

Informed Consent

DF/HCC & DFCI IRB

Policy, Guidance and Template Updates

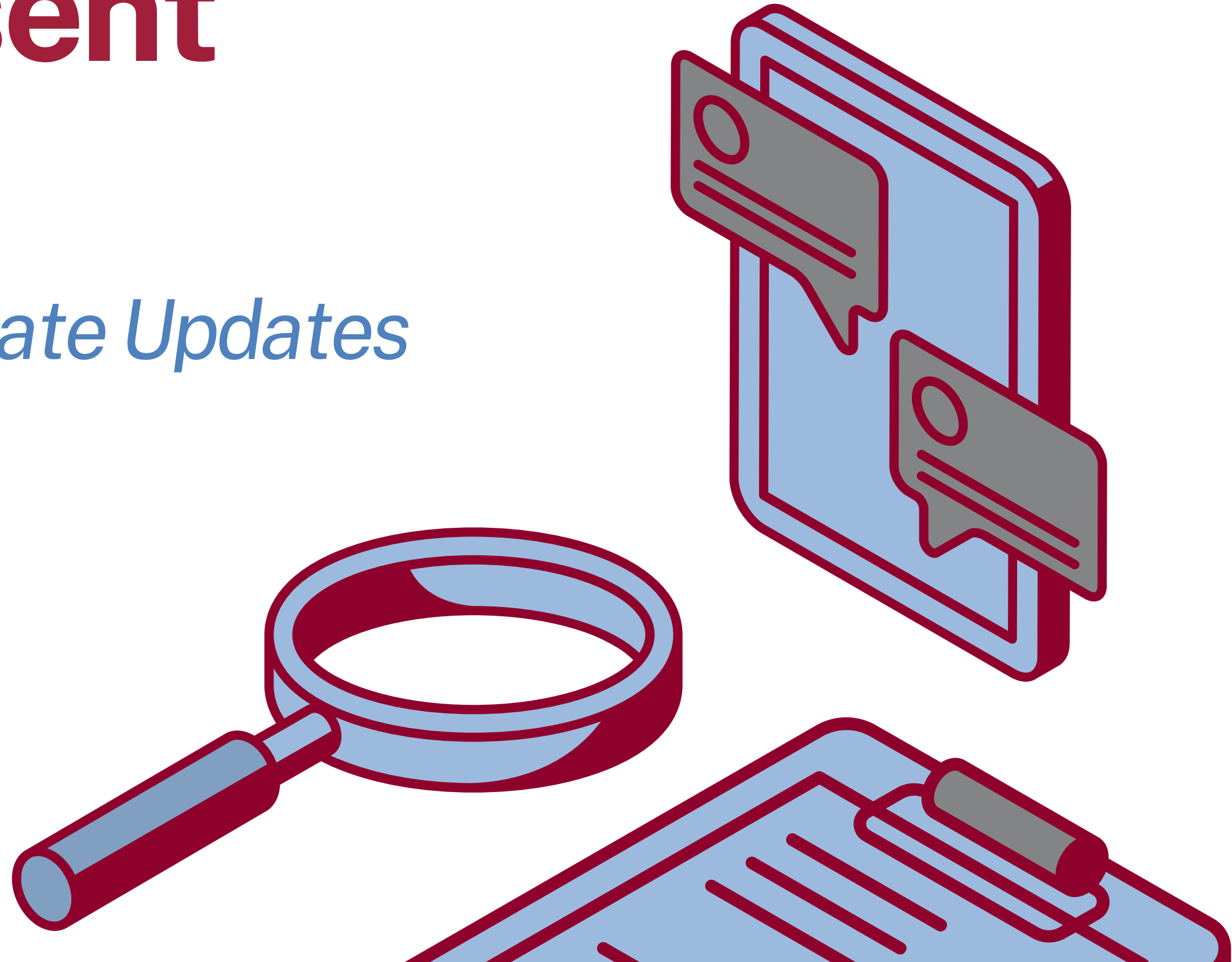
December 16, 2024



Dana-Farber/Harvard
Cancer Center



A Cancer Center Designated by the
National Cancer Institute



Agenda

1	Overview – Types of Documents
2	Updated Consent Documents
3	Key Updates – Subject Notification & Reconsent
4	Key Updates – Using a Legally Authorized Representative (LAR)
5	Other Policy Updates
6	Panelist Q&A



Dana-Farber/Harvard
Cancer Center



A Cancer Center Designated by the
National Cancer Institute

**Please submit questions
using the Zoom Q&A button!**

Overview – Types of Documents



Dana-Farber/Harvard Cancer Center (DF/HCC)



The **DF/HCC consortium** governs all cancer relevant research conducted at it's 7 member sites.



