th, 2016 to Present**

This footer format version was developed to clarify and more closely match the information found in OnCore. This includes reviews, versions, approvals and expirations dates.

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DFCI Protocol Number:	12-000	Approved Date (DFCI IRB Approval):	01/10/2015
Date Posted for Use:	01/25/2015	Expiration Date (Invalid for use on or after):	02/13/2016
Version Date (OnCore):	01/24/2015	Content Last Revised with OHRS Review:	AM #10

- **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.
Please Note: The "Approved Date" for Central IRB (CIRB) studies is the date the DFCI IRB acknowledged/Accepted the amendment.
- **Date Posted for Use:** The date the OHRS Online Team posted the protocol/consent to OncPro.
- **Expiration Date (Invalid for use on or after):** This date represents the day the consent form can NO longer be used. The expiration date on the Consent footer posted on OncPro will now match the date in OnCore.
Note: When matching the footer of a signed consent with the appropriate option in OnCore, the OnCore Expiration date may not match depending on the following scenarios:
 - a. The posted consent was due to a submission other than an Initial Review or continuing review (e.g., an amendment), which would result in the Expiration Date being blank.

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b. At some point the IRB determined that the Expiration Date should be shortened. In this case, the signed consent may have the original date in the footer, while OnCore would display the new date.

- **Version Date (OnCore):** This is the Consent Form Version Date entered into OnCore by OHRS staff. This version date corresponds with the consent form version date that study teams view in the clinical trials management system OnCore.
- **Content Last Revised with OHRS Review:** The OHRS Review Number associated with the Consent Form is included as a reference. This review number corresponds with an OHRS generated New Protocol (NP #1, same as Activation), Amendment (AM #), Continuing Review (CR#), Adverse Event (AE #), and Other Event (OE #) where the corresponding submission resulted in a revision to the content of the consent form document.

3) July 13th, 2015 through September 8th, 2016

Differences in this footer (highlighted) from the current footer format are:

- **Date DFCI IRB Approved this Consent Form:** This date is the first date the IRB conditionally approved or approved the submission.
Note: This date will not match the date found in OnCore if the submission was conditionally approved.

- **Date DFCI IRB Approval Expires:** This date represents the day before IRB approval expires and is the last day the consent form can be used. On the following day, in the event of IRB expiration, the consent form will be removed from OncPro. Accordingly, the expiration date on the footer of the consent form posted in OncPro will have a date that is one day earlier than the expiration date on the approval memo.

Please note:

- a. If the Expiration date does not appear in OnCore when selecting the appropriate consent, it is most likely because the consent was approved due to an amendment.
- b. When matching the footer of a signed consent with the appropriate option in OnCore, the OnCore Expiration date may sometimes be blank. This occurs if the posted consent was due to a submission other than an Initial Review or continuing review (e.g., an amendment).

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DFCI Protocol Number:	12-000	Date DFCI IRB Approved this Consent Form:	01/10/2015
Date Posted for Use:	01/25/2015	Date DFCI IRB Approval Expires:	02/13/2016
OnCore Version Date:	01/24/2015	Content Last Revised with OHRS Review:	AM #10

4) "Prior to July 13th, 2015

The main differences between this footer and format versions above are that:

- 1) "OHRS Version Date" stated rather than "OnCore Version Date", and
- 2) footer does not have "Content last reviewed with ORHS Review:" (note blank)

- **OHRS Version Date:** This is the date that a OHRS Human Research Coordinator routed the IRB-approved version of the submission to the OHRS Online Team for posting to OncPro. This version date is a required field in the OnCore database which is used for tracking versions for registration.

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DFCI Protocol Number: <u>12-000</u>	Date DFCI IRB Approved this Consent Form: <u>01/15/2012</u>
Date Posted for Use: <u>01/21/2012</u>	Date DFCI IRB Approval Expires: <u>02/13/2013</u>
OHRS Version Date: 01/20/2012	

Log Sheet Information

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

As of February 18, 2019 the Log Sheet will use the following headers:

- **Date Posted:** The date that ODQ posted the revised documents to OncPro.
- **Revised Sections:** A brief description of which documents have been posted / updated on OncPro.
- **Approved Date:** The final date the DFCI IRB approved the submission that prompted the change to the documents posted to OncPro.
- **Version Date (OnCore):** This date is entered when one or more consent form(s) is updated. This is 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	Version Date (OnCore)
1/16/15	Consent Form replaced due to AM #2	1/15/15	1/15/15

As of September 9th, 2016, the Log Sheet will use the following headers:

- **Date Posted:** The date the OHRS Online Team posts the most current version of the protocol/consent to OncPro.
- **Revised Sections:** A brief description of which documents have been posted / updated on OncPro.
- **Approved Date:** The final date the DFCI IRB approved the submission that prompted the change to the documents posted to OncPro. Prior to this date this field was called "IRB Approval Date."
- **Version Date (OnCore):** As of 7/13/2015 this date will match the OnCore Version Date in the consent form footer and in OnCore. Prior to this date this field was called "OHRS Version Date" and/or "OnCore Version Date".

Date Posted	Revised Sections	Approved Date	Version Date (OnCore)
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1/16/15	Consent Form replaced due to AM #2	1/15/15	1/15/15
1/21/15	Consent Form replaced due to AM #1 (including AM #2 revisions)	1/10/15	1/20/15

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).

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.

Special Cases and Examples

The following notes are provided to help explain how the footer information is updated for specific submission types or when submissions are approved and posted out of order:

Submissions approved and/or posted out of order: The footer will always reflect the latest IRB approval date. Here is an example:

AM #2: Submitted 1/12/15; Approved 1/15/15; **No Activation Needed**; Posted on 1/16/15

- The consent form that was revised under AM #2 is posted on 1/16/15.
- The footer will reflect an IRB approval date of 1/15/15.

AM #1: Submitted: 1/1/15; Approved 1/10/15; **Activation Signoff 1/20/15**; Posted on 1/21/15

- The consent form that was revised with AM #1 is posted on 1/21/15.
- The footer will reflect an IRB approval date of 1/15/15 because that is the latest IRB approval date.
- OHRS staff will confirm that the changes to the consent form posted as part of AM #2 are incorporated into the consent form posted in AM #1.

The **consent form footer** when AM #1 is posted would look like the following:

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DFCI Protocol Number: 12-000	Approved Date (DFCI IRB Approval): 01/15/2015
Date Posted for Use: 01/21/2015	

For this example, the **Log Sheet** would read:

Date Posted	Revised Sections	Approved Date	
1/16/15	Consent Form replaced due to AM #2	1/15/15	
1/21/15	Consent Form replaced due to AM #1 (including AM #2 revisions)	1/10/15	