1. Purpose

This policy describes the general requirements for obtaining and documenting informed consent and research authorization.

2. Policy

Informed consent must be legally effective and prospectively obtained.

Except as described in MSK IRB SOP IC-702, no investigator may involve a human being as a research participant unless the investigator has obtained legally effective informed consent of the research participant or the research participant's legally authorized representative (LAR). Consent shall be sought only under circumstances that provide the prospective research participant or the representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence.

Participant research authorization must be obtained for prospective use or disclosure of protected health information for research conducted at Memorial Sloan Kettering Cancer Center (MSK) except as described in MSK IRB SOP IC-702.

The person discussing the research and obtaining consent from the participant must be named on the protocol face sheet as a consenting professional.

Broad consent for the storage or maintenance of identifiable private information or identifiable biospecimens for secondary research is not permitted at MSK.

For MSK sponsored clinical trials conducted or supported by a Common Rule department or agency, MSK will post one IRB-approved consent form used to enroll participants on clinicaltrials.gov, unless an exception to post to another Federal publicly available website has been granted by the HRPP Director. For externally sponsored clinical trials, MSK relies on the sponsor to post their consent form, if required.

Participant and consenting professional signatures and dates must be obtained after the consent discussion and prior to enrollment and participation in any phase of the study. Study activity must start within 45 days after participant signature.

If using electronic informed consent for FDA regulated research, the consent platform must be 21 CFR Part 11 compliant.

3. Specific Procedures

3.1 Consent Form

The consent form may be either of the following:

A. A written consent document that embodies the elements of informed consent described in 21 CFR 50.25 and 45 CFR 46.116(a). The research participant or the LAR shall have adequate opportunity to read it before it is signed. The research participant must also be given a copy of the signed form.

B. A "short form" written consent document stating that the elements of informed consent as required above have been presented orally to the research participant or the research participant's LAR. When this method is used, there shall be an impartial witness to the oral presentation. The IRB must approve a written summary of what is to be said to the research participant or representative. The MSK IRB-approved English language consent document is used as the written summary. (See MSK IRB SOP IC-704).

3.2 Required Elements of Informed Consent

A. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the research participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
B. A description of any reasonably foreseeable risks or discomforts to the research participant.
C. A description of any benefits to the research participant or to others that may reasonably be expected from the research.
D. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the research participant.
E. A statement describing the extent to which, if any, confidentiality of records identifying the research participant will be maintained and that notes the possibility that the FDA may inspect the records.
F. For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
G. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the research participant.
H. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the research participant is otherwise entitled, and that the research participant may discontinue participation at any time without penalty or loss of benefits to which the research participant is otherwise entitled.
I. *One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
   i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or LAR, if this might be a possibility, or
   ii. A statement that the participant’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

*These elements are not required for studies in which the IRB has determined will remain under the pre 1/19/17 DHHS Regulations (45 CFR 46). Documentation of this determination is noted in the Protocol Information Management System (PIMS) on a study basis.

3.3 Additional Elements

When appropriate, one or more of the following elements of information shall also be provided to each research participant:

A. A statement that the particular treatment or procedure may involve risks to the research participant (or to the embryo or fetus if the research participant is or may become pregnant),

which are currently unforeseeable.

B. Anticipated circumstances under which the research participant's participation may be terminated by the Investigator without regard to the research participant's consent.

C. Any additional costs to the research participant that may result from participation in the research.

D. The consequences of a research participant's decision to withdraw from the research and procedures for orderly termination of participation by the research participant.

E. A statement that significant new findings developed during the course of the research, which may relate to the research participant's willingness to continue participation, will be provided to the research participant.

F. The approximate number of research participants involved in the study.

G. *A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

H. *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions.

I. *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

*These elements are not required for studies in which the IRB has determined will remain under the pre 1/19/17 DHHS Regulations (45 CFR 46). Documentation of this determination is noted in PIMS on a study basis.

3.4 Elements of HIPAA Research Authorization

A HIPAA Research Authorization is an individual's signed permission to allow a covered entity to use or disclose the individual's protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization. A research participant may revoke their Authorization at any time. However, a covered entity may continue to use and disclose PHI that was obtained before the individual revoked Authorization to the extent that the entity has taken action in reliance on the Authorization.

The HIPAA Research Authorization must include the following core elements and required statements as described in MSK IRB SOP FO-308.

3.5 Other Requirements

3.5.1 Language should be simple: The information provided in the informed consent documents must be in language understandable to the research participant. The reading level for consents should be 8th grade or lower. The informed consent document should not include complex language that would not be understandable to all research participants. Technical and scientific terms should be adequately explained using common or lay terminology.

3.5.2 Location and timing of obtaining informed consent from the participant must be taken into consideration by the consenting professional. Consent should not be obtained immediately prior to a procedure, e.g., surgical care. The consent discussion must also occur in a private location, i.e., consult room. Lastly, consenting for clinical research should not be conducted in the pre-operative unit unless IRB approved.

