Re-Consent or Notification of Subjects About Significant New Findings Developed During the Course of Research Policy

Scope

Applies to personnel in the Mayo Clinic Human Research Protection Program and others conducting human research for which Mayo Clinic Institutional Review Board (IRB) is the reviewing IRB.

Purpose

To define responsibilities for determining when and how research subjects will receive additional information about changes or findings that may affect the subject and/or their willingness to continue participation in the research.

Policy

The IRB has the authority to require investigators to re-consent or notify subjects if new information related to the study becomes available, new risks are identified, significant study alterations are made, or the initial consent process was inadequate.

IRB Responsibilities

- The IRB is responsible for determining when re-consent or other notification of subjects is required.
- The IRB may determine that re-consent or other notification is required for some or all of the subjects of the research project.

Investigator Responsibilities

- Inform the IRB according to specified timelines and via submission of an electronic IRB Modification form, of any new information or changes in study design or procedures that might have an impact on any subject's willingness to continue in the study. Include the Subject Notification Form attachment in the modification request.
- Re-consent or notify the subjects, as required by the IRB.
- Re-consent subjects prior to their involvement in the procedural change.
- For increased study risks, re-consent the subjects within 30 days after availability of the IRB approved updated consent document. The changed risks should be highlighted in the consent document presented to the subject.
- When mailing the consent document for subject's signature, summarize in an IRB-approved informational cover letter the changes or additions that have been made to the consent document. For efficiency, include the proposed letter in the same modification as the revised consent form.
- Re-consent or notify non-English speaking subjects using IRB-approved, study-specific, translated documents. Following IRB approval of the English language documents, promptly submit translated materials and corresponding certification documentation for IRB review. If, due to pending IRB approval of the translated consent form, there is potential to not meet the 30-day timeframe for completion of re-consent related to increased study risks, proceed with re-consent using the support of a qualified interpreter. Document the re-consent of the subject (or Legally Authorized Representative [LAR] if permitted) on the appropriate

translated Short Form. Refer to the IRB's Informed Consent and the Research Subject for instruction on use of interpreters and existing translated Short Forms. Follow-up with re-consent using the IRB-approved, study-specific, translated consent form at the next feasible opportunity.

- Report the status of required subject re-consenting/notification activities at the time of continuing review.

Considerations for Notification of Subjects

The table below lists questions and considerations to aid in determining notification requirements. Once the requirements are determined, recommended options for implementing the notification based on participant status may be found in the second table, Determining Methods of Notification.

Questions	**Considerations**
1. **Who** needs to be notified or reconsented? • Subjects actively undergoing research intervention • All subjects • Subset of subjects	• Does the change affect subjects differently? • If yes, clearly define each subset affected differently by the change (i.e. males, females, specific age groups, subjects in active treatment, specific study arm, subjects off study, etc.)
2. **What** is the change that requires communication? • Additional risks or change in risk severity or frequency • Change in level of discomfort or other inconvenience • Procedural changes including remuneration or reimbursement • New alternative options available • Other	• Could the change affect a subject's decision to remain in the study? • Regulatory, ethical or policy requirements • New research findings at Mayo or elsewhere • Will the change involve a different level of commitment from the subject?
3. **When** must notification or reconsent occur to protect subject safety and rights (regardless of logistics)? • Immediate • Before next study visit • Before specific study procedures • Within specified time period • Varies with affected participant subset • Alternate plan if revised consent version not yet available when needed for subject	• Are subjects coming in for visits or are study procedures done at home? • Are subjects impacted now or in the future? • Are subjects who have completed study procedures/visits impacted? • Logistics (including any travel, expense or inconvenience to subjects)

4. **"Where"** and "**How**" should notification be implemented? • Phone • Letter • Letter with phone follow-up • Revised consent form • In-person visit	• Complexity and need for interactive explanation and discussion • Need for physical demonstration or other presentation of information best done in person • Timeline for next subject visit • Verification of subject identity if not consented in person • Any subject limitations such as age, disabilities, language, level of understanding, vulnerable population

Determining Methods of Notification Based on Study Participant Status

Study Participant still active in study	
Participant Affected by Changes	**Participant Not Affected by Changes**
1. Examples: • New risk or increase risk of drug • New risk or increased risk of procedure subject will undergo • Changes to remuneration/reimbursement	Examples: • New procedure that the subject will not undergo (such as at baseline) • Arm/treatment not affected by change or risk (on a different treatment) • Subgroup not affected (women only - pregnancy testing)
2. Method of Notification: • Re-consent • If next study visit is greater than 30 days, notify via phone or letter, re-consent at next in-person visit	Method of Notification: • Typically, no notification needed
Study Participant has Completed Procedures and all Study Visits	
Participant Affected by Changes	**Participant Not Affected by Changes**
3. Examples: • Newly identified long term or late-occurring risk	Examples: • Changes to procedure or protocol • Newly identified immediate, short-lasting risk
4. Method of Notification: • Letter to notify of potential long term or late-occurring risk • Phone	Method of Notification: • Typically, no notification needed

Policy Notes

N/A

Related Procedures

Informed Consent and the Research Subject Policy

Modifications to Previously Approved or Exempt Research Procedure

Related Documents

Reporting Timelines for IRB Submission when Mayo Clinic is Serving as the IRB of Record (IRB 10539)

Subject Notification Form (IRB 10542)

Risk Notification Letter templates

Definitions

Re-Consent: Process of notifying research subjects of changes in the research including documentation of the subject's continued informed consent through signature on a revised written consent form.

Notification: Process of notifying research subjects of changes in the research by letter or phone, or during an in-person visit.

References

N/A

Owner

Michelle K. Daiss on behalf of Mayo Clinic Human Research Protection Program

Contact

Heidi M. Hanf

Revision History

Date	Synopsis of Change
06/09/2022	Scheduled review. Transferred to standardized template. Added information on investigator responsibilities for re-consent or notification of non-English speaking subjects. Updated contact and owner.
05/03/2019	Scheduled review - changed owner to Tammy Neseth
07/13/2018	Clarified that reconsent for increased risks is required within 30 days of availability of IRB-approved updated consent document.
06/01/2018	Revised to be consistent with IRB Submission Timelines. Added Subject Notification Form and Risk Notification Letter Template
10/07/2016	Scheduled Review - updated to current template format no content changes
05/03/2019	Scheduled review - changed owner to Tammy Neseth