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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 when new information about a study becomes known. IRBs are obligated to review and approve the new information prior to dissemination, except when updated safety information requires urgent action. IRBs also must determine whether current or past subjects should be informed or re-consented with the new information. 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.**

Subjects are currently enrolled:

- 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 should consult with the IRB before requesting a variance from this requirement.

Long-term Follow-up only:

- 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 the 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, they should be given a chance to talk to the study team and have any questions answered. On the other hand, written notification alone may be sufficient for new information such as a change in sponsor.

Off-study:

- Notify only if the new information impacts ongoing safety or subject rights.
- Use a letter format, 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 in FDA status of the test article • Change of PI • Change of sponsor • New contact information for the study team • Change to the HIPAA section • New information about conflicts of interest • 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 document, "re-consenting" is the process by which the study team obtains and documents the subject's expressed willingness to remain in the study. Each active subject 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. When re-consenting is required, it is documented through a signature on a revised consent form.

"Notification" is the provision of new information to the subject that occurs after their active participation has ended but may be relevant to their safety and welfare.

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, taking study drug, etc.)	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 procedures are not applicable (e.g., if subjects have completed a study visit where changes are being made)	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, FDA approval of the test article)	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 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.

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.