UNC SCHOOL OF MEDICINE	Standard Operating Procedure		
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402.1: Obtaining and Documenting Parental Permission and Child Assent

PURPOSE

This Standard Operating Procedure (SOP) describes requirements and procedures for obtaining parental permission (legal guardian) and child assent for human subjects research involving children.

SCOPE

This procedure applies to all SOM investigators and study personnel responsible for obtaining parental permission and/or child assent.

BACKGROUND

It is required to obtain legally effective informed consent (IC) even when children are subjects of research.[1, 2, 3, 6, 8, 11, 12, 13, 16, 18, 21, 24, 28] As children have neither the legal status nor the developmental capacity to understand many of the issues inherent in providing informed consent, additional protections are required. A parent (or both parents if required by the regulations and the Institutional Review Board (IRB)) or, in applicable cases, a guardian, must provide permission for the child's participation in the research study. The IRB may also require assent of the child unless it can be appropriately waived, or if the child is not capable of providing assent. Depending on the nature of the research activity as well as the age, maturity, and psychological state of the child, the IRB reserves the right to waive both parental permission and child assent requirements.[9, 18, 21]

If the child dissents from participating in research or does not provide affirmative agreement, even if the parents or guardian have granted permission, the child's decision prevails. However, the IRB may waive the assent requirements if the intervention or procedure involved in the research affords the distinct prospect of direct benefit to the health or well-being of the child. Conversely, if a child assents to participate in research, and parental permission has not been waived by the IRB, the permission of the parent(s) or guardian is also required prior to the child's enrollment in the research study. [21, 28] Therefore, in most cases, both parental permission and child's assent are required prior to participation in the research study.

Permission by parent(s) or guardian(s) must be documented by a written informed consent form (ICF), unless the IRB issues a waiver of documentation of IC.[12] The IRB has the discretion to determine the appropriate manner, if any, of documenting child assent.

Certain medical conditions, emancipation, marriage, military service, or other unique situations may exempt the requirements of assent and permission, as outlined above. You must consult with OHRE and/or University Counsel if you believe any of these exceptions may apply to your study.

PROCEDURES

1. **Develop the parental permission and assent process and materials**
    a. Consider the proposed research activity and the ages, maturity, and psychological state of the children involved when developing assent procedures and the content of information to be conveyed.[16, 21, 28]
        i. The assent procedure should reflect the reasonable effort to enable the child's understanding, to the degree they are capable, of what their participation in research would involve.
        ii. More than one child assent process may be needed for studies that have different cohorts of children (e.g., age, developmental level, physical and sensory impairment).
    b. Determine the most appropriate format of assent documentation, if any, based on the child's age, maturity, and degree of literacy.
        i. A written assent form is generally used for children developmentally seven years of age or older with reading level and content adapted for age.[28]
    c. Electronic parental permission and assent (eIC) may be utilized in certain circumstances.[30, Procedure 7.b.]
    d. Establish procedures for assessing, documenting, and managing circumstances when a child presents with a guardian or where it becomes known that one parent may have sole legal custody of the child.
    e. For research where the consent of both parents is required,[4, 5, 6, 14, 15] establish procedures for:
        i. Assessing, documenting, and determining if a parent is not reasonably available.[22]
        ii. Enable communication, permission, and documentation of IC of a second parent who may not be physically available.[10]
    f. Develop the parental permission and assent forms, scripts, and other materials, as applicable.[24, 28]
    g. Obtain IRB approval for all parental permission and assent processes, forms, scripts, and materials.
        i. If assent will not be obtained, provide the IRB with rationale.
    h. Confirm that the planned study procedures adequately reflect the child protections established by the IRB (included in the UNC-Chapel Hill IRB approval letter).
2. **Prepare for obtaining initial parental permission and child assent**
    a. Consider the child's routines when scheduling the study visit and build in extra time to allow for breaks, as necessary.
    b. Print or otherwise prepare one or more copies of the IRB-approved parental permission and/or assent form, scripts, and other materials, as applicable.
        i. Avoid crossing-out or writing-in any information on the ICF.
    c. As appropriate and based on the nature of the study and the person providing consent/assent, share a copy of the form(s) prior to the initial consent/assent discussion to allow ample time for review.
    d. Ensure privacy during the consent/assent process (e.g., private meeting space).
3. **Obtain and document parental permission**[6, 8, 16, 18, 20, 28]
    a. Conduct the parental permission discussion in accordance with the IRB-approved informed consent plan.

   i. Refer to *SOM SOP 401.1, Obtaining and Documenting Informed Consent from Adult Research Participants* for additional procedures specific to obtaining informed consent from adults.[30, Procedure 2]
   ii. Obtain consent from both parents when two-parent permission is required by the IRB, unless one parent is deceased, is unknown, is incompetent, is not reasonably available, or when one parent has sole legal custody of the child.[22]
b. Document parental permission using a written parental permission form, as approved by the IRB.
   i. Document parental relationship(s)/guardianship and any determination of "not reasonably available" for two parent consent.[22]
c. Document the discussion in a checklist, contextual note in the research record, or other format. Documentation should include who obtained the IC, when the IC was obtained (date/time), how the IC was obtained, and other exchanges of information related to the adequacy of the consent process.[31, 32]

