Informed Consent

DF/HCC & DFCI IRB

*Policy, Guidance and Template **Updates***

January 16, 2024 (Session 2)

To view a recording of this webinar presentation, please click here!

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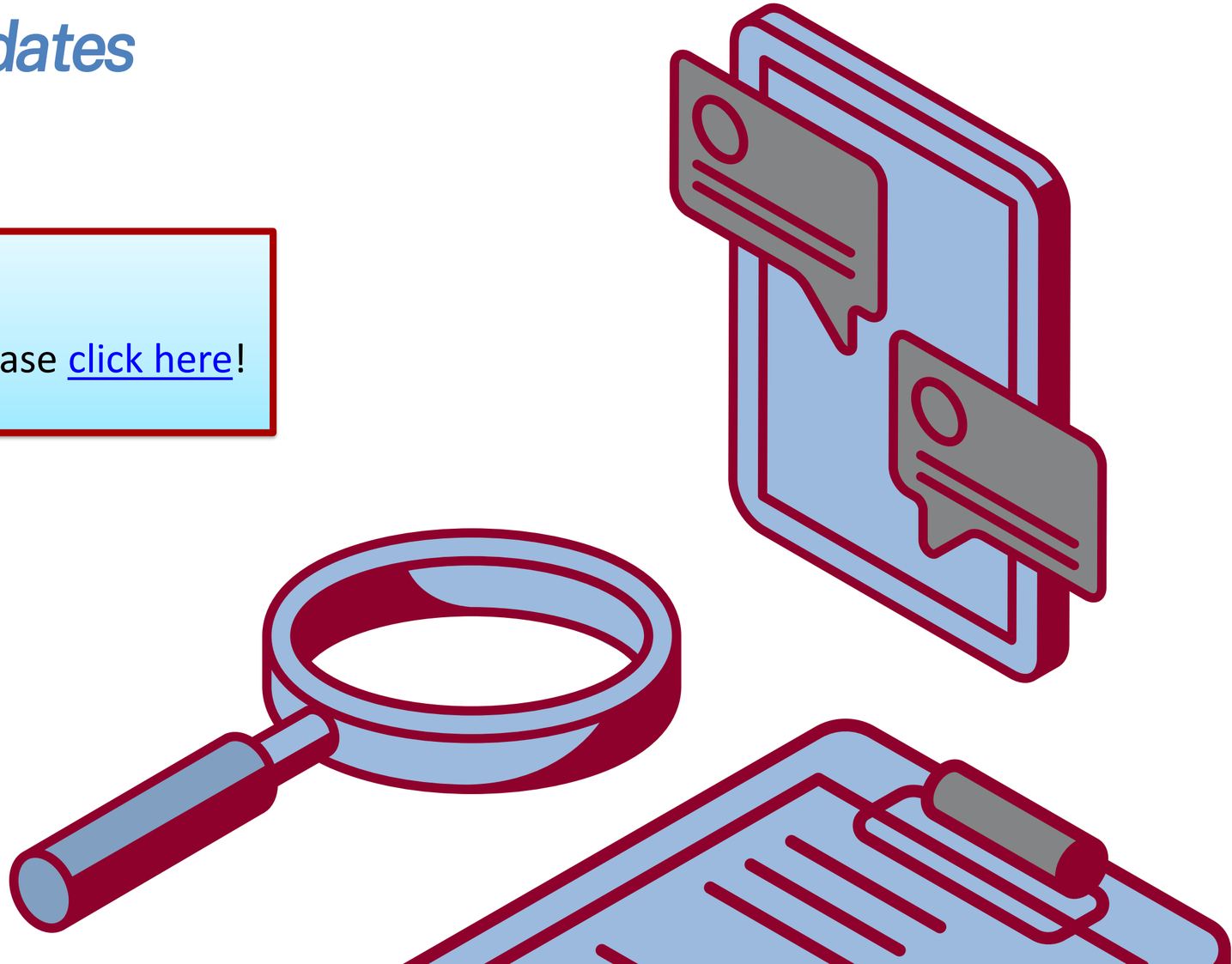

Agenda

1. Refresher of Key Updates
2. Translation of Long Form Consent Document Following Use of Short Form - Refresher & Rationale of New Requirement
3. DF/HCC Consent Templates – Timing and Use
4. Q&A – All Documents

Please hold questions, as they may be answered during the Q&A section!

