Title: DOCUMENTATION OF INFORMED CONSENT AND RESEARCH AUTHORIZATION

Version No.: 1.14

SOP No.: IC-706

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1. Purpose

This policy describes the requirements for documentation of informed consent/research authorization (RA) and circumstances when the IRB may waive the requirement to document informed consent/RA.

2. Policy

Unless specifically waived by the Memorial Sloan Kettering Cancer Center (MSK) IRB, all participants, or their legally authorized representatives (LARs), must document that they are consenting to participate in any research project that is conducted at MSK.

In most circumstances, the IRB will require that informed consent/RA is documented using a written consent/RA form approved by the IRB and signed by the research participant or the research participant's LAR. The consenting professional should allow the research participant or the LAR adequate opportunity to read the consent/RA document before it is signed.

For MSK patients, when written consents are used, the original source consent document is maintained in the Center's electronic medical record.

Epic eConsent is 21 CFR Part 11 compliant. For FDA-regulated research, signatures must be on a 21 CFR Part 11 compliant platform.

3. Specific Procedures

3.1 Documentation of Informed Consent/Research Authorization

The IRB may approve procedures for documentation of informed consent/RA that involve (a) a written consent and authorization form signed by the research participant; (b) a short form written consent form with oral presentation; or (c) in limited circumstances, waiver of signed written consent/RA form. Each of these three options is described in the below procedures. It is the responsibility of the IRB to determine which of the procedures is appropriate for documenting informed consent in protocols that it oversees.

In addition, the consent process must be appropriately documented in the participant's medical/research record. In most circumstances, the signed consent/RA document that is maintained in the participant's medical/research record can serve as adequate documentation. Consenting professionals can provide supplemental documentation in the medical/research record if they choose or if mandated by the protocol. However, the medical/research record must contain a note with a detailed description of the consent discussion if:

- the Short Form process is used.
- a fully translated consent/RA form is used.
- any scenario where an interpreter is used for a consent discussion
- there is a complex consent scenario as outlined in section 3.5.

For FDA-regulated research, the medical record must document that consent was obtained prior to participation in any phase of the study.

- If the signature of the consent form does not include a time/date stamp (i.e., paper consent with date field only), a statement must be added to the medical/research record.

- If the signature page of the consent form does include a time/date stamp (i.e., Epic eConsent), the signed consent/RA document that is maintained in the participant's medical/research record serves as such documentation.

3.2 Written Consent Form Signed by Research Participant or LAR

3.2.1 On the day of the consent discussion, MSK informed consent/RA documents must be obtained from an MSK approved eConsent platform noted in MSK IRB SOP IC-701, section 3.5.12, or printed from the MSK Protocol Web.

3.2.1.1 For extenuating circumstances when consent/RA documents cannot be obtained from an MSK approved eConsent or MSK Protocol Web, the documents can be obtained from the PIMS regulatory binder for reconsent purposes only.

3.2.1.2 If a participant receives a copy of the consent/RA prior to the day of the consent discussion, the consenting professional must confirm on the day of the consent discussion that 1) the study is not on an accrual hold and 2) the participant has the current IRB approved version of the consent form/RA.

3.2.2 If a study has any embedded sub-study questions, they must be answered by the participant. If the participant inadvertently omits answering these questions at the time of initial consent, the answers default to 'No'. If these questions are left unanswered at the time of reconsent, the answers default to the response on the last consent.

3.2.3 Each research participant or LAR must sign and personally date the MSK signature page prior to enrollment and participation in any phase of the study, unless the requirement is waived by the IRB.

3.2.3.1 The research participant/LAR must 1) sign/date electronically through an MSK approved eConsent platform noted in MSK IRB SOP IC 701, section 3.5.12 or 2) provide a wet signature and date.

3.2.4 The consenting professional must sign and personally date the MSK signature page prior to enrollment and participation in any phase of the study unless the requirement is waived by the IRB. The consenting professional signature indicates that the consenting professional has personally discussed the research protocol with the participant or LAR.

