SOM SOP 402.1

Obtaining and Documenting Parental Permission and Child Assent

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Session Outline

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Clinical Research Profile and Training System (PaTS) SOP Attestation Demo

Overview of SOP 402.1

Questions

Who is Required to Attest in PaTS?

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“Obtaining and documenting Parental Permission and Assent”

Instructions for creating a PaTS profile and attesting to documents in PaTS are available at www.med.unc.edu/crso/training/pats/

When Is the Attestation Due?

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30 Days from Issue Date

December 14, 2023

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SOP Attestation Demo

SOP 402.1 Format

Purpose
Scope
Background
Procedural Steps
Definitions
References

SOP 402.1 Overview

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Purpose

Describe requirements and procedures for obtaining parental (legal guardian) permission and child assent for human subjects research involving children

Scope

All SOM investigators and study personnel responsible for obtaining parental permission and/or child assent

Background

- Legally effective informed consent (IC) is required when children are subjects of research. As children do not have legal status, informed consent is obtained by the parents or a guardian, as applicable
- Permission by parent(s) or guardian(s) must be documented by a written informed consent document, unless the IRB issues a waiver of documentation of IC
- The IRB should require child assent unless it can be appropriately waived, or if the child is not capable of providing assent
- When the IRB determines that assent is required, it must also determine whether and how assent must be documented

Procedural Steps

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1. Develop the parental permission and assent process and materials
2. Prepare for obtaining initial parental permission and child assent
3. Obtain and document parental permission
4. Obtain and document child assent
5. Ensure ongoing parental permission and assent
6. Consider special circumstances for children and parent(s) or guardian

Step 1

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Develop the parental permission and assent process and materials

- Develop assent procedures that consider the nature of the proposed research activity and the ages, maturity, and psychological state of the children involved
- Establish procedures for managing various parental relationship(s)/guardianships
- Obtain IRB approval for all consent processes, forms, scripts, and materials
- Confirm that the planned study procedures adequately reflect the child protections established by the IRB

Step 2

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Prepare for obtaining initial parental permission and child assent

- Consider the child's routines and build in extra time to allow for breaks
- Ready consent materials
- Avoid crossing-out, writing-in or changing the IRB approved consent materials
- As appropriate, share a copy of the consent form(s) prior to the initial consent/assent discussion to allow ample time for review
- Ensure privacy during the consent/assent process

Step 3

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Obtain and document parental permission

- Conduct the consent discussion in accordance with the IRB-approved plan.
- Document parental permission using a written, IRB approved parental permission form, as applicable
- Document the consent discussion (checklist, contextual note in research record)

Step 4

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Obtain and document child assent

- Conduct the assent discussion using the IRB-approved method
  - The child must provide affirmative agreement to participate in the research.
- Document assent as approved by the IRB
  - Dissent must also be documented in the research record

Step 5

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Ensure ongoing parental permission and assent

- Ensure ongoing exchange of age-appropriate information about the research
- Verify and document ongoing understanding of key study information.
- Share new information once available, as applicable
- Should the child reach the age of majority during the study, seek and obtain the legally effective adult IC unless the IRB determines that the requirement can be waived

Procedure 6

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Consider special circumstances

- Make accommodation for specific needs to the extent possible
- Ensure that the child assent and parental permission forms are translated as applicable
  - Use the short form consent method when Limited English Proficiency (LEP) is not anticipated
- Obtain IRB approval to use an oral consent process for persons who are unable to read due to illiteracy or blindness
- Use an interpreter that is fluent in American Sign Language (ASL) if the IRB has approved a consent process using ASL
- Identify and obtain IRB approval for a consent advocate for children who are wards of the state

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Questions