BIDMC
Beth Israel
Deaconess



BCH
Boston
Children's



BWH
Brigham &
Women's



DFCI
Dana-Farber



HMS
Harvard Medical
School



HSPH
Harvard TH
Chan School
of Public Health



MGH
Massachusetts
General Hospital



DFCI
**Institutional Review
Board (IRB)**

Serves as the IRB of Record for all* cancer relevant research conducted at a DF/HCC site
**unless review is approved to be ceded to an external IRB*

DF/HCC Policy & DFCI IRB Policy and Guidance



DF/HCC Policies govern all cancer center research, regardless of IRB of record or site



DFCI IRB Policies and Guidance provide additional IRB-specific requirements, guidance, and context for studies relying on the DFCI IRB as the IRB of record (most of, but not all DF/HCC studies)

○Keep in mind that if your research is relying on an external IRB, their policies would apply in addition to DF/HCC policy



Dana-Farber/Harvard
Cancer Center



A Cancer Center Designated by the
National Cancer Institute

DF/HCC Policy & DFCI IRB Policy and Guidance

DF/HCC Document Library

Use the **Filter by Type** menu to select the type of document you are searching for and enter your relevant keyword(s) before searching. To view archived versions of all DF/HCC Policies (previously called SOPs), select the **Archive Only** option.

☒ **Archive Only**

<https://www.dfhcc.harvard.edu/research/clinical-research-support/document-library>

<https://www.dfhcc.harvard.edu/research/clinical-research-support/document-library/dfhcc-policy-and-operation-library/>

<https://www.dfhcc.harvard.edu/research/clinical-research-support/office-for-human-research-studies/ohrs-information-sheet-library>



Keep in mind



While DF/HCC and DFCI IRB policies and guidance should not contradict each other, one may provide additional or expanded requirements for research conduct. When applicable, your research should comply with both and/or the more stringent of the requirements outlined!

Updated Consent Documents



Which Consent-related Resources have been updated?

DF/HCC Policies *(effective 1/31/25)*

CON-100: Informed Consent Process

CON-101: Obtaining Informed Consent of Non-English Speakers

DFCI IRB Policy and Guidance

Guidance: Reconsent & New Risk Notification Guidance for Study Teams

Policy: Use of Legally Authorized Representatives (LAR)

iRIS – DFCI IRB Amendment Form: Reconsent Section

DF/HCC Informed Consent Form Templates



Key Updates

Notification of New Risks & Reconsent



Relevant Updates:

DF/HCC Policy CON-100: Informed Consent Process

DFCI IRB Guidance: Reconsent and New Risk Notification

iRIS Amendment Form – Reconsent Section

Key Updates – CON-100: Informed Consent Process



Section 5.5. Updated Information Based on New Significant Findings

- Simplified to outline overarching DF/HCC requirements that apply to all studies regarding updating participants of new information and (when applicable) obtaining reconsent in a timely manner.

Considerations for this update:

- Ultimately, the IRB of record must approve the protocol-specific plan for notifying participants and obtaining reconsent.
- Therefore, certain plan specifics that were previously outlined in this policy (e.g., different methods of notification/reconsent, specific timing requirements) have been moved to the DFCI IRB Guidance.

Key Updates – CON-100: Informed Consent Process

5.5.1. The participant (or legally authorized representative) must be informed in a timely manner when new information becomes available that may be relevant to the participant's willingness to continue participation in the research.

5.5.1.1. The IRB of record must review and approve any plan for how new information will be communicated to the participant (or legally authorized representative), including:

5.5.1.1.1. The method by which participants will be notified, including whether the use of a revised informed consent form will be required, or whether the use of a consent addendum or verbal or written notification (or a combination of these methods) will be used.

5.5.1.1.2. Timing of when participants will be informed.

5.5.1.1.3. Which participants need to be informed. (e.g., only participants that are actively receiving treatment, or all participants who were on the study).

5.5.1.1.4. Which study team members may present the updated information and when applicable obtain informed consent from the participant.

5.5.1.1.4.1. For interventional drug, device, biologic, surgery or radiation trials determined to be more than minimal risk:

5.5.1.1.4.1.1. When a signed full consent form is used, the person obtaining consent must be an attending physician.

5.5.1.1.4.1.2. When a signed consent addendum is used that includes new or increased severity of risks, the person obtaining consent must be an attending physician.

Defines overarching requirement for all DF/HCC studies and clarifies that the IRB of record must approve the specific plan for how new information will be communicated, including the below elements.

