Reconsent and New Risk Notification
DFCI IRB Guidance for Study Teams

Contents

1. Background and Definitions

When there is updated information based on new significant findings that may be relevant to the participant's willingness to continue participation in the research, the PI and study team must propose an appropriate and comprehensive notification plan and, when applicable, reconsent plan that includes the method of notification, who will notify and obtain consent (when appropriate) and the timing of when the notification will occur.

This document provides guidance for determining and submitting a plan for approval when the DFCI IRB is the IRB of record. All DF/HCC research, regardless of the IRB of record, must also comply with policy CON-100: Informed Consent Process.

For the purposes of this document, the following definitions apply:

- **Notification:** The process of informing research participants about new information without seeking their consent to continue participation. New information can be provided verbally or in a written letter.
- **Reconsent:** The process of informing research participants about new information and documenting their voluntary consent to continue participation in the study. Reconsent can be done with a consent addendum or using a revised consent form.

2. Overview of Notification/Reconsent Methods

Typically, the plan for notification and/or reconsent should align with one or more of the options presented below; however, ultimately the IRB must approve the proposed plan or any alternative plans, which will be outlined in the DFCI IRB Outcome Letter:

- **Full revised consent form**
  - As per CON-100, section 5.1, the individual obtaining reconsent must be an individual who is trained in human participant protections, trained on the protocol, listed on the Delegation of Authority Log when required per DF/HCC policy, and for all interventional drug, biologic, surgery, radiation, or device research determined by the IRB to be more than minimal risk, the person obtaining consent must be an attending physician.
  - The timing of the reconsent plan using the revised consent form must also be specified. If the plan is to reconsent at the next visit with an attending physician, consider whether to include a verbal notification prior to the next visit, per the below guidance.
- **Consent addendum**
  - Addendums offer a streamlined approach and may be useful for presenting changes to the study involving minimal risks or may be selected for clarity of outlining new or increased risks for current participants.
  - Use of an addendum may be selected to present updated information to current participants; however, **the full consent form document must still be revised**.

- Use of addendum allows other qualified team members to sign the addendum as outlined in section 8 of this document, but when the addendum includes changes to the risk/benefit ratio the consent via the addendum must be presented by an attending physician.

- The timing of the reconsent using the addendum must also be specified and when appropriate, the PI and study team should consider whether to include a verbal notification plan, per the below guidance.

- **Verbal or written notification**

  - Verbal (e.g., phone call) or written notification (e.g., notification letter) may be used in certain cases where it is determined that the updated information does not require obtaining informed consent for continued research participation, OR when the participant should be notified of updated information or risks prior to the next opportunity to obtain reconsent.

  - Verbal or written notification does not replace obtaining informed consent via a revised consent form or addendum when determined necessary. In order to inform participants in a timely manner, a verbal notification or letter may be considered for use prior to the next opportunity to obtain written consent.

  - Verbal or written notification of new information that involves new risks or increased severity of risks must be followed by obtaining informed consent either via a revised informed consent document or consent addendum by an attending physician, per the plan approved by the IRB.

  - Verbal notification must be presented by a qualified individual, per section 8 of this document; for interventional drug, biologic, surgery, radiation or device research, verbal notification must be presented by a clinical staff member (e.g., physician, dentist, NP, RN, PA). When there are new risks or increased severity of risks, verbal notification must be presented by an APP (NP/PA) or an attending physician.

  - Information communicated via written notification (e.g., a templated letter sent via mail, email or EMR) must be approved by the IRB prior to use.

3. Process for Submitting a Plan for Notification/Reconsent to the DFCI IRB

- The Core Site is responsible for submitting the amendment form outlining the reconsent/notification plan for IRB review. The reconsent/notification plan must include the method of notification, who will notify and obtain consent (when appropriate) and the timing of when the notification will occur.

- The DFCI IRB will make the final determination of what information will be communicated to the research participant, how the participant will be notified, the timeframe for notification, and which participants will be reconsented/notified. The IRB has the authority to require reconsent or participant notification regardless of whether the PI and sponsor proposed a reconsent plan..

- The DF/HCC Core Site is responsible for communicating the IRB approved reconsent plan to all participating sites.

4. Notifying Participants *Prior* to IRB Approval of Plan

- IRB approval of a notification/reconsent plan should be obtained prior to notifying participants; however, there may be situations when it is necessary for participants to be notified of new information *prior* to IRB review because there is the potential for immediate risk or harm. The sponsor and/or PI will determine if there are any safety implications for participants and if immediate notification is required.

Guidance in determining whether notification is warranted prior to IRB review		
Question	**Considerations**	**Example**
Are any participants at immediate risk and action is needed?	Do all participants need to be notified or only a specific subset (i.e., those on active treatment, only specific arms/cohorts, genders, etc.)?	Participants on active treatment are at immediate risk and need to stop taking study drug.

- If determined that participants should be notified prior to IRB approval of a plan, the study team should include in the amendment form submitted to the IRB that this determination was made, along with the timing and method that was used to notify participants.

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.

5. Initial Determination of a Notification / Reconsent Plan to Submit to the IRB

The PI and study team should use the following tables for guidance in determining an appropriate plan to submit to the IRB for review and approval, including:

- Which participants need to be notified / reconsented
- The appropriate method and timing for notification / reconsent
- Which study team members may notify / reconsent participants

6. Determining which participants need to be notified / reconsented.

There are four general categories for the PI to consider when determining which participants should be reconsented / notified: Active, Follow-up, Survival Follow-up, and Off Study. The study team should work with the PI to determine who needs to be reconsented within each category per the following considerations and examples.