3.2.4.1 The consenting professional must 1) sign/date electronically through an MSK approved eConsent platform noted in MSK IRB SOP IC-701, section 3.5.12, 2) provide a wet signature and date, or 3) sign/date electronically through the MSK Adobe Sign Platform. For FDA regulated research, MSK Adobe Sign Platform must be 21 CFR Part 11 compliant.

3.2.5 The MSK consent/RA document must include the current approval date and active version unless an exception has been granted from the HRPP Office.

3.2.6 Co-signing of consent/RA documents is not permitted. All MSK consenting professionals must be named on the face sheet of an IRB approved protocol document.

3.2.7 Copies of the informed consent/RA document are distributed as follows:

- Participant copy: The research participant must be given a copy of the entire signed document.
- Medical/Research record copy: If the participant is a patient at MSK, one complete signed copy must be sent to the electronic medical record. If the participant is a non-patient, the signed copy must be placed in the research record.

3.3 Oral Presentation Using Short Form

3.3.1 As an alternative to standard written informed consent/RA documents, oral presentation of informed consent information may be used. (Please refer to MSK IRB SOP IC-704). In such cases, the research participant must be provided with both:

- An MSK short form document stating that the elements of informed consent have been presented verbally to the research participant or the research participant's LAR;

and
- A written summary of the information that is presented verbally. The IRB approved consent/RA document serves as the written summary.

3.3.2 A witness to the oral presentation is required. The witness must sign both the short form document and a copy of the written summary (i.e., English consent/RA).

3.3.3 The research participant or the LAR must sign the short form document.

3.3.4 The consenting professional must sign a copy of the written summary of the information that is presented orally. The person obtaining consent may not be the witness to the consent.

3.4 Waiver of Documentation

The IRB may waive the requirement for the Investigator to obtain a signed consent form/RA for some or all research participants as defined in MSK IRB SOP IC-702.

3.5 Documentation for Complex Consent Scenarios

3.5.1 A person who speaks and understands English, but does not read and write, may be enrolled in a study by "making their mark" on the consent/RA document, when consistent with applicable state law. An impartial third party must witness the entire consent process and sign the consent/RA document as a witness.

3.5.2 A person who can understand and comprehend spoken English, but is physically unable to talk or write, may be enrolled in a study if competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent), and (2) can indicate approval or disapproval to study entry, enrollment is allowed. An impartial third party must witness the entire consent process and sign the consent/RA document as a witness.

3.5.3 If the consent/RA form contains embedded questions and the illiterate or physically limited English-speaking participant is unable to mark the answers on the consent/RA document, the participant can convey their responses to the consenting professional. The consenting professional indicates the participant’s responses on the English consent/RA form. This process must be documented in the medical record.

3.5.4 A person who communicates in sign language only may be enrolled in a study if a sign language interpreter assists in the consent discussion. A witness is not required if the person can read and understand the consent form.

3.5.5 The consent discussion must be fully documented by the consenting professional in the medical record (or research record if non-patient).

3.6 Documentation for Research Participants Who Do Not Speak English

Refer to MSK IRB SOP IC-704.

3.7 Documentation for Research Participants Who Are Minors (<18 years of age) or Who Have Impaired Decision-Making Capacity

Refer to MSK IRB SOPs SC-501, IC-702, and IC-703. As noted in those SOPs:

3.7.1 Upon reaching the age of 18, a participant who is continuing on a research study must be reconsented to confirm willingness to continue to participate.

3.7.2 If an adult with impaired decision-making capacity on a research study regains competency for making decisions, consent must be obtained to ensure willingness to continue to participate.

3.8 Informing Participants of Updated Information

Participants must be informed of updated information about the research study that might affect their willingness to continue in the study. Examples include a change that impacts the risk/benefit ratio, a new risk, or additional research tests/procedures. Participants do not typically need to be informed of editorial or administrative changes, or, at the time of continuing review unless there are newly discovered risks or other key information.