Defines which elements must be included in an IRB-approved plan.

Note, guidance for study teams in determining these elements for their protocol are now outlined in detail in the new DFCI IRB Reconsent Guidance

Important – DF/HCC requirement regardless of IRB of record determination.

Study team member notifying/reconsenting must be an attending physician in these scenarios



Dana-Farber/Harvard
Cancer Center



Key Updates –DFCI IRB Guidance: Reconsent and New Risk Notification

NEW Guidance for Studies under the DFCI IRB

- This new guidance has been merged with previous CON-OP-1 to help study teams determine and submit an appropriate risk notification/reconsent plan to the DFCI IRB for approval
- Currently posted and available for study team use
 - Also linked directly in the **iRIS Amendment Form – Reconsent section**

Quick links to jump to sections in the guidance

Reconsent and New Risk Notification DFCI IRB Guidance for Study Teams

Contents

General Information and Overview

1. [Background and Definitions](#)
2. [Overview of Notification/Reconsent Methods](#)
 - a. [Full Revised Consent Form](#)
 - b. [Consent Addendum](#)
 - c. [Verbal or Written Notification](#)
3. [Process for Submitting and Activating a Plan for Notification/Reconsent to the DFCI IRB](#)
4. [Notifying Participants Prior to IRB Approval of Plan](#)
5. [Notifying Participants After IRB Approval, but Prior to Activation \(when activation is delayed\)](#)

Guidance for Developing an Appropriate Plan to Notify/Reconsent Participants

6. [Initial Determination of an Appropriate Plan](#)
7. [Determining Which Participants Need to be Notified/Reconsented](#)
8. [Determining the Appropriate Method for Notification/Reconsent](#)
9. [Determining Which Study Team Members Can Notify/Reconsent](#)
10. [Sample Language: Amendment Submission to the DFCI IRB](#)



Dana-Farber/Harvard
Cancer Center



A Cancer Center Designated by the
National Cancer Institute

Key Updates –DFCI IRB Guidance: Reconsent and New Risk Notification

Key Sections - Guidance

Overview of Methods

- Full revised consent form
- Consent addendum
- Verbal or written notification

Process for submitting a plan to the DFCI IRB

- Core site submission process and communication of the IRB-approved plan

Notifying participants prior to IRB approval of plan

- When is it necessary or appropriate to notify participants prior to IRB approval?

Notifying participants after IRB approval, but *prior* to activation (e.g., when activation is delayed)

- When reconsent is required for increased or new risks, activation is expected within 30 days; For cases where there is a delay in activation, OHRS has implemented a notification process:
 - 21 days following IRB approval – initial notice to PI
 - 30 days following IRB approval – second notice and requirement to begin verbally notifying impacted participants if appropriate

Key Updates –DFCI IRB Guidance: Reconsent and New Risk Notification

Key Sections - Guidance

Initial determination of a notification/reconsent plan to submit to the IRB

- The following sections outline key elements that each plan should include, along with considerations and examples for the study team, including:
 - Which participants** need to be notified/reconsented
 - The **appropriate method and timing** for notification/reconsent
 - Which study team members** may notify/reconsent participants

For example:

7. Determining the appropriate <u>method</u> of reconsent / notification		
Use the following considerations when determining the appropriate method (s) of notification / reconsent to present in the proposed plan to Saved to this PC		
Method of notification / reconsent	Considerations when determining the appropriate method	Examples of when this method is appropriate
☐ Revised Consent Form	- Consider how extensive the changes to the research are? - This method of reconsent involves a review of the entire consent form, including the embedded optional studies. If optional studies have been completed at an earlier time point, "N/A" can be selected. - Keep in mind that verbal notification may also be appropriate to communicate new information such as increased risk in a timely manner to participants, prior to the next opportunity to obtain consent via the revised consent form. - The PI makes the initial determination as to whether the revised consent form should be used for the reconsent of existing participants or if a consent addendum would be more appropriate (see below).	- Extensive changes have been made to the study - New information is available that impacts alternative treatment options for participants. - A new risk is added, there is an increase in risk severity, or increase in risk frequency (e.g., a risk is moved from occasional to frequent). - A change to the study design such that more intervention/interaction with participants will be required (e.g., drug administration schedule changed). - A change that may result in new inconveniences or discomforts. - New FDA approval of a drug or device.

