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GUIDANCE ON INFORMING SUBJECTS OF NEW INFORMATION

Investigators and study teams frequently ask questions about when and how to inform subjects about new information during the study. The guidance below aims to assist investigators in determining their proposed plan for re-consenting and/or notification when new information is submitted for IRB review. **For specific examples, please refer to the attached chart that provides specific strategies based on participant status.**

Key Points to Consider

- Federal regulations require subjects to be informed of new information that relate to their safety or may impact their willingness to continue participation.
- Prior IRB approval is required before subjects are informed of new information except when updated safety information requires urgent action.
- For each circumstance, the IRB will determine whether re-consenting or notification is required and the acceptable notification strategy. Please refer to the Strategy charts in this document for various options. If re-consenting is required, study teams should revise the consent documents or create a consent addendum to be signed by participants. When notification is approved, the new information could be provided in a letter format.
- Whenever a consent form is revised and subjects have been enrolled, study teams should complete the form entitled "**Informing Research Subjects about New Information**." The form is used to document plans for re-consenting/notification or for the study team to provide rationale that re-consenting/notification is not applicable.
- The form "**Informing Research Subjects about New Information**" also should be submitted when new information about the study will be shared with participants. Examples include a premature closure or suspension, data breach or delay in study visits due to equipment problems.

General Guidelines

Subjects are currently enrolled and having in-person visits:

- Re-consent all subjects who are affected by the new information. (For example, if baseline procedures were changing, only those who have not had a baseline visit would be re-consented.)
- Re-consenting at an in-person visit with a revised consent document is the default requirement. Investigators may consult with the IRB before requesting a variance from this requirement. Other methods, such as a consent addendum, can be considered if enrollment is closed and study procedures are not changing.

Long-term participation (off drug/device; still having in-person visits):

- Re-consent all subjects who are affected by the new information.
- Re-consenting at an in-person visit may be appropriate, depending on the nature of the information. Other methods, such as a consent addendum or notification letter, can be considered if enrollment is closed and study procedures are not changing.

Long-term Follow-up (data collection only with no study visits):

- Inform all subjects who are affected by the new information. (For example, subjects must be informed if the new information is relevant to their current health or impacts their rights as research participants.)

- A letter describing the new information is typically the most effective approach since research interventions are complete and most of the consent document would no longer be relevant.
- The letter should accomplish the following:
    - Deliver only information that is relevant to subjects who are in long-term follow-up
    - Provide the new information in lay terms
    - When the new information is related to safety, outline the actions the subject should take at this time (e.g., watch for symptoms, undergo additional testing, etc.)
    - When the new information is related to safety, discuss any costs for additional visits or monitoring
    - Provide contact information for any future questions
    - When required, document receipt of the information by having the subject return a signed letter. (See the attached chart for specific instructions.)
- In addition to the letter, a phone discussion may be required, depending on the nature of the new information. For example, if subjects are being informed of new risks, the study team should call the subjects after they have received the letter in order to answer questions and confirm understanding. The phone call should be documented in study records. On the other hand, written notification alone may be sufficient for new information such as a change in sponsor.

Off-study (study involvement and data collection are complete or subject has withdrawn):

- Notify only if the new information impacts ongoing safety or subject rights.
- Send a letter, followed by a phone call and documentation of receipt as described above.

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EXAMPLE SCENARIOS RELATED TO PROVIDING NEW INFORMATION

RE-CONSENTING/NOTIFICATION IS REQUIRED*	RE-CONSENTING/NOTIFICATION IS NOT REQUIRED
• New procedures (affected subjects only) • New risks • Change in the frequency of the risks • Change in costs or payments • Change of PI • Change of sponsor • New contact information for the study team • Change to the HIPAA section • New information about conflicts of interest, when specified in the COI management plan • New treatment options or alternatives to participation • New use of identified data or specimens • Minor subject turns 18 years of age • Subject, enrolled by a surrogate, regains ability to consent for themselves • The subject has a new surrogate decision-maker	• Minor administrative changes such as change to the version date, typographic corrections or formatting changes • Change in the dates of approval on the consent form (at continuing review), if no other changes are made • Minor increase in the number of subjects • Other changes, depending on the subject's status, that do not impact their safety, the nature of their participation or protection of their rights

*For the purpose of this guidance, "re-consenting" means giving new information to subjects by having them sign an updated consent document. Re-consenting is the default approach for any subject who is affected by the new information. When re-consenting is required, it is documented through a signature on a revised consent form or consent addendum.

