Title: ASSENT **Version No.:** 1.9

SOP No.: IC-703 **Effective Date:** November 6, 2023

1. Purpose

This policy describes the requirements for assent in research.

2. Policy

The principle of respect for persons requires that the choice of an autonomous person be respected. Under the usual conditions of clinical research, this is accomplished by soliciting the informed consent of the prospective research participant.

When participants have diminished capacity to consent, the consent of the parent or legally authorized representative (LAR) is required. However, any individual capable of some degree of understanding (generally, a child of seven or older or an adult with mildly impaired decision-making capacity), should participate in research only if they assent.

When assent is required by the IRB, the decision of the individual assenting should be binding.

3. Specific Procedures

3.1 Use of Assent

In instances where the participant is not legally capable of giving informed consent and consent is obtained from the LAR, the IRB must find that adequate provisions are made for soliciting the assent of the participant when in the judgment of the IRB, the participant can provide assent.

3.1.1 Assent means a participant's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

3.1.2 In determining whether participants are capable of assenting, the IRB shall consider the age, maturity, and psychological state of the participants involved. This judgment may be made at the time of (initial) review for all participants to be involved in research under a particular protocol, or for each participant, as the IRB deems appropriate.

3.1.2.1 At the time of assent, the consenting professional may determine that assent is not appropriate based on the maturity or psychological state of the participant.

3.1.3 If the IRB determines that the capability of some or all of the participants is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participant and is available only in the context of the research, the assent of the participant is not a necessary condition for proceeding with the research. Even where the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived.

3.2 Documentation of Assent

3.2.1 When the IRB determines that assent is required for a child of seven or older or an adult with mildly impaired decision-making capacity, the IRB has determined that assent should be obtained and documented as outlined in the below procedures. If the consenting professional determines that assent is not appropriate for a participant based on maturity of psychological state, it must be documented in the medical record.

3.2.1.1 The consenting professional must sign the MSK assent signature page. By signing, the consenting professional is attesting that the research participant

can provide assent and the research participant has given affirmative agreement to participate.

3.2.1.1.1 For active protocols as of 5/10/2018, updating to the new Informed Consent Template and MSK assent signature page (if needed) is optional. If not updated, the consenting professional should continue to document assent by checking off the appropriate box on the consent signature page.

3.2.1.2 The participant should sign the MSK assent signature page by either personally providing a signature or making a mark. The participant date field is optional. If the participant verbally assents but refuses to sign the form or is unable to, the consenting professional must document this on the assent signature page.

3.2.1.3 For MSK patients, the original assent signature page that is maintained in the Center's electronic medical record is considered the source.

3.3 Waiving Assent for Research involving Children and/or Adults with Impaired Decision-Making Capacity

The IRB may waive requirements for obtaining or documenting assent if the IRB determines:

- Capability of the children/adults with impaired decision-making capacity is limited such that they cannot be reasonably consulted;
- The child/adults with impaired decision-making capacity are not capable of providing assent based on the age, maturity or psychological state; or
- The research intervention or procedure(s) involved hold out a prospect of direct benefit that is important to the health or well-being of the children/adults with impaired decision-making capacity, and is available only in the context of the investigation; or
- When the following criteria are satisfied:
    - the research involves no more than minimal risk to the participants; and
    - the waiver will not adversely affect the rights and welfare of the participants; and
    - the research could not practicably be carried out if assent was required; and
    - when appropriate, pertinent information is provided after participation.

If the IRB determines any of the above criteria are met and waive the requirement for obtaining assent, the IRB determines and documents which children/adults with impaired decision-making capacity are not required to assent.

4. Applicable Regulations and References

- 45 CFR 46 Subpart D
- 21 CFR 50.55 Subpart D
- MSK IRB SOP SC-501
- MSK IRB SOPs 701-706

Revision History

Revision	Effective Date	Reason for Change
1.0	6/15/09	NEW
1.1	6/4/12	• Clarification of verbal assent procedures. • Expanded assent requirements to include mildly cognitively impaired adults.

		• Clarified the requirements for high risk pediatric studies require the permission of both parents. • To comply with the Federal Regulations, specified that upon reaching 18 of age, re-consent would be required for any participant continuing on a study.
1.2	2/29/16	• Updated Signature page, MSK branding, formatting. • 3.2.4 Clarified requirements for FDA-regulated research. • 3.3 New section on Waiver of Assent • 3.4 New section on Waiver of Parental Permission
1.3	6/23/16	• Corrected numbering for 3.4 • 3.4.1 Additional detail on waiving parental or guardian permission
1.4	5/10/18	• 3.2 New section on documentation of assent was added to reflect change in requirements for obtaining assent on a written signature page. • 3.4/3.5 Updated titles to reflect waiving assent and waiving parental permission sections.
1.5	5/11/20	• Replaced the term cognitive impairment with impaired decision-making capacity throughout • 3.2.1.1 Clarified requirements that were effective as of 5/10/2018
1.6	11/23/20	• 3.3.2, 3.5.4 Updated to note that if one parent is not reasonably available to sign and date the consent, the reason why must be documented in the medical record • 3.5 Removed duplicative text regarding permission from both parents; renumbered sections
1.7	5/10/21	• 3.1.2.1 Added section to clarify that at the time of assent, the consenting professional may determine that assent is not appropriate based on the maturity or psychological state of the participant • 3.2.1.1 Updated to note that if the consenting professional determines that assent is not appropriate for a participant, it must be documented in the medical record • 4 Updated section to include MSK IRB SOPs 701-706
1.8	1/31/22	• Removed former section 3.3 (parental permission and assent for research involving children) as this is covered in MSK IRB SOP SC-501 • Removed former section 3.5 (waiving parental permission for research involving children) as this is covered in MSK IRB SOP IC-702 • Grammatical revisions
1.9	11/6/23	• Moved “If the consenting professional determines that assent is not appropriate for a participant based on maturity of psychological state, it must be documented in the medical record” from 3.2.1.1.1 to 3.2.1 • 3.2.1.3 Removed “The assent process must be documented in the participant’s medical/research record.”