Newly defined requirement, per DF/HCC policy and DFCI IRB guidance: When using a Consent Addendum to notify of new or increased risk for greater than minimal risk drug, device, biologic, surgery radiation, attending physician must sign

For example:

8. Determining <u>which study team member</u> may notify participant or obtain reconsent for <u>interventional drug, device, biologic, surgery and radiation studies determined to be more than minimal risk</u> (per DF/HCC policy and DFCI IRB guidance):			
	Verbal Notification	Consent Addendum	Full Revised Consent Form
New or increased severity of risks	APP (PA/NP) or attending physician	Attending physician	Attending physician
All other changes	Qualified clinical staff member (attending physician, dentist, RN, PA, NP)	Qualified clinical staff member (attending physician, dentist, RN, PA, NP)	Attending physician

Determining <u>which study team member</u> may notify participant or obtain reconsent for <u>minimal risk studies</u>			
	Verbal Notification	Consent Addendum	Full Revised Consent Form
All changes	Qualified staff member as designated by the PI and in accordance with CON-100	Qualified staff member as designated by the PI and in accordance with CON-100	Qualified staff member as designated by the PI and in accordance with CON-100

Consider: When risks are being updated, participants should at a minimum be verbally notified by an APP or attending physician prior to proceeding with treatment/intervention (even if timing does not allow signing of addendum/ICF prior to next protocol intervention)

Key Updates –DFCI IRB Guidance: Reconsent and New Risk Notification

Key Sections in the Guidance

- **SAMPLE** language to be included in submission to the IRB

9. SAMPLE language to be included in submission to the IRB for reconsent plan:	Considerations for this example:
<i>“Upon activation, patients in active treatment will be reconsented at their next study visit with a provider. If the next visit is not scheduled with an attending physician and the attending physician is not available to conduct a full reconsent at that scheduled visit, the patient will be verbally notified by the APP or attending physician, this verbal notification must be documented by the person completing the notification. Verbally notified patients will then be reconsented at the next scheduled study visit with the attending physician.”</i>	• This language would be appropriate for significant amendments that include new/increased risk changes, where there is a chance amendment activation may be delayed, and verbal notification may be needed. • Need to consider if APPs within the team are trained and comfortable to complete verbal notifications.
<i>“Upon activation, participants in active treatment will be reconsented at their next study visit with an attending physician.”</i>	• This language would be appropriate when there is an extensive protocol amendment that did <u>not</u> include new/increased risk changes and therefore would not need any verbal notification. • Though the timing of the physician visit should be considered, if the amendment makes any procedure changes (e.g. new lab tests or an additional PK), the participant must be reconsented prior to completing added procedures.
<i>“Upon activation, participants in active treatment will sign a revised addendum at their next study visit. The addendum will be signed by a qualified clinical staff member (attending physician, RN, PA, NP).”</i>	• This language would be appropriate in a situation where the addendum was utilized and does <u>not</u> include new/increased risk updates or a need for verbal notification prior to the next visit.

Key Updates – iRIS – DFCI IRB Amendment Form

The AM Form section regarding reconsent plans has been updated to align with the newly posted DFCI IRB Guidance

Reconsent Section

All consented subjects who have not yet begun receiving research interventions or are actively receiving research interventions

Will any consented subjects who have not yet begun receiving research interventions or are actively receiving research interventions be reconsented / notified?

☐ Yes ☐ No

If applicable, please specify the reconsent plan details below including:

- Timing of the reconsent
- Who can perform the reconsent
- Method of the reconsent
- Verbal notification plan (if needed)

For additional guidance in developing and submitting an appropriate reconsent plan, please see the [OHRs DFCI IRB Reconsent Guidance](#)

Clearly defines elements of the plan that need to be included in the free text field

Guidance document linked directly in form

Method of Reconsent / Notification	Process of Reconsent / Notification
☐ Consent Form	☐ Next study visit with an attending physician. If the attending physician visits are infrequent on this study, please consider verbally notifying participants of the added risks prior to the attending physician reconsent visit. ☐ Minimal risk studies: next study visit ☐ Send consent and call prior to next scheduled study visit
☐ Consent Addendum	☐ Next study visit ☐ Increased Risk: Next study visit with an attending physician. If the attending physician visits are infrequent on this study, please consider verbally notifying participants of the added risks prior to the attending physician reconsent visit. ☐ Send consent addendum and call prior to next scheduled study visit.
☐ Verbal Notification	☐ Next study visit prior to full attending physician reconsent ☐ Next study visit ☐ Call prior to next scheduled study visit
☐ Notification Letter	☐ Send letter ☐ Letter will be given when they are next seen by a member of the study team

- Aligns options for method and timing with current guidance
- Prompts consideration for when verbal notification may be appropriate prior to full reconsent
- Multiple options may be checked (e.g., if you plan to verbally notify prior to next scheduled study visit with attending physician)

Key Updates

Use of Legally Authorized Representatives (LAR)



Relevant Updates:

DF/HCC Policy CON-100: Informed Consent Process

DFCI IRB Policy: Use of a Legally Authorized Representative

DF/HCC Consent Form Template – LAR Signature Block

Key Updates – CON-100: Informed Consent Process



- **Section 5.7. Inclusion of Persons with Diminished Decision-Making Capacity and Use of a LAR**
 - This section has been revised to clearly state that for persons lacking the capacity to provide informed consent, the use of a LAR is required.
 - Further, the **use of a LAR in DF/HCC research requires approval by the IRB of record**.

