***Obtaining and Documenting Informed Consent/Assent***

1. **PURPOSE**

To describe the process and procedures for developing, obtaining, documenting and storing informed consent and/or assent of clinical trial subjects.

**(MANDATORY LANGUAGE)**

1. **SCOPE**

This procedure applies to the Principal Investigator (PI) and, when delegated by the PI, Co-Investigators (Co-Is), Study Coordinators (SCs), and other designated site personnel who are tasked with writing, obtaining and documenting Informed consent/assent. Out of scope for this SOP are specialty consents per University of Michigan Institutional Review Board of the Medical School(IRBMED) such as Compassionate Use of an FDA Investigational Agent, Emergency Use and Humanitarian Use Device (HUD).

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details necessary to further define the scope of this SOP.]*

1. **POLICY**

This Standard Operating Procedure supports the Good Clinical Practices guidelines established by the International Conference on Harmonization (ICH). Section 4.8 details the process for obtaining and documenting informed consent, including Section 4.8.*1: In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles in the Belmont Report. In addition, it is supported by University of Michigan guidance on the informed consent process,. See the University of Michigan HRPP Operations Manual, Part 7.*

FDA Regulation ☐ N/A

*[If this SOP is not intended for FDA regulated clinical trials, check the N/A box]*

Per 21 Code of Federal Regulations Part 50 Subpart B Section 50.20, *…no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.*

Note that in emergency situations there are exceptions to this rule, which can be found in 21CFR50.23 Subpart B “Exception from general requirement” and “Exceptions from Informed Consent for Emergency Research” 21CFR50.24.

In addition, federal regulations require*, The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.* 45CFR46.408

Additional FDA regulations require that IRBs give special considerations to protecting the welfare of particularly vulnerable subjects such as prisoners, pregnant women, human fetuses, and neonates, please refer to 45CRF46 subpart B for more information regarding these regulations.

**Additional Regulations or Policies ☐ N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional project, department, sponsor, institution, state or federal policies that apply.]*

1. **DEFINITIONS**

ASSENT: Agreement to participate in proposed research, given by an individual not competent to give legally valid informed consent (e.g., a child or mentally limited person).

* Assent means a child's affirmative agreement (verbal or written) to participate in a clinical investigation. Children age 10 and up are generally able to provide their assent.
* Assent is an adult's affirmative agreement (verbal or written) to participate in a clinical investigation. Adults may be assented (instead of consent) if they have a cognitive disability rendering them unable to consent for themselves.

COGNITIVELY IMPAIRED: A person having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from post-traumatic or degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

ELEMENTS OF CONSENT**:** Elements that are required by law or regulation to be included in an informed consent document. This includes study purpose, study procedures, foreseeable risks, expected benefits, etc.

INFORMED CONSENT (IC):Informed consent is the exercise of a free power of choice without undue inducement, force, fraud, deceit, duress or other form of constraint or coercion. If the subjects are minors or are not capable of giving consent, parental, guardian or other legal representative consent is required.

* Use of a written consent form that includes all of the basic elements.
* The process of learning the key facts about a research study.
* A process by which a subject voluntarily confirms his or her willingness to participate in a particular research project.
* It is a continuing process throughout the study to provide information for participants.

INSTITUTIONAL REVIEW BOARD (IRB):An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

LEGAL REPRESENTATIVE:

1. Legally authorized representative means 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 procedure(s) involved in the research.
2. A person authorized either by statute or by court appointment to make legal decisions on behalf of another person. In human subject research, 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 procedure(s) involved in the research.

NEONATE: A neonate is a baby who is 4 weeks old or younger

PRISONER: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial. See <http://www.hhs.gov/ohrp/policy/faq/prisoner-research/regulations-define-prisoner.html> for additional HHS regulatory definitions of prisoners and parolees.

SHORT FORM: A written document stating that the elements of informed consent required by regulation have been presented orally to the participant or the participant's legally authorized representative. The short form consent document must be written in a language understandable to the participant or the participant's legally authorized representative.

VULNERABLE SUBJECTS: Vulnerable populations can be defined as children, prisoners, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged

persons. If vulnerable individuals are involved in clinical trials, IRBs must ensure that additional safeguards have been included to protect the vulnerable group. Safeguards may include the presence of interpreters or social workers to explain the research and ensure informed consent. IRBs have a specific obligation to protect those individuals who are particularly susceptible to coercion or undue influence.