You will have the opportunity to submit additional questions following the presentation.

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Refresher of Key Updates

Refresher of Key Updates

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

CON-100: Informed Consent Process

- **Witness definition** updated to clarify the role of, and who may serve as witness.
- **Section 5.1.2.** updated to include radiation and surgery to types of interventional trials that require an attending physician to obtain consent (when greater than minimal risk). This is in addition to drug, device, and biologic interventional trials.
- **Section 5.4.6.** Requirement update – a copy of the signed consent document must be uploaded to the electronic medical record (EMR) for interventional drug, device, biologic, radiation, and surgery trials.
- **Section 5.5**. Language simplified to outline overarching DF/HCC requirements for updating participants of new information and when applicable, obtaining reconsent in a timely manner. Language outlining certain plan specifics (exact timing, method, etc.) that are ultimately the determination of the IRB of record has been removed and is now captured in the DFCI IRB guidance on reconsent.
- **Sections 5.9. and 5.10.** Language updated to clarify requirements for seeking assent from minor participants, as well as more clearly defining requirements for when a minor participant reaches the age of majority during the course of research, therefore requiring consent be obtained of the now adult participant.

Tracked Changes and Summary of Updates: [DF/HCC Policy Updates Page]

Refresher of Key Updates

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

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

- **Interpreter definition** updated to allow for a family member **only** when a professional interpreter is not available.
- **Section 5.1.** When a translated copy of the long form consent document is used to obtain consent, the requirement for a separate witness to be present when a qualified study team member acts as interpreter has been removed, as this is not required per the regulations.
- **Section 5.2.5.1.1.1.** Updated to clarify that when a remote interpreter is used and is also acting as witness, institutional policy *may* require a physical witness signature, and writing the interpreter ID or name on the consent document will not suffice.
- **Section 5.2.8.** New requirement – When a short form is used in lieu of a fully translated consent document, the investigator must subsequently obtain a translated copy of the long form consent to be provided to the participant, and it must be documented that this has occurred.
- **Section 5.4.** Language simplified to outline overall requirements for notifying subjects of new information in a timely manner, in accordance with CON-100 and the plan approved by the IRB of record.

Tracked Changes and Summary of Updates: DF/HCC Policy Updates Page

Refresher of Key Updates

DFCI IRB Policy and Guidance

Guidance: Reconsent & New Risk Notification Guidance for Study Teams

- New guidance for teams in developing and submitting a notification/reconsent plan to the DFCI IRB for review and approval.
- Outlines new process for notifying participants after IRB approval but prior to activation (when activation is delayed).
  - *Note* - This document has been combined with previous DF/HCC operation CON-OP-1: Reconsent, which has been retired.

Policy: Use of Legally Authorized Representatives (LAR)

- Updated IRB policy to clarify and expand on the criteria and considerations for using a LAR, and the process for obtaining DFCI IRB approval.

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OHRS Website – DFCI IRB Policies & Information Sheets

Refresher of Key Updates

DF/HCC Informed Consent Form Templates

- Multiple updates, including to the signature block to clarify role of interpreter and witness when applicable.

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OHRS Website – Protocol and Consent Templates

Translation of Long Form Consent Following Use of Short Form

Refresher & Rationale of New Requirement

Translation of Long Form Consent Following Use of Short Form

Current state for obtaining consent from non-English speakers:

- Use of a fully translated consent form in the language of the participant is the preferred method. In lieu of this, use of a short form in the language of the participant is allowed, in conjunction with the full English consent document and a qualified interpreter.

- Currently there is no policy requirement for translating the full informed consent into the language of the non-English speaking participant.

Why are modifications needed at this time?

- Recent FDA Guidance (August 2023) provided more specific language requiring translation after the first use of the short form in a particular language. The participant would then have a copy of the translated consent form in a language they understand; it would be also available to use for this participant in any future re-consent that may be required.

- The FDA and DHHS allow the short form as a tool when a non-English speaker is “unexpected” and it is clear that the FDA interprets the previous need for an interpreter and short form as an indicator that obtaining consent for future participants or obtaining reconsent of enrolled participants is “unexpected”, and therefore, a fully translated consent form should be available for the duration of the study.