4. **Obtain and document child assent**
   a. Conduct the assent discussion using the IRB-approved process appropriate for the child.
   b. Document assent using the IRB-approved method.
      i. The child must provide affirmative agreement to participate in the research. The failure to object should not be construed as assent.[21, 28]
      ii. If a child dissents, document the dissent in the research record.
5. **Ensure ongoing parental permission and assent**
   a. Ensure ongoing exchange of age-appropriate information (e.g., information that corresponds with assent language approved for different age groups) about the research during the participant's time in the study.
   b. Verify and document ongoing understanding of key study information.
   c. Provide participant, parents(s) and/or guardian with new information once available, as applicable (e.g., changes in study procedures, identification of new risks, availability of new alternative therapies, etc.).
   d. Should the child reach the age of majority[29] during the study, seek and obtain the legally effective adult IC unless the IRB determines that the requirement can be waived.[8, 18, 21,
6. **Consider special circumstances for children and parent(s) or guardian**
   a. Accommodate, to the extent possible, the specific needs of the child, parent, or guardian (e.g., for a person with a sensory or physical impairment).
   b. If a child, parent, or guardian has Limited English Proficiency (LEP), ensure that the assent form and/or parental permission is translated into a language understandable to the person providing permission or assent. Use the short form consent method when LEP is not anticipated.[8, 18, 23, 25]
   c. If a parent or guardian is unable to read due to illiteracy or blindness, obtain IRB approval to use an oral consent process[27]
   d. If a child, parent, or guardian is deaf or hard-of-hearing and the IRB has approved a consent process using American Sign Language (ASL), use an interpreter that is fluent in ASL.[26]
   e. If children who are wards of the state are to be included in the research, identify an advocate in the consent/assent process (in addition to the child's legal guardian) for each child and obtain the IRB's approval of the advocate's involvement.[7, 17, 21, 28]

i. The advocate should be adequately informed about the potential risks and benefits of the proposed study, and how the intervention is likely to affect the individual child.[8]

DEFINITIONS, ABBREVIATIONS, ACRONYMS

Click the link or scan the QR code to access the SOM Clinical Research Glossary for definitions, abbreviations, and acronyms pertaining to the SOP.

ASSOCIATED POLICIES, REGULATIONS, GUIDELINES, RESOURCES

Federal Regulations and Guidelines:

1. FDA: 21 CFR 50.20
2. FDA: 21 CFR 50.27
3. FDA: 21 CFR 50.3
4. FDA: 21 CFR 50.53
5. FDA: 21 CFR 50.54
6. FDA: 21 CFR 50.55
7. FDA: 21 CFR 50.56
8. FDA: Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors
9. FDA: IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects, Guidance for Sponsors, Investigators, and Institutional Review Boards
10. FDA and OHRP: Use of Electronic Informed Consent Questions and Answers, Guidance for Institutional Review Boards, Investigators, and Sponsors
11. HHS Common Rule, 2018 Requirements: 45 CFR 46.116
12. HHS Common Rule, 2018 Requirements: 45 CFR 46.117
13. HHS Common Rule, 2018 Requirements: 45 CFR 46.402
14. HHS Common Rule, 2018 Requirements: 45 CFR 46.406
15. HHS Common Rule, 2018 Requirements: 45 CFR 46.407
16. HHS Common Rule, 2018 Requirements: 45 CFR 46.408
17. HHS Common Rule, 2018 Requirements: 45 CFR 46.409
18. HHS OHRP: Children: Information on Special Protections for Children as Research Subjects
19. HHS OHRP: Informed Consent FAQs
20. HHS OHRP: Informed Consent Tips
21. HHS OHRP: Research with Children FAQs
22. HHS OHRP SACHRP Recommendation, October 2018: Attachment D – Parental Permission in Research Involving Children

UNC-Chapel Hill Policies, Standards, Guidelines, Resources:

23. OHRE: Sample Consent Forms
24. OHRE: SOP 1101: Obtaining Informed Consent from Research Subjects

25. OHRE SOP 1101: Obtaining Informed Consent from Research Subjects, 2.7.1 Enrollment of Persons with Limited English-language Proficiency
26. OHRE SOP 1101: Obtaining Informed Consent from Research Subjects, 2.7.3 Consent in American Sign Language (ASL)
27. OHRE SOP 1101: Obtaining Informed Consent from Research Subjects, 2.7.4 Oral Consent
28. OHRE: SOP 1201: Vulnerable Subjects in Research, 2.6 Research Involving Children
29. OHRE: SOP 6001: Definitions, Children
30. SOM SOP 401: Obtaining and Documenting Informed Consent from Adult Research Participants
31. SOM SOP 401.1 Appendix A: Template Checklist for Documenting the Informed Consent Discussion
32. SOM SOP 401.1 Appendix B: Template Contextual Note for Documenting the IC Discussion in the Study Record

Revision History		
Version	**Effective Date**	**Change Summary**
401.1	12.14.2023	New