1. BACKGROUND:

1.1. The participant (or legally authorized representative) must be informed when new information becomes available that may be relevant to the person's willingness to continue participation in the research. Minor editorial or administrative changes to the consent are unlikely to affect participants and generally do not require reconsent.

The principal investigator (PI) assesses the new information and makes an initial determination as to the need for reconsent/notification and the method of that communication. This determination to notify the IRB and the proposed reconsent/notification plan must be communicated to the Core Site since the Core Site will be responsible for submitting the amendment form for IRB review. The PI must take into consideration the status of participants at all institutions using the IRB when considering the reconsent/notification plan. For example, if it will be several months before a participant at a participating site is back for a visit, the PI should consider checking off the option allowing the consent form to be mailed and discussed over the phone so the participant is informed of the new information in a timely matter.

The 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 feel it is necessary.

The IRB approved reconsent/notification plan will be communicated to all PIs at the participating DF/HCC sites in the IRB outcome letter. All processes related to obtaining and documenting consent in DF/HCC CON-100 Informed Consent Process must be followed for reconsents. Failure to follow the IRB determination and instructions for reconsent and/or notification is considered non-compliance.

1.2. **Definitions:**

1.2.1. **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.

1.2.2. **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 an updated consent form.

2. ASSOCIATED DF/HCC POLICIES:

2.1. CON-100

3. PROCEDURE:

3.1. **Notification Plan Prior to IRB Amendment Approval**

3.1.1. 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 harm. The sponsor and/or PI determine if there are any safety implications for participants and if immediate notification is required. For studies under the DFCI IRB, information specifying how the information was relayed and to which participants is captured on the Amendment Form. In situations where participants have been notified of new information prior to IRB review, the IRB may still require full reconsent.

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.

3.2. **Plan for Reconsent / Notification after IRB Amendment Approval / Action**

Determining who needs to be reconsented / notified.

The PI makes an initial determination regarding which participants should be reconsented / notified. There are four general categories 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 Reconsented / Notified	**Considerations when determining who needs to be reconsented / notified**	**Examples of when reconsent / notification applies**
☐ **Active** All previously consented participants, participants who have not yet begun receiving research interventions, and participants receiving active research interventions	Do all participants on treatment need to be notified or only a specific subset (i.e., only specific arms/cohorts, genders, 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 women 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. • New FDA approval of the study drug.

Participants to be Reconsented / Notified	**Considerations when determining who needs to be reconsented / notified**	**Examples of when reconsent / notification applies**
☐ 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. May want to 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.
☐ 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. • Change in PI contact or study sponsor • Change in the PI(s)' conflict of interest.
☐ 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 or are planning to receive the drug need to be informed. • Change in PI contact or study sponsor • Change in the PI(s)' conflict of interest.

Determining the appropriate method of reconsent / notification

Once the PI determines which participants need to be reconsented/notified, he or she establishes the method by which the information will be relayed to the participants. The study team should work with the PI to determine the appropriate method of reconsent / notification per the following considerations and examples.

Method of reconsent / notification	**Considerations when determining the appropriate method of reconsent / notification**	**Examples of when the method is appropriate**
☐ Revised Consent Form	How extensive are the changes to the research? 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. When a revised consent form is used, the person obtaining reconsent for all interventional drug, biologic, or device research must be an attending physician. If the study is open to enrollment, the consent form must be revised for use with new participants. The overall 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 so it is not practical to reconsent participants using a consent addendum. • New information is available and it impacts alternative treatment options for participants. This information needs to be relayed to participants by an attending physician.
☐ Consent Addendum	A consent form addendum should only be used when the amount of new information or changes is limited. When a consent addendum is used, the person obtaining reconsent for all interventional drug, biologic, or device research must be a clinical staff member (e.g., licensed physician, dentist, NP, RN, or PA). If the study is **actively enrolling, temporarily closed, and/or has subjects receiving active treatment or follow-up**, the main consent form must also be revised with the new information.	• Addition of a blood draw. • The follow-up period has increased from 6 months to 12 months. • Change in the PI(s)' conflict of interest. • A questionnaire is changed from optional to mandatory • Changes in costs associated with participation (e.g., previously provided drug is now being charged to participants' insurance).