Translating the long form consent benefits both the currently enrolled non-English speaking participant and future participants who speak that language.

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Translation of Long Form Consent Following Use of Short Form

What do the regulations say?

Department of Health and Human Services (DHHS) Code of Federal Regulations Guidance

Where informed consent is documented in accordance with §46.117(b)(1), the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them. OHRP strongly encourages the use of this procedure whenever possible.

OHRP Informed Consent from Non-English Speakers Guidance (1995)

FDA Guidance:

"The information given to the prospective subject, which includes both information provided orally during the consent discussion and written information in the consent form, must be in language understandable to the prospective subject or LAR (21 CFR 50.20). "Understandable" means the information presented to prospective subject is in a language and at a level the subjects can comprehend (including an explanation of scientific and medical terms)."

"After the subject has been enrolled in the research, the investigator takes the following additional actions:

…(2) The investigator must obtain a translated copy of the IRB-approved English version of the long form that served as the written summary, which should be done promptly. The investigator promptly submits it to the IRB for review and approval. Once the translated long form/written summary is approved by the IRB, the investigator must provide it to the subject or LAR and should do so as soon as possible. FDA considers this step essential to the requirement that informed consent be documented by the use of a written consent document and that the subject be provided a copy (21 CFR 50.27). Many of the clinical investigations regulated by FDA involve ongoing interventions and may involve long-term follow-up. For this reason, translation of the long form is critically important as a means of providing subjects or their LAR an ongoing source of information understandable to them."

FDA Informed Consent Guidance (2023)

Translation of Long Form Consent Following Use of Short Form

Result:

Updated requirement in **DF/HCC Policy CON-101: Obtaining Consent From Non-English Speakers** to comply with **DHHS federal regulations, FDA guidance**, and **ethical considerations for inclusion of diverse participants** and the obligation to ensure an informed consent process occurs.

Importantly, this must occur following the **first use** of the short form in that language.

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.

Translation of Long Form Consent Following Use of Short Form

Additional Guidance for Teams:

Work with your institutional clinical trials office and/or program leadership for additional guidance in how best to operationalize this new requirement.

Process &Timing

- DF/HCC policy states that obtaining the full translated consent form “should be done promptly following use of the short form”. Once the translated ICF is approved by the IRB, a copy must be provided to the participant.
- If, prior to obtaining the fully translated consent form, another participant who speaks that language needs to be consented, the short form may be used to facilitate a timely consent and enrollment.
- The translated consent document should be provided to the participant by a research team member who is able to document that this occurred in the research chart or medical record when applicable.

Translation Services

- If externally sponsored, contact the sponsor – they may have a preferred company or service that provides translations
- If investigator-sponsored, contact your institutional clinical trials office for guidance – there may be pre-vetted vendors or services they recommend using.

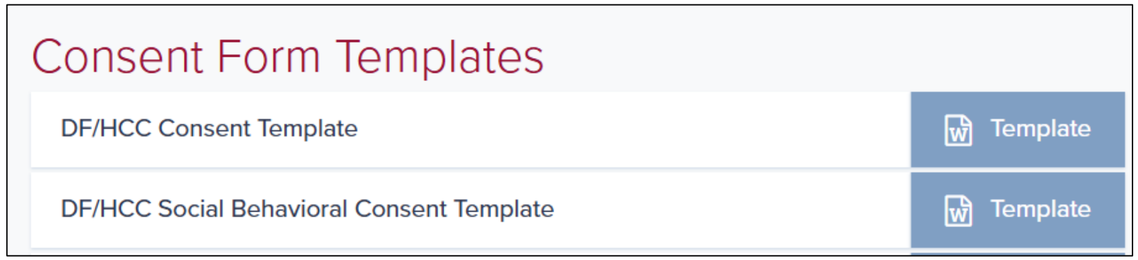
Costs & Budgeting

- The cost of translating consents is the investigator’s responsibility. Investigators should include the cost of written translations, as well as medical interpreter services, in their study budgets.
- Industry sponsors are often willing to pay the cost of translating consent forms.