Participants to be notified / reconsented	Considerations when determining who needs to be notified	Examples of when these participants may need to be notified
☐ Active *All consented participants who have not yet begun receiving research interventions or are actively receiving research interventions*	Do all participants on treatment need to be notified or only a specific subset (i.e., only specific arms/cohorts, etc.)? Examples of when only a subset of participants would need to be notified: • Addition of a pregnancy test 24 hours prior to the first treatment cycle. This would only impact individuals of childbearing potential who have not started cycle 1. • A new drug risk is added but only participants on Arm B of the study receive drug X (therefore does not apply to participants on Arm A receiving drug Y).	• 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 has changed) • A change that will result in new inconveniences or discomfort for participants • Added Reimbursement/Stipend • Change in data collection/sharing language (i.e., sponsor extending the time they are keeping data/biospecimens from 10 years to indefinitely, etc)
☐ Follow-up *Participants in follow-up (i.e., no longer on treatment) who are within days of last dose.*	Do all participants in active follow-up need to be notified or only a specific subset? • How are participants in follow-up grouped in the protocol? i.e., 90-day FU, LTFU, etc. • Use the protocol language to clearly state which participants are to be consented/notified and which are not.	• There is a newly identified side effect of the study drug which can occur up to 3 months after permanent drug discontinuation • Increasing duration of follow-up visits • Added assessments or increased frequency of assessments that impacts active follow-up • Added or changed reimbursement/stipend that impacts active follow-up participants • Increased duration of contraception requirements during active follow-up

☐ Survival Follow-up *Participants in survival follow-up*	• Do all participants in survival follow-up need to be notified or only a specific subset?	• There are newly discovered long term side effects of the study drug so all participants who have received or are planning to receive the drug need to be informed • Increased frequency/duration of survival follow-up
☐ Off Study *Participants off study*	Does this change need to be communicated to participants who completed follow-up and/or those who withdrew from the study?	• There are newly discovered long term side effects of the study drug so all participants who have received the drug while on study need to be informed

7. Determining the appropriate method of reconsent / notification

Use the following considerations when determining the appropriate method (s) of notification / reconsent to present in the proposed plan to the IRB.

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 has changed) • A change that may result in new inconveniences or discomfort for participants • New FDA approval of the study drug

☐ Consent Addendum	• May be appropriate if the changes involve a few news risks or procedures that are discrete from the other study risks or procedures in the full ICF. In this case, , it may be more efficient to communicate the new information to the participant via addendum. • Keep in mind that the consent form must still be revised. • Keep in mind that verbal notification may also be appropriate to communicate new information such as increased risks in a timely manner to participants, prior to the next opportunity to obtain consent via addendum.	• Addition of a blood draw • Addition of an eye exam • The follow-up period has increased from 6 months to 12 months • A questionnaire is changed from optional to mandatory • A few new risks or increased severity of risk • Changes in costs associated with participation (e.g., previously provided drug is now being charged to participants' insurance)
☐ Verbal Notification	• Consider the complexity of the new information and whether it requires an interactive discussion, the likeliness it may change a participant's willingness to continue participation, and/or addition of any new or increased risks. If none of these apply, verbal notification may be sufficient. • Consider how important it will be for participants to be notified in a timely manner. Verbal notification followed by reconsent via revised consent form or addendum may be appropriate in these cases. • All requirements detailed in DF/HCC CON-100 for verbal notification must be followed, including documentation requirements	• There is a decrease in the number of blood draws • MD/Clinic visits for full reconsent are infrequent and or distant enough that the PI and/or IRB determine that written or verbal notification is necessary to facilitate timely notification of changes, to be followed by full reconsent

☐ Written Notification Letter	• Consider the complexity of the new information. Is there a need for an interactive explanation or discussion or is the new information / change straight forward? • The letter can also be followed by verbal notification to the participant from a qualified (e.g., clinical) member of the study team to answer any questions. • Any written correspondence to the participant must be approved by the IRB of record. • The letter must be translated for all non-English speaking participants into a language that is understandable to the participant. • The notification letter must be prepared on official letterhead and must contain the PI's contact information. The letter is mailed to participants using a method that allows for the shipment to be tracked. • All requirements detailed in DF/HCC CON-100 for notifications via a letter must be followed, including documentation requirements.	• There is a decrease in the number of blood draws • The follow-up period has decreased from 12 months to 8 months • Study results become available • MD/Clinic visits for full reconsent are infrequent and or distant enough that the PI and/or IRB determine that written or verbal notification is necessary to facilitate timely notification of changes, to be followed by full reconsent

8. Determining which study team member may notify participant or obtain reconsent for interventional drug, device, biologic, surgery and radiation studies determined to be more than minimal risk *(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 which study team member may notify participant or obtain reconsent for minimal risk studies			
	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

9. SAMPLE language to be included in submission to the IRB for reconsent plan:	Considerations for this example:
"*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.*	• 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
"*Upon activation, participants in active treatment will be reconsented at their next study visit with an attending physician."*	• This language would be appropriate when there is an extensive protocol amendment that did not 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
"*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)."*	• This language would be appropriate in a situation where the addendum was utilized and does not include new/increased risk updates or a need for verbal notification prior to the next visit