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| SOP Number:  [SOP NUMBER] – [VERSION] | Page Number:  1 of [X] | Effective Date:  [DATE] |

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| Originated by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |
| Reviewed by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |
| Approved by:  [NAME(S)], [TITLE(S)] | Signature: | Date: |

##### Standard Operating Procedure (SOP)

**Obtaining Informed Consent/Permission and Assent**

***Please note that italic font is used within templates to indicate areas where site-specific information must be included, and to describe the type of information needed.***

1. SCOPE

The scope of this SOP applies to all staff involved in obtaining informed consent/permission and assent. This SOP describes the steps required for fulfilling the regulatory and ethical requirements for developing the informed consent/assent document and obtaining informed consent/assent.

1. PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the process by which informed consent/permission and assent is obtained and documented. The ethical conduct of clinical investigations is based on the voluntary consent of the subject, who has been appropriately informed about a study’s risks and benefits, and is designed to protect the rights, safety and wellbeing of human subjects. It is the responsibility of the investigator to ensure that compliance with all ethical standards, guidelines and federal and state regulations has been met through the language of the informed consent document and that informed consent has been properly obtained from the subject or the subject’s legal representative. Documentation of the informed-consent process is required to establish that the subject was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent.

1. DEFINITIONS AND/OR ABBREVIATIONS & ACRONYMS (optional)
2. **Clinical research organization (CRO)** is a company that provides support to the pharmaceutical, biotechnology and medical device industries in the form of research services outsourced on a contractbasis.
3. **Legal authorized representative (LAR)** is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research.

*[Include any additional general definitions needed for understanding by reader, and/or abbreviations and meaning that will be used throughout the SOP.]*

1. GENERAL STANDARDS
2. This SOP should be read and followed when creating the documents and conducting the informed consent and assent processes.
3. PROCESS AND PROCEDURES
4. Writing the consent/assent document
   1. PI and/or research coordinator will develop the consent/assent documents based on the protocol and the investigator’s brochure.
      * 1. The consent form should be written at the 8th grade reading level or lower in most cases. Link to web source that helps assess reading level – see http://www.readabilityformulas.com/free-readability-formula-tests.php for an example.
        2. The assent form should be written in a simpler format with language appropriate to the youngest child in the study’s age range.

*[Add your institutional guidelines for level of reading.]*

* 1. PI and/or research coordinator will verify that all required and additional elements of the informed consent form are incorporated.
  2. Research coordinator will submit draft consent/assent document to sponsor for approval prior to submitting to the IRB.
  3. Research coordinator, in consultation with the sponsor/CRO, will make modifications requested by the IRB.
  4. Research coordinator will file the original IRB approval letter and approved informed consent form document appropriately and send copies of both documents to the sponsor/CRO, where required.
  5. Research coordinator will submit informed consent/assent amendment changes to the IRB for approval, ensure that applicable revisions are made in conjunction with the sponsor and ensure that the revised IRB-approved version replaces the previous version.
  6. PI and/or research coordinator will, if required, ensure that currently enrolled subjects are re-consented with the new version of the consent/assent. The IRB may specify if all subjects must be re-consented with the new version and may specify the timing (if subjects should be consented at their next scheduled visit or brought in sooner for safety reasons).

1. Process for conducting the informed consent/assent
2. Research coordinator will ensure that the most recent version of the IRB-approved consent/assent form is used to document that the prospective subject has given consent/assent.
3. PI and/or research coordinator will ensure that the above procedure is implemented in the subject’s language (if the subject does not speak English) by using a qualified interpreter. *[Add your institutional guidelines for consenting in another language.]*
4. PI and/or research coordinator will provide the above information to the subject’s legally authorized representative (LAR).
5. Conduct discussion in a private area.
6. PI and/or research coordinator will provide the consent form/assent to the subject or LAR to allow an adequate opportunity for the document to be read in its entirety before it is signed. This may include the subject or LAR taking the document home to discuss with family prior to signing.
7. PI and/or research coordinator will confirm with the subject or LAR, as appropriate, that all questions have been answered (by medically appropriate staff) and the process should be documented.
8. PI and/or research coordinator will ensure that the subject, LAR, interpreter and/or an impartial witness sign and date the IRB-approved informed consent document prior to initiation of any study-specific procedures.
   * + 1. If the subject is unable to provide written informed consent, document the reason the subject is unable to give consent (e.g., age, cognitive ability). *[Add your institutional guidelines for documentation.]*
9. PI and/or research coordinator will ensure that the subject or LAR reads and understands HIPAA authorization and signs the authorization after the informed-consent process has been completed (if the HIPAA language has not been included as a part of the approved consent document).
10. PI and/or research coordinator will ensure that currently enrolled subjects be re-consented with the new version of the consent/assent (as applicable).
11. Research coordinator will conduct a quality assurance process for ensuring consent/assent has been completed in its entirety. Consent/assent should be reviewed to ensure:
    1. All signatures are dated with the correct date by the individuals signing.
    2. All sections where initials are requested are initialed by the correct party.
    3. All information is complete (e.g., all required boxes are checked).
12. PI and/or research coordinator will ensure the following:
    1. The subject is provided with a copy of the informed consent document.
    2. The original is retained and kept in the research record.
    3. The process is documented.
13. Supporting Documents
14. ORHP 45 cfr 46
15. FDA 21 CFR 50
16. FDA 21 CFR 50 SubPart D
17. REFERENCES (if applicable)

Include both local and federal regulations cited to create the SOP.

1. ATTACHMENTS
2. Attachment 1 – Attachment title: Informed Consent/Assent Process Checklist
3. REVISION HISTORY

Major changes should be identified. Show history in descending order of versions.

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| --- | --- | --- |
| Version Number | Summary of Changes | Replaces |
|  |  | Document Number, Revision Number |
| 02 | Enter the summary of changes in a bulleted list, highlighting the major changes | SOP XXX-###, 01 |
| 01 | Original Document |  |

1. FOOTER

[Version number], [Version date], [Page count], [Any sort of a confidentiality statement]