5.7. Inclusion of Persons with Diminished Decision-Making Capacity and Use of a Legally Authorized Representative

5.7.1. Federal Regulations provide for potential additional protections for participants that may be vulnerable to undue influence such as those lacking the mental capacity to consent for themselves. For persons who lack capacity to provide informed consent, the signature of a legally authorized representative (LAR) is required.

5.7.2. The use of a LAR in DF/HCC research requires approval by the IRB of record. When the use of a LAR is approved by the IRB:

5.7.2.1. The person obtaining consent will provide a copy of the signed and dated informed consent document to the LAR and present the information in accordance with section 5.3.



Dana-Farber/Harvard
Cancer Center



A Cancer Center Designated by the
National Cancer Institute

Key Updates – CON-100: Informed Consent Process

5.7.2.2. If an LAR is used, the following should be **documented** in the description of the consent process (in addition to the documentation requirements outlined in section 5.4.):

5.7.2.2.1. That decision-making capacity was **assessed by the individual obtaining consent** and it was **determined that the use of an LAR was appropriate**.

5.7.2.2.2. That the **potential participant was included in the process of consent** to the extent possible and consistent with their desires and abilities.

When a LAR is used, the individual obtaining consent should document that both of these occurred



Dana-Farber/Harvard
Cancer Center



A Cancer Center Designated by the
National Cancer Institute

Key Updates – DFCI IRB Policy: Use of a Legally Authorized Representative (LAR)

- This document has been updated to provide additional requirements and context for the appropriate use of a LAR for studies reviewed by the DFCI IRB

Contents

1. [Backgrounds and Definitions](#)
2. [Criteria and Considerations for Use of a LAR Under the DFCI IRB](#)
 - a. [Determining Capacity to Consent](#)
 - b. [Criteria for Acting as a LAR for Research Conducted in Massachusetts](#)
 - c. [Identifying a LAR for Research Conducted Outside of Massachusetts](#)
3. [Process for Proposing and Obtaining IRB Approval for the Use of a LAR](#)

Criteria under which the DFCI IRB will consider approving the use of a LAR



The DFCI IRB will consider the use of a LAR with regard to the following groups:

- Individuals whose medical condition, or treatment effects may render them decisionally impaired and temporarily unable to provide informed consent
- Individuals who have a cognitive impairment such as intellectual disabilities, dementia, or psychosis that are enduring or that may worsen over time. In some cases, individuals with this type of impairment may be excluded by the sponsor due to inability to complete participant responsibilities

Key Updates – DFCI IRB Policy: Use of a Legally Authorized Representative (LAR)

Process for Obtaining DFCI IRB Approval for the use of a LAR

- The PI should prospectively determine whether the use of an LAR may be appropriate and necessary for each specific research project. When the determination is that an LAR may be used, this should be included in the submission to the DFCI IRB, either in the New Protocol Application (NPA) or via an amendment.
- The NPA or amendment must include the following for review by the DFCI IRB:
 - Indication that there is a desire to include participants that may lack decisional capacity by checking the box indicating the inclusion of vulnerable participants
 - A description of an anticipated circumstance in which participants with fluctuating capacity may be included or identify conditions involving more permanent disability.
 - In the latter case, there may be a record of a cognitive impairment in the EMR and a previously appointed legal representative that will be utilized for consent
 - Methods by which the investigator will assess decision-making capacity, prior to invoking the participation of a LAR.
 - Investigator assessments should include the four competency dimensions of understanding, appreciation, reasoning, and expression of a choice.
- Additionally, the consent form document submitted to the DFCI IRB for approval must include the “Legally Authorized Representative signature block” (found in the DF/HCC Consent Form Template).
 - Prior to this policy update, all DF/HCC consent forms included the LAR signature box regardless of whether the IRB had approved the use of an LAR. Per this updated policy, prospective IRB approval should be obtained for any study seeking approval for use of an LAR. If IRB approval was not previously obtained for any study that is or plans on including cognitively impaired participants, an amendment should be submitted to the DFCI IRB to obtain approval.