3.5.3 Exculpatory language: Informed consent documents may not contain any exculpatory language through which the research participant is made to waive or appear to waive legal

rights or releases or appears to release the Consenting Professional, the Sponsor, or MSK from liability for negligence.

3.5.4 *Informed consent must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's or their LAR's understanding of the reasons why one might or might not want to participate.

The prospective participant or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or LAR in understanding the reasons why one might or might not want to participate in the research. This summary must be organized and presented in a way that facilitates comprehension.

Any consent procedure that differs from the standards outlined above will require IRB approval.

*These elements are not required for studies in which the IRB has determined will remain under the pre 1/19/17 DHHS Regulations (45 CFR 46). Documentation of this determination is noted in PIMS on a study basis.

3.5.5 FDA-regulated test articles:

- For all research involving test articles regulated by the FDA, informed consent documents must include a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article.
- The consent form must also include a statement that the FDA has access to the research participant's medical records.
- The IRB determines there is a statement that the results of the research will be posted on clinicaltrials.gov. "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

3.5.6 For MSK sponsored clinical trials conducted or supported by a Common Rule department or agency, one IRB-approved informed consent form used to enroll participants must be posted to clinicaltrials.gov.

- The informed consent form must be posted 1) after the clinical trial is closed to accrual, and 2) no later than 60 days after the last study visit by any participant, as required by the protocol.
- Some information that should not be made publicly available may be redacted after discussing with the HRPP office.

3.5.7 The MSK Informed Consent and Research Authorization template must be used when written consent is required by the MSK IRB.

3.5.8 The written informed consent document should embody, in language understandable to the research participant, all the elements necessary for legally effective informed consent (see above).

3.5.9 Research participants who do not understand English should be presented with an informed consent document written in a language understandable to them. See MSK IRB SOP IC-704.

3.5.10 The IRB must receive and approve all consent and research authorization versions (e.g., English or any other language).

3.5.11 Remote Written Informed Consent Process:

The IRB considers consent discussions via telephone or an MSK approved teleconference or video conference platform to be equivalent to when conducted in person.

The informed consent document can be obtained using an MSK approved eConsent platform (see section 3.5.12) or sent to/from the potential participant or their LAR via the MSK patient portal. It can also be sent to/from the potential participant or their (LAR) via mail, email, or fax.

All other applicable conditions for documentation of informed consent as outlined in MSK IRB SOP IC-706 must also be met when using this procedure unless waived by the IRB.

3.5.12 Electronic informed consent is allowed through the MSK Epic eConsent and/or other MSK approved eConsent platforms (e.g., RedCap, etc.). Electronic consents are identical to the IRB-approved version of the written consent. MSK Epic eConsent is 21 CFR Part 11 compliant. If using an electronic informed consent platform other than MSK Epic eConsent, it must be specifically outlined in the protocol.

3.5.13 For studies utilizing electronic consent, the IRB may approve an alternative consent procedure that does not include a consent discussion and consenting professional signature documentation.

3.5.14 Additional MSK requirements for informed consent forms are outlined in other MSK IRB SOPs such as SC-516 and IC-707.

3.5.15 Consent form addendums to present new or additional information to MSK participants (e.g., new risks, participation in optional studies, etc.) is not permitted unless an exception has been granted by the HRPP Office. The new or additional information must be incorporated into the main consent form.

3.5.16 As outlined in MSK IRB SOP FO-301, the IRB functions in compliance with the International Council for Harmonization Good Clinical Practice Consolidated Guidelines insofar as those guidelines are consistent with FDA and DHHS regulations pertaining to the protection of human subjects.

3.5.17 Regardless of IRB of record, consent forms/agreements between an external entity and an MSK participant that do not require MSK staff signature (e.g., travel reimbursement consent between an external entity and an MSK participant) are not considered consent to participate in research and will not be reviewed by IRB.

3.6 Observation and Monitoring of the Informed Consent Process

The IRB foresees circumstances that may arise under which the IRB may want to observe the consent process. In this situation, the IRB may delegate the administration or observation of the consent process to a qualified third party to determine whether the informed consent process has been appropriately completed and documented.

3.7 NCI-National Clinical Trials Network (NCTN) Studies

For NCTN studies, the side effects and other choices sections should match the model consent form which must be included in the submission to the IRB. When MSK is the IRB of record, the MSK IRB reserves the right to request edits to the side effects or other choices sections if needed to protect the safety and welfare of participants.

3.8 Participant Withdrawal

When a participant chooses to withdraw from a study, the researcher should ask the participant if they wish to withdraw from the study completely or from a portion of the study.