“Many of the definitions above were obtained from the IRBMed Glossary.  These definitions were current as of 12-Jun-2015 and are subject to change.  Please see the [IRBMed Glossary](http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/glossary) for the most current definitions and additional guidance”.

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional definitions for technical or special terms used within the Standard Operating Procedure that may not be familiar to the lay reader]*

1. **ROLES AND RESPONSIBILITIES**

**Principal Investigator/Designee**

An individual filling the role of Principal Investigator (PI) is accountable for obtaining consent and/or assent for research subjects in the clinical trial. The PI or Designee shall be responsible for the following activities:

**(MANDATORY LANGUAGE)**

* Ensures that all required elements of consent (Informed Consent Checklist -

<http://medicine.umich.edu/medschool/sites/medicine.umich.edu.medschool/files/res_irbmed_Informed%20Consent%20Checklist.doc> )

are contained within the consent document and the language is understandable to the subject or the representative

* Ensures that staff conducting part, or all of the informed consent process have been trained to the protocol, educated on the informed consent process and are qualified to answer subject questions about the research
* Ensures that each potential subject (or subject’s legal representative) understands the nature of the research and participation in the clinical trial, the risks, and that all questions about the trial are answered to their satisfaction
* Ensures that the consent process is conducted without coercion and the subject makes a voluntary decision to participate
* Conducts the IC discussion (using the most currently approved IRB version) in a location that allows for privacy and gives the subject ample time to review the consent
* Ensures that the consent/assent document(s) is signed and dated by the subject or their legal representative prior to performing any clinical trial procedures
* Obtains assent from children when applicable
* Appropriately files and stores consents according to the IRB approved storage plan for the clinical trial
* Re-consents subjects as appropriate and documents this process
* Revises the consent when information pertaining to the risk/benefit ratio and/or subject’s willingness to participate in the research changes
* Ensures that proper steps and processes (short forms, summaries, UM interpreters, witnesses etc.) are taken when consenting foreign speaking subjects and illiterate subjects
* Ensures proper IRBMED approval has been obtained when consenting vulnerable subjects such as prisoners, pregnant and lactating women, cognitively impaired, neonates, etc.
* Ensures appropriate educational materials (if applicable) and related documentation are provided for studies that require or request HIV testing (or other reportable diseases)
* Delegates activities to other research team members, as appropriate
* Follows the process for obtaining consent as stated in the eResearch application
* Responsible for the informed consent process at other sites (multisite trial) when it has been approved by the IRB and when it is conducted at any engaged site

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Principal Investigator/Designee]*

**Study Coordinator(s)/Designee**

An individual filling this role shall be responsible for the following activities:

**(MANDATORY LANGUAGE)**

* Creates consent/assent document(s) utilizing IRBMED templates
* Reconciles consent language provided by sponsors or non-UM sites to ensure required elements of informed consent are present and meet IRBMED requirements
* Obtains consent/assent or re-consent from subjects according to IRB approved processes
* Provides documentation of signed consent to the subject or their representative
* Reports to the IRB any deviation to the consent process

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Study Coordinator/Designee]*

**Additional Roles and Responsibilities**  **☐ N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional role(s) and responsibilities that apply to this SOP]*

1. **PROCEDURE**

The Institutional Review Boards of the University of Michigan Medical School (IRBMED) oversee human subjects research conducted at the Medical School and University of Michigan Health System

(UMHS). This includes research conducted off-site by University faculty and staff when acting as University employees or in connection with their University appointments. Please follow IRBMED policies and procedures for the development, implementation and amendment of informed consents. This includes the use of IRBMED templates and guidance documents. If the IRBMED templates are not utilized, all essential elements of Informed Consent must be addressed. Additional details regarding the development, implementation and amendment of Informed Consent documentation and the informed consent process are described below.