"Notification" is the provision of new information to the subject by another means, such as through a documented phone call and letter as outlined in the strategies below.

Regardless of the method used, subjects should be provided with the opportunity to discuss the changes with a member of the study team so that they understand the new information and can have any questions answered.

STRATEGIES FOR INFORMING RESEARCH SUBJECTS ABOUT NEW INFORMATION

Participant Status	Nature of New Information	Notification Strategy	Documents to be Used	Signature Requirements
Active participation (ongoing study visits)	Urgent safety information or instructions that cannot wait for the next study visit	1. Call subjects and document the phone call in study records. Alternatively, a certified letter may be appropriate if PI and sponsor agree. 2. Re-consent with revised consent document at earliest face-to-face opportunity	1. Sponsor's instructions for phone call or certified letter. 2. Revised consent document, when approved by IRB*	Subjects sign the IRB-approved revised consent form at the earliest face-to-face opportunity.
	Non-urgent information or other changes that can be provided at the next study visit	• Subjects are re-consented with the IRB-approved revised consent form at the next study visit. • Re-consent is not required if new information is not applicable (e.g., if subjects have completed a study visit where changes are being made or new risks only apply to those on active drug or those still using the device)	Revised consent document*	Subjects affected by the changes sign the revised consent form.
Long-term follow-up (no longer taking study drug, data collection only)	Information that is not relevant for subjects who are not actively participating in the study (e.g., new study procedures for active subjects only; new risks that only apply to persons currently receiving the study drug or within a specified time of last dose)	None required	None required	None required
	Information that does <u>not</u> require the subject to take action (e.g., sponsor change, PI change, other updates from the sponsor)	Send a letter to the subject providing the new information and a contact phone number for any questions.	Letter approved by IRB	None required. Document the sending of the letter in the subject's study record.
	Information that requires the subject to take action (e.g., new risks that necessitate a return visit for further safety follow-up; watching for symptoms, notifying PCP, etc.)	• Send a letter to the subject providing the new information and potential implications. Give instructions on steps to be taken and confirm the sponsor will cover any new costs. Provide a contact phone number for questions. • Follow up with a phone call to the subject so that new information and questions can be discussed. • Document sending the letter and the phone	Two copies of the letter approved by IRB Self-addressed envelope	Subject is instructed to sign and return one copy of the letter to the study team and keep the other copy for their reference.

		call in study records.		
Participant Status	**Nature of New Information**	**Notification Strategy**	**Documents to be Used**	**Signature Requirements**
Off-Study (study data is no longer being collected or the subject has withdrawn)	Information that impacts the safety or welfare of former subjects (e.g., new information that has long-term safety implications; privacy breach of identifiable data)	• Send a letter to the subject providing the new information and potential implications, instructions on steps to be taken, contact phone number for questions. • As applicable, the letter may need to address the cost associated with new safety monitoring steps • Follow up with a phone call to the subject so that new information and questions can be discussed. • Document sending the letter and the phone call in study records.	Two copies of the letter approved by IRB Self-addressed envelope	Subject is instructed to sign and return one copy of the letter to the study team and keep the other copy for their reference.
New Information on a study that has been closed with IRB	Information that does not impact the safety or welfare of former subjects (e.g., a summary of study results, information about unblinding)	• Submit a Report of New Information in the eIRB system seeking IRB approval to send the information. • Send a letter to the subject providing the new information and a contact phone number for any questions.	Letter approved by IRB	None required. Document the sending of the letter in the subject's study record.
	Information that impacts the safety or welfare of former subjects (e.g., new information that has long-term safety implications; privacy breach of identifiable data)	• Submit a Report of New Information in the eIRB system seeking IRB approval to send the information. • Send a letter to the subject providing the new information and potential implications, instructions on steps to be taken, contact phone number for questions. • As applicable, the letter may need to address the cost associated with new safety monitoring steps • Follow up with a phone call to the subject so that new information and questions can be discussed. • Document sending the letter and the phone call in study records.	Two copies of the letter approved by IRB Self-addressed envelope	Subject is instructed to sign and return one copy of the letter to the study team and keep the other copy for their reference.

*Depending on the circumstances, the IRB may approve a consent addendum rather than a full revised consent. If a consent addendum is used, it is acceptable to cite the portions of the original consent that are still valid, as long as a copy of the subject's signed consent is provided for their reference.