DF/HCC Consent Form Templates

DF/HCC Informed Consent Form Templates

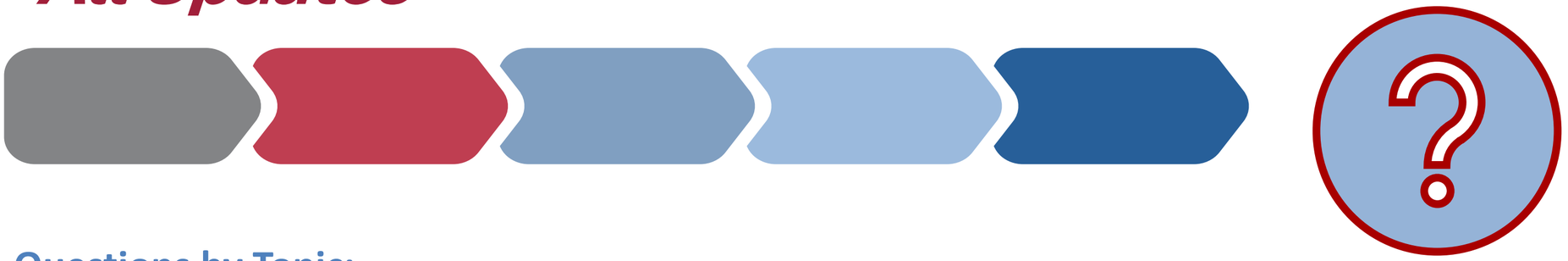
- The following updated consent form templates are now available online (version 01.06.2025)
  - DF/HCC Consent Template
  - DF/HCC Social Behavioral Consent Template
  - Screening Consent Template



- Consent forms are available for use and will be effective January 31, 2025. Please begin to use with any new protocols as soon as possible.
  - OHRS will not require consent forms to be updated retrospectively, however at the time of amendment research teams may update their consent forms, or the IRB may request edits to the new template for a given study
- An overview of changes from the prior version will also be available on the OHRS website

Q&A

All Updates



Questions by Topic:

- Translation of Long Form Consent Following Use of Short Form (CON-101)
- Minors reaching age of majority during research (CON-100)
- OHRS Reconsent Guidance – Timing and verbal notification when activation is delayed
- OHRS LAR Policy – Use of an LAR
- Updated DF/HCC Consent Form Templates

Q&A

CON-101: Obtaining Consent from Non-English Speakers

Section 5.2.8. Translation of the Long Form Following Use of the Short Form

> 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.

Questions & Answers

1. Is this requirement retrospective for participants currently on an active study who were previously enrolled using a short form? Or only for when consent is obtained using the short form following the policy effective date of January 31, 2025?

The requirement applies to participants that consent to participate after the policy effective date.

2. Does this requirement apply to all research studies, including minimal risk?

Yes. DF/HCC policy does not differentiate between study types for this requirement.

3. What is the Core Site's responsibility when it comes to this requirement?

The Core Site is responsible for ensuring the translated consent document is submitted to, reviewed, and approved by the IRB of record.

4. Is the Core Site responsible for coordinating translation of the consent document?

No. Typically, the site where the participant is being enrolled is responsible for coordinating translation of the documents. As with all amendments, the Core Site is responsible coordinating submission of the translated document to the IRB for review and approval.

For clarification on any of question on this slide, please reach out to ODQEducation@dfci.Harvard.edu

Q&A

CON-101: Obtaining Consent from Non-English Speakers

Section 5.2.8. Translation of the Long Form Following Use of the Short Form

> 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.
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>
> 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.

Questions & Answers

1. What should teams do if there is a delay in obtaining approval of an updated, translated consent document, impacting the timeliness of reconsenting a participant?

Consider including a plan for this in the notification/reconsent plan submitted to the IRB. For example, it may be appropriate to use verbal notification or use a short form with the updated English consent document to obtain reconsent. Keep in mind that if verbal notification is appropriate, you would still need to obtain reconsent once the translated consent document is approved and if you use the short form, you will still need to provide the fully translated consent document to the participant in a timely manner.

2. Once a consent form is translated, do we need to continue to keep it updated (e.g., with any amendment changes) going forward?

Yes, best practice is to keep the translated consent form updated. If the enrolled participant requires notification of new risk or reconsent, the fully translated, updated consent form should be available. Even if the participant initially enrolled speaking that language is off study, there is still a possibility of new risks that require notification or reconsent of off-study participants. Further, the regulations clearly state that once a short form is used, it should be considered “expected” that another participant speaking that language may be enrolled, and the short form should not be used when this is expected.

