SM-401 REVISION HISTORY

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SM-401 STANDARD OPERATING PROCEDURE FOR INFORMED CONSENT DEVELOPMENT AND IMPLEMENTATION

I. INTRODUCTION AND PURPOSE

The ethical conduct of clinical investigations is based upon the voluntary consent of the subject who has been appropriately informed about a study's risks and benefits. It is the responsibility of the investigator to ensure that all federal and state regulations have been met through the language of the informed consent document, and that informed consent itself 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.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and ethical requirements for developing the informed consent document and for appropriately obtaining the subject's informed consent.

2. SCOPE

This SOP applies to the activities involved in preparing the informed consent form, submitting it for IRB approval, and for obtaining informed consent from research subjects who participate in all clinical studies conducted at this investigative site. It applies to obtaining consent under general requirements or routine circumstances as well as identifies the specialized procedures for obtaining informed consent from subjects who do not speak English and from children. This SOP also specifies the conditions for exceptions from the general requirements for obtaining informed consent and for emergency research.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.25	Elements of informed consent
21 CFR 56.109	IRB review of research
21 CFR 56.111	Criteria for IRB approval of research
21 CFR 312.54	Emergency research under §50.24 of this chapter
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
45 CFR 46.116	General requirements for informed consent

4. REFERENCES TO OTHER APPLICABLE SOP'S

GA-102	Responsibilities of the Research Team
PM-302	Interactions with the Institutional Review Board
PM-303	Regulatory Files and Subject Records
SM-403	Subject Management While on Study
SM-404	Adverse Event Reporting

5. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in drafting or reviewing the sponsor-provided informed consent form, submitting it to the IRB for approval, and for obtaining informed consent from research subjects. This includes the following:

- Principal Investigator
- Sub-Investigator
- Research Coordinator
- Research Director/Manager
- Interpreter
- Support Staff

6. DEFINITIONS

The following definitions from the International Conference on Harmonisation; Good Clinical Practice: Consolidated Guideline apply to this SOP.

Confidentiality: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

Impartial witness: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject.

Informed consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

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.

Legally acceptable representative: An individual or juridical or other body authorized under applicable law to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.

Vulnerable subjects: Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

7. PROCESS OVERVIEW

A. Drafting or adapting the written informed consent form

B. Obtaining written consent from the subject (or the legal representative)
C. Documenting the informed consent process
D. Revisions to the informed consent form
E. Consent of children

8. PROCEDURES

A. DRAFTING OR ADAPTING THE WRITTEN INFORMED CONSENT FORM

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research Director/Manager Research Coordinator	Based upon the protocol and investigator's brochure, prepare a draft informed consent form and/or use a template provided by the IRB.
PI Research Director/Manager Research Coordinator	**OR** Adapt an informed consent document provided by the sponsor/CRO for use at this clinical site. Verify that all required and additional elements of the informed consent form are incorporated by using the Informed Consent Checklist (Attachment A) and inserting the appropriate language as required by the IRB. Ensure the document also meets all state and local requirements.
PI Research Director/Manager Research Coordinator	Submit the draft informed consent form to the IRB for review and approval along with the other IRB-required documents. In consultation with the sponsor/CRO, make modifications requested by the IRB. After the informed consent form document has been approved by the IRB, file the original IRB approval letter and informed consent form document appropriately and send copies of both documents to the sponsor.

B. OBTAINING WRITTEN CONSENT FROM THE SUBJECT (OR THE LEGAL REPRESENTATIVE)

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Sub-investigator Research coordinator	Ensure that the most recent version of the IRB-approved consent form is used. In a location that provides privacy, review the informed consent form with the subject by discussing all of the elements: provide an overview of the study, explain its purpose, procedures, risks and benefits, drug and comparative agent (if applicable), alternatives, research-related procedures, etc Allow the subject time to read the document and ask questions. Encourage input from family members and other care providers, if appropriate. If the subject is unable to give written informed consent, provide the above information to the subject's close relative (as per local law) or the legal guardian.
PI Sub-investigator Research coordinator Interpreter	If the subject does not speak English, ensure that the above procedure is implemented in the subject's language, using a qualified interpreter. Ensure that both the subject and an impartial witness sign and date the informed consent document that has been translated into the language of the subject and approved by the IRB.

C. DOCUMENTING THE INFORMED CONSENT PROCESS

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Sub-Investigator Research Coordinator	After consenting to participate in the clinical study, ensure that the subject signs and dates the document.
PI Sub-Investigator Research Coordinator	Provide a copy of the informed consent form document to the subject (or the legal representative). Note in the subject's records the date of informed consent, indicating that consent was obtained prior to initiation of any screening procedures or study-related activities.

D. REVISIONS TO THE INFORMED CONSENT FORM

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Sub-Investigator Research Coordinator	Review changes to the protocol and investigator's brochure as well as IND safety reports, to assess the need for revising the informed consent form. Submit the revised informed consent form with changes requested by the sponsor and/or investigator to the IRB for approval. If appropriate, contact all subjects enrolled in the study to request that they sign the revised informed consent form.
PI Sub-Investigator Research Coordinator	Follow all procedures for obtaining and documenting the original informed consent process as outlined above.

E. CONSENT OF CHILDREN

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Sub-Investigator Research Coordinator	Anyone under the age of 18 will require consent from a legal guardian. If the subject is considered to be a legal minor, obtain consent from one or both parents, or legal guardian.
PI Sub-investigator Research coordinator	Follow all procedures for obtaining and documenting the informed consent process as outlined above. Provide a copy of the informed consent form to the parent(s) or legal guardian(s).
PI Sub-investigator Research coordinator	Consult with the IRB regarding their requirements for the assent of minors. If not provided by sponsor, develop a form to be used by children for their verbal or written consent/assent for their participation in the study that describes the risks and benefits in age-appropriate language.
PI Sub-investigator	Follow all procedures for obtaining and documenting the informed consent process outlined above.

Research coordinator	Provide a copy of the informed consent/assent form to the child and parent(s) or legal guardian(s).

ATTACHMENT A

GUIDELINES FOR OBTAINING INFORMED CONSENT

- Informed consent must be obtained from each subject (or the subject's legally authorized representative) before the subject can take part in any research study, including post-marketing studies of approved drugs and devices.
- Informed consent must be obtained from each subject prior to initiating any requirements of the study protocol, including pre-enrollment washout periods.
- The investigator must give the subject sufficient opportunity to consider whether or not to participate in the study. The investigator cannot coerce or use undue influence to get a subject to participate.
- Non-English speaking subjects must have the information presented in a language that they understand. If non-English speaking subjects will be enrolled, the informed consent should be translated into the appropriate language.
- Each subject must be given a copy of the consent document for his or her reference.
- The original (or certified copy) signed consent will be kept with the patient’s source documents.
- Regulatory Binder if required by the sponsor. In that instance, a copy should be placed in the patient’s source document.