- If a participant withdraws from the treatment/interventional portion of the study but agrees to all or some of the follow-up requirements, the researcher is permitted to continue to follow the participant according to the participant's wishes. The researcher must obtain the participant's consent for this limited participation in the study.
- If a participant withdraws from the study completely (i.e., withdraws from all treatment/intervention and follow-up), the researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. A researcher may:
  - review study data related to the participant that was collected prior to the participant's withdrawal from the study.
  - consult public records as defined in MSK IRB SOP IC-707 to obtain survival status, if the research is FDA regulated.
  - continue to follow a participant who is experiencing an adverse event at the time of withdrawal for safety reporting reasons.
- The researcher must document the participant's decision to withdraw (either completely from the study or a portion of the study) in the participant's medical record and/or research file.

4. Applicable Regulations and References

- 21 CFR 50
- 45 CFR 46.116, 46.117
- 45 C.F.R. §164.508(c)(1))
- 45 C.F.R. §164.508(c)(2))
- FDA Information Sheets, 1998
  - SC 501 3.3.2 consent and pregnant women
  - SC501 3.4.2D Consenting w Cognitive impairment
  - SC512 3.5 HUD and consenting
- SC513 2.8 Consenting with DoD subjects
- MSK IRB SOPs IC 702, IC 704, IC 706, IC 707, FO 308, SC 516
- FDA Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials
- FDA Guidance for Industry: Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects
- MSK Electronic Consent System Compliance Letter, 1/24/2025

Revision History

Revision	Effective Date	Reason for Change
1.0	6/15/09	NEW
1.1	8/14/09	Added clarification in section 2.0 Policy of who can discuss consent with participant
1.2	8/23/10	Deleted "and documentation" from SOP title
1.3	6/4/12	Updated to reflect one combined signature page for RA and consent

1.4	2/29/16	• Updated Signature page, MSK branding, formatting. • Removed RA elements (see IRB SOP FO-308) • 3.5 Added location & timing of consent discussion • 3.7 Updated NCTN nomenclature and requirements
1.5	6/23/16	• Reformatted 3.5.4, added text on www.clinicaltrials.gov requirements (3.5.4.c) • Added section 3.8 Participant Withdrawal
1.6	1/21/19	• 2 Added policy statement to indicate that MSK will not participate in broad consent; added policy statement regarding the requirement to post consents to a Federal publicly available web site • 3.2 I Added one new required element of informed consent • 3.3 G, H, I Added three new additional elements of informed consent • 3.5.4 Added new key information informed consent requirement • 3.5.6 Added language regarding the requirement to post consents to a Federal publicly available web site • Renumbered section 3.5
1.7	5/11/20	• 3.1B Clarified that the MSK IRB-approved English language consent document can used as the written summary • 3.5.4 Added that any consent procedure that differs from the standards outlined in this section will require IRB approval
1.8	5/10/21	• 2 Removed consent documentation language as this is covered in IRB SOP IC-706; Added policy statement: Participant and consenting professional signatures and dates must be obtained after the consent discussion and prior to enrollment and participation in any phase of the study. Study activity must start within 45 days after participant signature. • 3.5.11 (remote written informed consent procedures) Added • 3.5.12 (electronic informed consent) Added • 3.8 Clarified requirements for when a participant completely withdraws from a study or withdraws from a portion of the study; clarified the use of public records for obtaining participant survival status; added that a researcher can continue to follow a participant who is experiencing an adverse event at the time of withdrawal for safety reporting reasons
1.9	1/31/22	• Removed gendered language throughout SOP • 3.5.13 Added that the IRB may approve an alternative consent procedure that does not include a consent discussion and consenting professional signature documentation when utilizing electronic consent for low risk studies • 3.5.14 Added that additional MSK requirements for informed consent forms are outlined in other MSK IRB SOPs • 3.5.15 Added language to note that the use of consent form addendums to present new or additional information to MSK participants (e.g., new risks, participation in optional studies, etc.) is not permitted unless an exception has been granted by the HRPP Office. • 3.7 For NCTN studies when MSK is the IoR, clarified that MSK reserves the right to request edits to the side effects and other choices sections of the consent if needed to protect participants • 4 Updated to include all MSK IRB SOPs referenced in this SOP
1.10	11/6/23	• 3.5.16 Added subsection regarding the International Council for Harmonization Good Clinical Practice Consolidated Guidelines

		• 3.5.17 Added this section to state that consent forms/agreements between an external entity and an MSK participant are not considered consent to participate in research and will not be reviewed by IRB.
1.11	1/21/25	• Grammatical edits • Indicated that the IRB determination of whether a study will remain under the pre 1/19/17 DHHS regulations is noted in PIMS • 3.5.12 Removed references to MSK eConsent and indicated that electronic informed consent is allowed through MSK Epic and/or other MSK approved eConsent modules.
1.12	1/20/26	• 2 Updated to state that if using electronic informed consent for FDA regulated research, the consent platform must be 21 CFR Part 11 compliant. • 3.5.13 Removed mention of to low risk studies • 3.5.17 Clarified that this section applies to consents that do not require MSK staff signature • Updated to add the MSK Electronic Consent System Compliance Letter