**(MANDATORY LANGUAGE)**

**Writing and Amending the Informed Consent Document:**

*[Describe the process for drafting the Informed Consent document and submitting it to the IRBMED]*

*[For Sponsor initiated trials, describe the process for coordinating the development of the Informed Consent to meet the needs of the sponsor and the IRB]*

*[For multi-site trials, describe the process for coordinating the development of the Informed Consent to meet the needs of PI Sponsor and the sites IRB]*

*[Describe the process for amending the Informed Consent document]*

*[Describe the process for drafting and amending the Informed Consent when working with a centralized, non-UM IRB]*

*[Describe the process for drafting and amending the Informed Consent for multi-site trials]*

**Obtaining Informed Consent**

*[Describe the process for obtaining informed consent documentation, including research team members responsible for obtaining consent, and obtaining consent from a legal guardian or legal representative]*

**Obtaining Assent for Children**

*[Describe the process for obtaining assent, include age group breakdowns where applicable]*

**Obtaining** **Consent for Cognitively Impaired or Vulnerable Subjects**

*[Describe the process for obtaining informed consent from vulnerable populations]*

**Obtaining Consent for Non-English Speaking or Illiterate Subjects**

*[Describe the process for consenting non-English speaking or illiterate subjects]*

**Re-consenting Procedures**

*[Describe the process and conditions needed for re-consenting subject and when applicable notifying other sites of this]*

***Tracking Informed Consent Documentation***

*[Describe the process for storing and tracking the signed Informed Consent for subjects in a clinical trial]*

*[Describe the process for managing and tracking Informed Consent templates; version control, storage of retired versions, amendments, etc.]*

**Additional Consent Procedures** **☐ N/A**

*[Optional: Insert any additional relevant consent procedures. Provide enough detail to ensure the procedure is consistently carried out, without providing so much detail that violations occur due to normal or expected variations in the work.]*

1. **REFERENCES**

FDA Title 21CRF50.20 Subpart B - Informed Consent of Human Subjects:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.20>

FDA Title 21CFR50.25 - Elements of Informed Consent:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=50.25>

FDA Title 21CFR50.27 - Documentation of Informed Consent:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.27>

FDA Title 45CFR46 Subpart B - Requirements for Permission by Parents or Guardians and for Assent by Children:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

FDA Title - General requirements for informed consent:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>

Human Research Protection Program (HRPP) University of Michigan - Vulnerable Subjects: <http://hrpp.umich.edu/om/Part7.html>

Human Research Protection Program (HRPP) University of Michigan - Roles and Responsibilities of Investigators and Research Staff:

<http://www.hrpp.umich.edu/om/Part6.html>

International Council on Harmonisation - Informed Consent of Trial Subjects (Section 4.8):

<http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf>

Michigan Department of Community Health - Brochure for HIV:

<https://michigan.gov/documents/mdch/What_you_need_to_know_about_HIV_438247_7.pdf>

Michigan Department of Community Health - Consent for HIV:

<http://michigan.gov/documents/mdch/Routine_testing_CONSENT_TO_TREATMENT_SAMPLE_193175_7.pdf>

University of Michigan IRBMED - Central IRB Information:

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/central-irb-information>

University of Michigan IRBMED - [Checklist of Federally Required Elements of Informed Consent](http://medicine.umich.edu/medschool/sites/medicine.umich.edu.medschool/files/res_irbmed_Informed%20Consent%20Checklist.doc):

http://medicine.umich.edu/medschool/sites/medicine.umich.edu.medschool/files/res\_irbmed\_Informed%20Consent%20Checklist.doc

University of Michigan IRBMED - Foreign Language Short Forms:

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/informed-consent-templates/foreign-language-short-forms>

University of Michigan IRBMED - Informed Consent:

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/informed-consent>

University of Michigan IRBMED - [Informed Consent](http://medicine.umich.edu/medschool/sites/medicine.umich.edu.medschool/files/res_irbmed_Informed%20Consent%20Checklist.doc) Templates:

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/informed-consent-templates/>

University of Michigan IRBMED - Specialty Consents:

http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/informed-consent-templates/specialty-informed-consent-templates

University of Michigan IRBMED - STATEMENT OF PRACTICE Version Control of Informed Consent Document(s):

<http://medicine.umich.edu/medschool/sites/medicine.umich.edu.medschool/files/res_irbmed_SP%20VersionControlInformedConsent%202014%2010%2021.pdf>

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SOP references]*

1. **APPENDICES**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SOP appendices]*