Existing LAR Signature Lines

If your current ICF includes a LAR signature line, but the IRB has not approved the use of a LAR, this section should be removed at the next amendment.

Teams are not required to submit a special amendment to make this update.

[Please only include this section when it is anticipated that a Legally Authorized Representative will be signing on behalf of a participant, and it is noted in the protocol application. **If it is not, delete this section.**]

Please sign here when a Legally Authorized Representative will sign on behalf of the Participant:

Signature of Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant

Key Updates

Additional Updates to CON-100: Informed Consent Process



Relevant Updates:

DF/HCC Policy CON-100: Informed Consent Process

DF/HCC Consent Template – Signature Block

Additional Key Updates – CON-100: Informed Consent Process

Section 5.8. Inclusion of Persons with Physical Limitations or Limitations with Reading or Writing

5.8.1. A person who is physically unable to talk, read, or write, or may have difficulties with reading or writing, may provide informed consent for the research if; (1) they are **competent and able to indicate approval or disapproval by other means** and (2) the person retains the ability to understand the **concepts of the research and evaluate the risk and benefit** of being in the research when it is explained verbally.

In these cases, a LAR should not be used because the participant retains the ability to understand the concepts of the research, risks and benefits, and can provide consent.

5.8.2. The designated research team member obtaining informed consent should **document in the medical record** (as applicable) **the method used for communication** with the prospective participant and **the specific means by which the prospective participant communicated** agreement to participate in the research. The informed consent process must take place in person. A witness must also be present for the entire consent process and sign the informed consent document.

Documentation is key, including the method of communication and the specific means by which they communicate agreement to participate in the research.

A separate **witness** must be present, and sign the ICF

5.8.2.1. Participants may be permitted, due to physical limitations or limitations with reading or writing, to verbally consent if it meets the requirements of documentation of consent. **In these cases, the individual will indicate their consent with a mark, such as an “x”, in the event they cannot provide a signature. A participant who is physically unable to write out a mark, and unable to speak, can be entered into a study if they are competent and able to indicate approval, or disapproval, by other means.**

In lieu of a signature, the participant may be permitted to indicate consent with a mark (e.g., “x”) OR if unable, may be able to provide an alternative form of approval (e.g., indicating approval or disapproval with eye movement or a technical communication aid).

Key Updates – DF/HCC Informed Consent Form Templates

- Updated signature block for obtaining consent from an adult who is unable to sign the consent form and required a witness, per CON-100:

CON-100 requires a witness be present when an individual with a physical limitation or limitation with reading or writing is consented, and is therefore unable to sign the consent form

Clearly identifies reason participant is unable to sign the consent and required a witness.

Updated attestation language clarifies the role of the witness.

☐ 3) The participant is an adult and provided consent to participate but required a witness. They were unable to sign the consent form because:

☐ The participant is unable to read and write.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

☐ I am serving as witness.

I was present during the oral presentation of the study informed consent information, the participant had an opportunity to ask questions, and was told that their participation is voluntary.

Witness Signature

Additional Key Updates – CON-100: Informed Consent Process

Section 5.9. Inclusion of Children and Minors

5.9.1. Children or minors will be asked to provide assent prior to enrollment in the research, as required by the IRB of record.

5.9.2. The IRB of record will determine the age at which providing assent is expected.

5.9.2.1. For research conducted under the DF/HCC, children under the age of 10 are not expected to provide assent. Children aged 10-17 are expected to provide assent unless an alternate determination is made by the IRB of record.

Ultimately, the IRB of record will determine the age assent is expected. DF/HCC outlines general expectations here, but alternate determination may be made by the IRB.

5.9.4. As required by the IRB, the parent(s) or legally authorized representative must sign the informed consent document to provide permission for children or minors to participate in the research.

5.9.4.1. If during the course of the research there is a change in legal guardianship of the minor, the study team should reach out to the DF/HCC Office of Human Research Studies (OHRs) for guidance.

DF/HCC acknowledges that these scenarios may occur, however they typically need to be handled on a case-by-case basis, hence the lack of strict policy requirement. OHRs will provide guidance in determining the most appropriate course of action.

Additional Key Updates – CON-100: Informed Consent Process

Section 5.10. Continued Participation for Minor Who Reached the Age of Majority During Research

5.10.1. If a minor participant turns 18 while research activities are ongoing, the participant who has reached the age of majority must now provide informed consent and HIPAA Authorization for their continued participation in the research. The prior assent is no longer legally valid, and informed consent must now be provided on an IRB approved research consent form, unless a waiver of consent is obtained.