Method of reconsent / notification	**Considerations when determining the appropriate method of reconsent / notification**	**Examples of when the method is appropriate**
☐ Verbal Notification	Consider the complexity of the new information. Is there a need for an interactive explanation or discussion? Consider how important it will be for participants to notified in a timely manner. Will it be a long time before their next protocol exam visit? Is the information likely to change a participant's willingness to participate? If no, then reconsent may not be necessary. Verbal notification, may be sufficient. For all interventional drug, biologic, or device research, the individual conducting the verbal notification must be a clinical staff member (e.g., licensed physician, dentists, NP, RN, and PA).	• There is a decrease in the number of blood draws. • The risk of nausea increased from frequent to likely. • There is a change in the study sponsor.
☐ 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 a phone call to the participant from a qualified (e.g., clinical) member of the study team to answer any questions. The letter must be translated for all non-English speaking participants into a language that is understandable to the participant.	• There is a decrease in the number of blood draws. • The follow-up period has decreased from 12 months to 8 months. • There is a changed in the study sponsor. • Study results become available.

Determining the appropriate method of reconsent / notification Lastly, the PI makes an initial determination regarding where and when the reconsent / notification should take place. The study team should work with the PI to determine the appropriate process per the following considerations.		
Process of reconsent / notification	**Considerations when determining the appropriate method of reconsent / notification**	**Procedure**
☐ Next scheduled protocol exam visit with a member of the study team who is qualified to conduct the reconsent / notification per CON-100.	The reconsent / notification (using a revised consent form, consent addendum, or verbal notification) takes place the next time the participant comes in for a scheduled protocol exam visit with a member of the study team who is qualified to conduct the reconsent / notification per CON-100. Consider how long it will be before the participant's next protocol exam visit where reconsent or notification could take place. Participants on active treatment will likely be in clinic on a regular basis so reconsent / notification would take place in a timely fashion. Participants who have been on treatment for a while may be coming in for protocol visits but they may not be scheduled to see a member of the study team who is qualified to conduct the reconsent / notification or participants in follow-up may not be seen for many months so a call (see below) could be more appropriate.	All requirements detailed in DF/HCC CON-100 for reconsent or verbal notification must be followed. For non-English speaking participants, the process of obtaining reconsent or notifying them of updated information follows the policy on consenting non-English speakers. See DF/HCC CON-101 for details.

Process of reconsent / notification	**Considerations when determining the appropriate method of reconsent / notification**	**Procedure**
☐ Call prior to next scheduled visit	Reconsent / notification (using a revised consent form, consent addendum, or verbal notification) may be conducted over the phone. Consider how long it will be before the participant's next protocol exam visit where reconsent or notification could take place. If it will be a while, consider how important it is for participants to notified of the new information or change in a timely manner. Reconsent / notification for non-English speakers must be conducted in person per institutional interpreter services policies.	All requirements detailed in DF/HCC CON-100 for reconsent or verbal notification must be followed. The consent form or addendum is sent via a secure communication (e.g., mail, fax, Physician Gateway) to the participant. There is a phone discussion between a member of the study team who is qualified to conduct the reconsent / notification per CON-100 and the participant once they have received a copy of the document. After reviewing the form and answering all the participant's questions, the participant is instructed to sign and return the form. If feasible, the participant can scan and return the sign formed using a secure electronic communication. If this is not possible, the signed form should be returned by mail.
☐ 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? In most cases, the letter will be mailed to the participants but if the participant is scheduled to come in for a visit, they can also be given the letter in person.	The notification letter must be prepared on the PI's letterhead and must contain the PI's contact information. The letter is mailed to participants using a method that allows for the shipment to the tracked. All requirements detailed in DF/HCC CON-100 for notifications via a letter must be followed.