3. Do other participant-facing documents also need to be translated following the use of a short form? (drug diary, surveys, etc.)

DF/HCC policy specifically requires that the consent document be translated. It is generally best practice to obtain translated copies for other participant facing documents when possible. For documents that are provided by an external sponsor, we recommend reaching out to the sponsor to determine whether they will be providing translated copies.

For clarification on any of question on this slide, please reach out to ODQEducation@dfci.Harvard.edu

Q&A

CON-100: Informed Consent Process

Section 5.10. Continued Participation for a Minor Who Reached the Age of Majority (AOM) 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 used for future research purposes (e.g., additional research tests performed on previously collected samples.)

Questions & Answers

1. Do we need to use the full consent form for AOM consent, or can we still use the AOM consent form on OHRS Website?

You may use either, provided it has been approved by the IRB for use on the study.

2. Are we allowed to do AOM consent conversations over the phone and send the hard copy of the consent to the participants to sign and send back to us?

All regular consent requirements outlined in CON-100 and IRB approved consent plan apply – this process is essentially obtaining consent for the first time from the AOM participant, so must be fulfilled in compliance with all standard consent requirements.

3. How do we manage AOM consents if participants on a treatment study had multiple risk groups and signed multiple consents throughout treatment? Do we need to have participants reconsent to all risk groups consents for the treatment they received on study? If there are optional questions in the initial consent form regarding samples, do we need participants to reconsent to these questions at the time of AOM to allow us to continue to use their samples?

Yes – again, consider this a full consent process, so any applicable risk groups, ancillary studies, optional components, or other parts of the consent that would typically need to be completed apply in this scenario as well.

4. Is there guidance on the timing for when a participant should be marked lost to follow up after the AOM is reached? E.g., if it has been 1 year and consent has not been obtained, should they be marked lost to follow-up?

DF/HCC policy does not specify – We recommend study teams connect with the sponsor for guidance on this.

For clarification on any of question on this slide, please reach out to ODQEducation@dfci.Harvard.edu

Q&A

OHRS DFCI IRB Reconsent Guidance

30 Day Activation Delay – Timing & Verbal Notification

Notifying Participants After IRB Approval, but Prior to Activation

- If an amendment requires reconsent and adds increased risk or new risks and there are participants that require notification of these risks, the amendment is expected to activate within 30 days of IRB approval to ensure that the participants are notified in a timely way that is consistent with the IRB approved reconsent plan.
- 21 days after IRB approval, if an amendment has not activated, the Principal Investigator and study team will be reminded by OHRS that the amendment includes risks and must be activated within 30 days.
- If the amendment is not activated by day 30, then the study team must begin verbally notifying all impacted participants and document this notification in the medical record.

Questions & Answers

2. The new Reconsent Guidance requires verbal reconsent to occur if an amendment does not activate within 30 days of IRB approval. Is this 30-day timeline from IRB approval to activation? (E.g., If IRB approval occurs on 1/1, we should start verbally notifying patients on 1/31).

Yes, 30 days from IRB approval to activation.

2a. What happens if we receive IRB approval on 1/1 and activation on 1/25, but then participant does not come in for their next visit for an additional 45 days – Would the 30-day reconsent timeline would apply here? the 30-day timeline for verbal notification if "immediate verbal notification" is not checked on the original amendment form would only apply for IRB approval to Activation?

The 30-day timeline is from IRB approval to activation, not after activation. The IRB will approve the reconsent plan submitted or condition the timeline submitted if necessary for that specific situation.

2b. Once the 30-day timeline does occur what is the timeframe to verbally notify participants? Does it need to be done same day on day 30, do we have a week? What are the timelines around "as soon as possible" for the verbal notification?

The timeline is “as soon as possible” since the IRB does not always know the visit schedule or status of all the participants. The FDA regulations also state “as soon as possible.” If there are questions about a specific situation or concern, please reach out to the OHRS with the submission information and we can assist.

2c. If, for example, 2 out of 4 participants have been verbally notified and then the amendment activates, do the other 2 participants still need to be verbally notified if they do not come into clinic right away? Or once it activates can we stop verbally notifying?