5.10.1.1. Informed consent must be obtained at the participant's next protocol visit, and at a minimum prior to performing any further research interventions, procedures, or activities involving this participant or their previously collected identifiable research samples or data, when applicable.

5.10.1.2. The same requirements outlined in sections 5.1. for who may obtain informed consent apply.

5.10.1.3. If the participant is no longer reachable (e.g., lost to follow-up), and it is not possible for the participant to provide informed consent, any previously collected specimens or research data must be de-identified if they will be used for future research purposes (e.g., additional research tests performed on previously collected samples.)

Once a minor participant turns 18, no further research activities may occur until they provide informed consent on an IRB approved consent form.

For the DFCI IRB, this may be the long form consent document or the consent template for Continued Participation in a Research Study by a Young Adult Who Has Reached Age 18

Importantly, if consent is not obtained, no further research activities may continue; this includes on any previously collected specimens or research data from that individual, unless they are de-identified.

Key Updates

Obtaining Consent from Non-English Speakers



Relevant Updates:

DF/HCC Policy CON-101: Obtaining Consent from Non-English Speakers

DF/HCC Consent Templates – Signature Block

Key Updates – CON-101: Obtaining Informed Consent from Non-English Speakers



Interpreter Definition – Clarification to align with regulatory guidance:

- Use of an adult family member for interpretation is not permitted *unless a professional interpreter is not available, and it is allowable per institutional policy.*



Section 5.1. Translation of Entire Consent Form

- Removed requirement for a separate witness when a qualified study team member (fluent in both the participant's language and English) obtains consent without the need of a separate oral interpreter.

**Note – a separate witness IS required when a study team member acts as the interpreter for the Short Form Consent*



Section 5.4. Updated Information Based on New Significant Findings

- Language in this section has been simplified to align with CON-100 updates
- Clarifies requirements for either using a fully translated or short form consent, and/or appropriate verbal or written correspondence using a translator or interpreter when applicable.



Dana-Farber/Harvard
Cancer Center



A Cancer Center Designated by the
National Cancer Institute

Key Updates – CON-101: Obtaining Informed Consent from Non-English Speakers



Section 5.2. Short Form Consent

There are two key updates in this section:

5.2.5. The witness will sign the Short Form and Addendum, indicating the oral presentation was conducted, **and** will also sign the IRB-approved written summary (i.e., the IRB-approved English language consent document).

5.2.5.1. When using a **remote interpreter** (i.e., the interpreter is not present to sign the documents), The person obtaining consent then documents the following additional information:

5.2.5.1.1. If the **interpreter is also acting as the witness, the name and ID# of the remote interpreter on the witness signature lines** of both the short form and the witness signature line on the long form English consent.

5.2.5.1.1.1. **Individual institutions may require a physical witness signature.**

Depending on your institution, you may be required to obtain a physical witness signature in this circumstance; documenting the name and ID of the remote interpreter on the witness signature line will not suffice (e.g., MGB requires a physical signature)

5.2.8. **When a short form is used to consent a participant, the investigator must then also obtain a translated copy of the IRB-approved English version of the long form consent document in the language of the participant, which should be done promptly following the use of the short form.**

5.2.8.1. The translated full consent form must be submitted to the IRB for approval, in accordance with section 5.1.3.

5.2.8.2. **Once approved, the translated full consent form must be provided to the participant (or LAR), and it must be documented that this has occurred.**

Important Notes:

- The participant just needs to be provided a copy and **does not** need to sign the translated long form in addition to the previously signed short form.
- If in the interim between use of the short form in a specific language and obtaining IRB approval of a fully translated ICF another participant who speaks that language needs to be consented, the study team should proceed with consenting that participant using the short form. Their ability to provide consent and participate in the research should not be contingent on the timeline of obtaining the fully translated ICF.

Key Updates – DF/HCC Informed Consent Form Templates

• Updated Signature Block for Obtaining Consent of Non-English Speaking Adults

Witness signature is required when using a short form.

This updated attestation language clarifies the role of the witness, which is the same when the interpreter is also serving as the witness.

Interpreter's signature is not required UNLESS they are also serving as the witness

☐ 2) The participant is a non-English speaking adult and provided consent to participate.

☐ 2a) Participant or legally authorized representative was provided the consent information orally in a language they understand and received and signed the translated Short Form in lieu of English consent document. The participant was provided a copy.

Interpreter Name (printed) and/or remote Interpreter's ID number

☐ I am serving as the interpreter and witness.
I was present during the oral presentation of the study informed consent information, the participant had an opportunity to ask questions, and was told that their participation is voluntary.