Participants can be verbally notified in real-time of updated risks or other safety-related information received via the Safety Information Form while the updated consent form is pending IRB submission and/or approval. This must be carried out by a consenting professional.

Informing participants of updated information is required where, (1) the investigator requests to do so and the IRB confirms this; or (2) the IRB specifically requires it. The IRB will make the final determination if and how participants are informed of new/updated information.
There are three different methods of informing participants of new/updated information.

- Reconsent: Participant is reconsented by signing a revised IRB approved informed consent/RA document after a discussion with a consenting professional. For low-risk studies where a verbal consent script is used, a consent discussion must occur, and the consenting professional must sign the revised verbal consent script.
    - For risk or treatment changes, participants must be reconsented before the next treatment.
        - For participants on non-treatment protocols, reconsent must occur before the next investigational intervention.
        - For participants taking medication at home (e.g., daily oral medication), reconsent must occur before the next protocol required visit with a consenting professional or sooner at the discretion of the treating investigator.
    - For all other changes requiring reconsent, participants must be reconsented at or before the next protocol required visit with a consenting professional.
    - Documentation requirements of the “reconsent” are the same as initial consent when using a signed written consent/RA or verbal consent script.
    - If the study has embedded sub-study questions, the participant does not have to re-answer these questions and the answers default to the responses on the last consent. An exception to this is if the participant wishes to change the answers to these questions.
    - Unless otherwise noted in the recruitment section of the protocol, participants who do not start study activity within 45 days of signing consent/RA must be reconsented before beginning any study activities.
- Verbal Notification: Participant is verbally notified. This may be conducted by consenting professionals or research staff in accordance with the impact to the participant (e.g., verbal notification must happen before a new test/evaluation is carried out) or within 60 calendar days of IRB approval, whichever is first.
    - Any discussions with the participant must be documented in the medical record or research file.
- Participant Letter: An IRB-approved letter outlining the updated information can be provided to participants.

4. Applicable Regulations and References

- 21 CFR 50
- 21 CFR 11

- 45 CFR 46.116, 46.117
- 45 CFR 46.164.508(c)(1))
- 45 CFR 46.164.508(c)(2))
- FDA Information Sheets, 1998
- MSK IRB SOPs SC-501, RR-402, RR-408, IC-701, IC-702, IC-703, IC-704
- CR SOP 434

Revision History

Revision	Effective Date	Reason for Change
1.0	6/15/09	NEW
1.1	8/23/10	• Reiterates that the electronic medical record contains the source consent for MSK patients • Clarifies documentation and re-consent expectations.
1.2	6/4/12	• Clarification of mailing consent procedures and the documentation required in the progress note when consenting.
1.3	11/24/14	• Clarified the timeframes for when re-consent is required. • Clarified documentation requirements in progress notes. (section 3.1)
1.4	2/29/16	• Updated Signature page, MSK branding, formatting. • 3.2 Clarification on optional sub-study questions. • 3.8 Additional detail for documentation for minors or cognitively impaired adults • 3.9.2 Clarified timeframes for re-consent requirements.
1.5	10/29/18	• 3.1 Clarified when a progress note is required; removed requirement for IRB notification of physical impairments • 3.2.2.1 Added • 3.2.2 Clarified optional study questions at the time of reconsent • 3.2.5 Removed MSK watermark requirement • 3.3 Renumbered section • 3.1.1.1 Clarified that the short must be MSK IRB approved • 3.3.4 Removed • 3.6.4 Removed • 3.9.5 Added
1.6	1/21/19	• 3.1 removed “MSK-held” from IND/IDE studies • 3.4 Removed criteria for waiver of documentation of consent and replaced with reference to IRB SOP IC-702 • 4.0 Added section on electronic consent • 5 Updated references
1.7	5/11/20	• 3.6.1 and 3.6.2 Clarified that the impartial third party must, not should, witness the consent process and sign the consent • 3.8 Replaced the term cognitive impairment with impaired decision-making capacity • 3.9.5 Replaced intervention/interaction with activity
1.8	5/10/21	• 2 Added that the MSK eConsent module and MSK adobe esign are 21 CFR Part 11 compliant • 3.1 To align with IRB SOP IC-704, added that a consent discussion note is needed when a fully translated consent form is used to consent a participant • 3.2.1 Updated to include eConsent platforms • 3.2.1.2 Added section to describe requirements for when a participant receives a copy of a consent prior to the day of the consent discussion