This depends on the reconsent plan submitted and approved by the IRB – very dependent on patient status, risk being added, etc. If after activation, you can get written consent, you should do that. If it will take a while, you can continue to notify. So, in this example, for the two remaining participants, if they are coming in soon, get written consent. If not, then verbally notify.

For clarification on any of the questions on this slide, please reach out to OHRS@dfci.Harvard.edu

Q&A

OHRS DFCI IRB Policy: Using a Legally Authorized Representative (LAR)

IRB Approval and Use of a LAR

Questions & Answers

1. **To confirm, are we required to get IRB approval ahead of using an LAR? What if you don't know you need a LAR until the day the participant shows up in clinic?**
   While we prefer that you anticipate whether the population you intend to enroll may have decision impairments, you may submit a request for an eligibility exception, including the information about who will assess capacity and that the sponsor agrees (or it is stated in the eligibility criteria.)

2. **Is a LAR the same thing as the parent of a child under the age of 18? How do they differ?**
   The parent of a minor child provides "parental permission" and the child provides assent where appropriate. Typically, this doesn't involve as assessment of the specific child's capacity. The IRB or the sponsor selects an age range that is deemed mature enough to understand the study and provide assent

3. **How do we know whether a previous study has been approved for use of an LAR?**
   As of this year on Jan 31, 2025, the LAR signature line will appear on the ICF only when the IRB has approved it's use. The policy requiring prior IRB review will not be retroactive.

4. **As LAR use is approved by the NCI CIRB in our ASIW and PIWs, is it correct that we use LARs without obtaining another IRB approval for a specific instance?**
   If the IRB of record has approved the use of an LAR, it is correct to assume you may proceed without additional IRB approval

5. **If we do have a patient who requires the use of an LAR and we submit for approval to add that line on the ICF, would we then have two different versions of the ICF posted for use, ow would the ICF for that specific study then include the LAR line for all subsequent participants?**
   You would amend the protocol and consent to include the use of the LAR, the explanation of the assessment process and sponsor agreement and it would then be approved for use on the protocol for subsequent participants (who are assessed in the same manner)

For clarification on any of the questions on this slide, please reach out to OHRS@dfci.Harvard.edu

Q&A

DF/HCC Consent Form Templates

Questions & Answers

1. **Regarding the Witness line – I was told to disregard this unless an LAR is used. Some physicians are using this line to document husband or sister (e.g.) as a witness? Is this correct or not appropriate?**

   In discussion of the witness line thus far, we have been talking about its use when the short form is used. When a LAR is used, the research team should indicate the relationship of the LAR to the participant, which is the line directly below the LAR signature line.

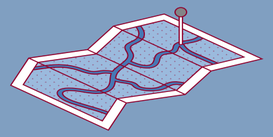
2. When are we required to use the updated consent templates? For example, if we have already been developing a consent form on the current posted template, do we need to update that prior to submission if submitted after a certain date?

We would like you to use the updated consent template after the effective date of January 31 , however OHRS will not send a submission back if the consent is not on the current form. However, please keep in mind that the IRB may require changes to the consent template based on the given context of a research study.

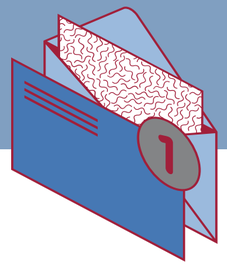
3. Are there plans to develop a template for studies that are approved for verbal consent?

Yes! OHRS has been working on updating the consent form information on our website to be inclusive of a consent form template for when documentation of informed consent is waived. In the meantime, please reach out to OHRS for any questions regarding how to format this.

For clarification on any of the questions on this slide, please reach out to OHRS@dfci.Harvard.edu



Resources & Support



Reach out to your institutional clinical trials office for guidance

BIDMC CCTO

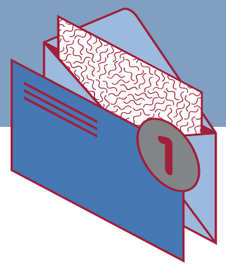
DFCI CTO

MGH CCPO

DF/HCC Policy Updates

DFCI IRB Policies & Guidance Library

DFCI IRB Protocol & Consent Templates



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We want to help!

We strongly encourage everyone to digest the updates and Q&A presented today, share and discuss with your teams, and then submit any follow up questions as needed.

If you don't know who to ask, feel free to use the centralized question submission form here: Submit a question about these updates

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