IRB Guidance on Re-Consenting Participants on a Research Protocol

Version 2

SCOPE
Compliance with this guidance document is the responsibility of all MD Anderson workforce members.

PURPOSE
It is the policy of The University of Texas MD Anderson Cancer Center Institutional Review Board (MD Anderson IRB) to comply with the regulations governing human subjects research to ensure that human subjects participating in research protocols are informed about ongoing or newly identified risks and benefits related to participation in a protocol.

POLICY STATEMENT
The purpose of this guidance document is to protect human subjects’ safety by ensuring that protocol subjects receive adequate information regarding their participation in the research protocol in the appropriate manner, timing, and setting. The Principal Investigator (PI) remains responsible for ensuring the information contained in the protocol that may affect the participant’s decision to enroll or continue in a study is reflected in the informed consent document.

DEFINITIONS
Form Letter: Study-specific template letter that describes changes to the research and provides instructions to the participant. The form letter, which must be approved by the IRB, is typically used as the initial step in conducting the reconsent process. The form letter provides a mechanism for delivering information to the participant in an expedited manner. There may be a signature line for the PI or the IRB Chair on the form letter. However, participants usually will not sign this form letter.

Verbal Script (e.g. – used for a phone call): Study-specific template that describes changes to the research and provides instructions to the participants. The verbal script, which must be approved by the IRB, is typically used when participants will be informed of changes to the research via telephone or some other oral manner. The script provides a mechanism for delivering information to the participant in an expedited manner. There are no signature lines on the verbal script.

Reconsent Cover Sheet: If a full reconsent is required by a sponsor or the IRB, a Reconsent Cover Sheet may be created to help highlight the changes in the ICD that necessitated the reconsent. The Reconsent Cover Sheet lists relevant changes in the ICD that may impact a participant’s willingness to continue to take part in order to guide the reconsent process.
Reconsent Cover Sheet may be distributed to participants along with the full-length informed consent document. The Reconsent Cover Sheet does not include signature lines.

**Full-length informed consent document:** Document that contains the required regulatory elements for conducting the informed consent process. Used for the initial informed consent process and may be used throughout the course of the study to provide information to the participant regarding the study such as changes to the risk/benefit ratio or changes to the expected participation of the patient. The informed consent document contains signature lines for the PI or person designated to obtain consent, the participant or LAR, and the witness and/or translator, when applicable. This document may also contain an assent section for use in assenting pediatric participants.

**Abbreviated informed Re-consent document:** Document that contains the specific changes due to identification of new safety issues, protocol amendment, or other significant changes that may affect the participant’s willingness to continue participation on a study. The abbreviated consent document contains signature lines for the PI or person designated to obtain consent, the participant or LAR, and the witness and/or translator, when applicable. This document may also contain an assent section for use in consenting pediatric participants.

**Considerations for Re-Consent of Participants Tool:** Reference tool provided by the IRB to assist investigators in determining when participants should be re-consented. The tool divides types of changes into major and minor impact, includes recommendations on the mode and timing of re-consent, and provides guidance on who should conduct the re-consent process.

### PROCEDURE

#### I. Determining when re-consent is required

It is the responsibility of the PI and the research staff to ensure that participants are informed of any changes or new information that may influence their decision to continue to participate in a research protocol. Consenting participants is an ongoing process and the investigator or research team should continuously engage the participant in a discussion regarding changes to the study that might impact the participant’s willingness to continue participation.

Investigators should reference the attached tool “Considerations for Re-Consent of Participants” to determine when a participant must be re-consented. As a general rule, any change in the risk/benefit profile that would significantly impact the participant’s willingness to participate in the study will require re-consent. Such changes include, but are not limited to, 1) identification of new significant risks; 2) greater risk of harm than was previously known or recognized or 3) a decrease in expected benefit to the participant.

Not all changes to the informed consent document require re-consenting of participants. Changes such as updating the consent template and correcting grammatical or typographical errors generally do not require re-consent. The addition of certain elements may also not require full re-consent. If for example a Certificate of Confidentiality (CoC) is added, full reconsent may not be required. However, participants currently on study would still need to be notified via letter if such a change was made.
Depending on the change, the re-consent process may be conducted using a stepwise approach: **step one** may include use of the verbal script or form letter when expedited notification of the participant is indicated, **step two** is completed when required signatures are obtained on the informed consent document. When determining whether a re-consent process is appropriate, the IRB will consider the type of new information included in the changes, the frequency of interaction with the participants, and the participant population.

II. Submitting Changes to the IRB for Review

When new risks or procedures have been identified, the PI should describe in the submission to the IRB, the re-consenting determination, and where applicable a re-consent plan. The submission must include the following items:

1. A description of the new risks that have been identified
2. The groups of patients that may be impacted by the change
3. The expected timeframe in which the re-consent process will be completed
4. Titles of delegated authority for research team member re-consent
5. Procedures for re-consenting participants including how participants who have completed the research interventions will be notified (if applicable)

Examples of re-consent methods include utilization of one or more of the following documents:

- An IRB-approved form letter
- An IRB-approved verbal script
- An IRB-approved abbreviated informed re-consent document
- A full-length revised IRB-approved informed consent document

Any tool used to conduct the re-consent process must be submitted to the IRB prior to use. The IRB may require that a revised full-length informed consent document be used in the re-consent process even if the consent process is conducted using a stepwise approach, or the study did not utilize a full-length consent document initially.

The IRB will indicate in its determination letter to the PI whether the re-consent process has been approved. Should the IRB determine that re-consent is unnecessary or disagree with the re-consent process outlined by the PI, the IRB will communicate this to the PI and may require additional actions and/or make additional recommendations.

The PI should remain cognizant of sponsor or other regulatory agency requirements. If a sponsor or regulatory agency requires that participants be re-consented for safety reasons, it is the investigator’s responsibility to comply with the requirements and notify the IRB of the safety concern immediately.

III. Documenting the Re-Consent Process

The re-consent process must be documented in the participant’s medical record or the essential documents for the study. The documentation must reflect the oral and/or written re-consent process including protocol number and the title of the protocol (abbreviated title is acceptable), the date the participant was notified of the change, a note stating that the participant understood the new information, and the participant’s decision about continued participation in the study. If applicable, the date the new ICD was signed or the date that the
form letter was sent or given to the participant should also be included. Documentation for each step of the re-consent process must be included as part of the essential documents or in the medical record. As an example, if the IRB approves a 2-step re-consent process with step 1 allowing for verbal contact and step 2 requiring that the participant sign a revised consent document; then the documentation would include separate notes for both steps 1 and 2.

The PI should make every attempt to contact the participant to complete the re-consent process as outlined in the IRB determination letter. The PI should maintain documentation of the number of contact attempts in either the medical record or the essential documents. This documentation may be requested by the IRB or auditors.

IV. Penalties for Non-Compliance


Per IRB policy, participants need to be informed of total amounts that may be reimbursed, such as travel expenses.

The options below indicate what reimbursement documents are required in the protocol, if any, depending on the study.

REFERENCES

21 CFR 50
21 CFR 56
45 CFR 46
ICH GCP 4.8
Obtaining Informed Consent for Participation and Authorization for Uses and Disclosures of Protected Health Information for Clinical or Health Services Research Protocols
UTMDACC Informed Consent Policy – CLN0547
Considerations for Re-Consent of Participants Tool
IRB Template – Reconsent Template

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