		• 3.2.3.1 Added to outline participant signature and date allowances • 3.2.4.1 Added to outline consenting professional signature and date allowances • Removed former section 3.2.7 (For MSK patients, the only original source consent document is maintained in the Center's electronic medical record). • Removed former section 3.5 (Use of Facsimile, E Mail, or Mail to Document Informed Consent) as this is now covered in MSK IRB SOP IC-701 • Removed former section 4 (Electronic Consent) as this is now covered in MSK IRB SOP IC-701 • 4 Updated references
1.9	1/31/22	• Removed gendered language • Grammatical revisions throughout • Replaced the term optional sub-study questions with embedded sub-study questions • 3.3.1 Clarified that the IRB approved consent document serves as the written summary • 3.5.4 Added to describe the process for how illiterate or physically limited participants can answer questions embedded within the consent form • 3.8.3 Replaced "forms of reconsent" with "methods to notify participants; clarified the methods
1.10	1/23/23	• Editorial changes made throughout • 3.8 Removed language about sponsor requirements for reconsent as IRB makes final determination
1.11	11/6/23	• 2 Removed "The consent process must be appropriately documented in the participant's medical/research record." • 3.1 Section updated to note that consent discussions must be documented in the medical record only if the short form process is used, a fully translated consent form is used, or if there is a complex consent scenario; updated to note that consenting professionals can provide supplemental documentation in the medical/research record if they choose or if mandated by the protocol. • 3.5 Updated section heading to "Documentation for Complex Consent Scenarios"; Added "A person who communicates in sign language only may be enrolled in a study if a sign language interpreter assists in the consent discussion. A witness is not required if the person can read and understand the consent form." (3.5.4); Added the consent discussion must be fully documented by the consenting professional in the medical record (or research record if non-patient (3.5.5) • 3.8 Updated section to outline IRB's new requirements and timelines for informing participants of updated information, which includes: o Reconsent by signing a consent form after a discussion between the consenting professional and participant o Verbal notification that can be caried out by a consenting professional or research staff o Participant letter Added a statement to note that participants can be verbally notified by a consenting professional in real-time of updated risks or other safety-related information received via the Safety Information Form while the updated consent form is pending IRB submission and/or approval.
1.12	7/23/24	• 3.1 Clarified that the signed consent/RA document that serves as adequate documentation is the document maintained in the participant's medical/research record

		• 3.1 To ensure compliance with FDA regulations, the following was added: "For FDA-regulated research, the medical record must document that consent was obtained prior to participation in any phase of the study.
		  • If the signature of the consent form does not include a time/date stamp (i.e., paper consent with date field only), a statement must be added to the medical/research record.
		  • If the signature page of the consent form does include a time/date stamp (i.e., MSK eConsent), the signed consent/RA document that is maintained in the participant's medical/research record serves as such documentation. "

1.13	1/21/25	• Editorial updates. • Replaced references to MSK eConsent with MSK Epic econsent platform. • 3.1 Revised to state that a consent discussion note is required for any consent scenario where an interpreter is used for a consent discussion.
1.14	1/20/26	• 2 and 3.2.4 Updated to state for FDA-regulated research, signatures must be on a 21 CFR Part 11 compliant platform • Editorial updates.