Witness Signature

☐ I am serving as witness.
I was present during the oral presentation of the study informed consent information, the participant had an opportunity to ask questions, and was told that their participation is voluntary.

Witness Signature

☐ 2b) Participant or legally authorized representative is a non-English speaker who received and signed a translated consent form in the language they understand and was provided a copy. An interpreter was used to facilitate the consent discussion.

Updating Current Interpreter/Witness Signature Lines

Teams do not need to submit a separate amendment to update the signature block to the new version but should consider updating it when already submitting an amendment.

Other DF/HCC Policy Updates

Minor Revisions and Clarifications



Additional DF/HCC Policy Updates



DATA-100: Data Management of Investigator-Sponsored Treatment Protocols

- Updated to adjust language from “therapeutic” to “treatment” to align with current regulatory guidance.

DATA-101: Case Report Form Development

- Updated to adjust language from “therapeutic” to “treatment” to align with current regulatory guidance.
- DF/HCC operation **DATA-OP-3: EDC Receipt** also updated to align language.

RCO-104: New Protocol Submission Requirements

- **Section 5.1.** updated to clarify requirements for the pre-submission form process which went into effect in April 2024.

REGIST-101: Subject Registration

- Updated to adjust language from “therapeutic” to “treatment” to align with current regulatory guidance.

REGIST-200: Registration of Clinical Trials on ClinicalTrials.gov

- **Section 5.2.** Language added to define the requirements and process for transferring clinical trial records between institutions (e.g., when a PI changes institutions).

Additional DF/HCC Policy Updates



REGIST-200: Registration of Clinical Trials on ClinicalTrials.gov

- **Section 5.2.** Language added to define the requirements and process for transferring clinical trial records between institutions (e.g., when a PI changes institutions).

5.2. Transfer of Clinical Trial Records Between Institutions

5.2.1. PIs who change institutions must consult with their institutional PRS administrator to discuss the potential transfer of existing clinicaltrials.gov records to their new institution. Prior to the transfer of a clinical trial record from an external (non-DF/HCC institution) to a DF/HCC institution in clinicaltrials.gov, the following conditions must be met:

5.2.1.1. The protocol must be approved and activated at DF/HCC.

5.2.1.2. The clinicaltrials.gov record must be error-free, up to date, and compliant prior to transfer.

5.2.1.3. The new Responsible Party within DF/HCC must accept responsibility for all future record maintenance, updates, and results reporting (when applicable).

5.2.1.3.1. This means the Responsible Party must ensure they have access to all clinical trial data and/or other information needed to fulfill these responsibilities.



**Dana-Farber/Harvard
Cancer Center**

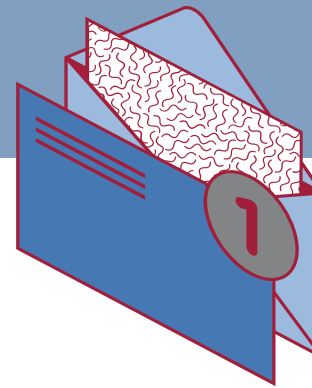


A Cancer Center Designated by the
National Cancer Institute

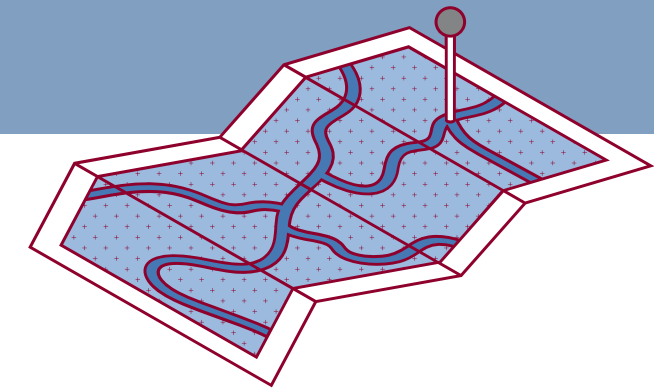
Resources & Support



[DF/HCC Policy Updates](#)
[DFCI IRB Policies & Guidance Library](#)
[DFCI IRB Protocol & Consent Templates](#)



ODQEducation@dfci.harvard.edu
OHRs@dfci.harvard.edu



**Reach out to your institutional
clinical trials office for site-
specific guidance**



Dana-Farber/Harvard
Cancer Center



A Cancer Center Designated by the
National Cancer Institute

Reminder

Session 2 – January 16



Session 2 – Refresher of Consent-Related Updates and FAQs	Thursday, January 16 3:00pm-4:00pm	Click here to register
---	---------------------------------------	--

[Click here](#) to submit a question ahead of the Office Hours