

103.1 OBTAINING AND DOCUMENTING INFORMED CONSENT

This SOP is harmonized with the UTGSM local IRB SOP for obtaining consent

1. PURPOSE

To define the policies and procedures for ethically obtaining and documenting the consent of study subjects participating in clinical trial research. This SOP describes the procedures for 1) drafting an ethical consent form, 2) submission of the consent form to an IRB for review, approval and recurring review, 3) approaching and explaining the consent process to the study subject, and 4) documenting the process of consent acquisition. The procedures outlined in this SOP are intended to meet FDA/GCP regulations and guidelines for the proper acquisition of a study subject's informed consent. This SOP does not outline the procedure for the consent of minors, or those whose first language is not English.

2. SCOPE

The PI is responsible for ensuring that informed consent is obtained from each research subject before he/she participates in the clinical trial. The FDA does not require the PI to personally conduct the consent interview; however, the PI remains ultimately responsible even when delegating this task. Appropriate members of the study team who may obtain informed consent include any of the following:

- Principal Investigator
- Sub Investigators
- Qualified Clinical Trials Personnel as delegated by the PI

Responsible team members will be identified for each individual research projects including clinical trials on the "Delegation of Authority" log and document the consent process according to GCP practice.

3. BACKGROUND

The primary purpose of the consent process is to protect the rights, safety, and welfare of human subjects. The informed consent process is more than just a signature on the form. It is a process of information exchange to ensure that the potential participant or legally authorized representative is well informed. The consent process consists of 1) sharing information, 2) active communication, 3) education, 4) building trust and rapport. The consent process begins when a potential subject is initially contacted about the clinical trial and continues throughout the subject's participation in the clinical trial. It allows sufficient opportunity to consider whether or not to participate, thus minimizing the possibility of coercion or undue influence. The key components of the consent process are giving of information, discussion, clarification, assuring comprehension, verbal and written voluntary participation, and signature indicating consent.

In accordance with:

- Title 21 CFR 50.20 - General Requirements for Informed Consent
- Title 21 CFR 50.23 - Exception from General Requirements
- Title 21 CFR 50.25 - Elements of Informed Consent
- Title 21 CFR 50.27 - Documentation of Informed Consent
- Title 21 CFR 50.40, 50.42, 50.44, 50.46, 50.48 - Protections Pertaining to Investigators Involving Prisoners as Subjects.
- Title 45 CFR 46.116 - General Requirements for Informed Consent (when applicable)
- Title 45 CFR 46.117 - Documentation of Informed Consent (when applicable)
- Title 45 CFR 46.408 - Requirements for Permission by Parents or Guardians and for Assent by Children (when applicable)
- ICH GCP Consolidated Guideline - Part 4.8 Informed Consent of Trial Subjects
- The Declaration of Helsinki

4. **PROCEDURE**

- 4.1. The principal investigator is responsible for assuring that the content of the consent form is in compliance with GCP regulations and IRB requirements. The principal investigator may delegate the development of the consent form to appropriate clinical research personnel.
- 4.2. The principal investigator is responsible for assuring study subject informed consent. The principal investigator may delegate the duty of obtaining informed consent to appropriate IRB-approved clinical site research personnel. The principal investigator is responsible for assuring that any such designated member of the team is knowledgeable about the specific research study and the process of informed consent.
- 4.3. The principal investigator is responsible for assuring that the written consent form and any other written information to be provided to subjects is revised whenever new information becomes available that may be relevant to the subject's willingness to participate. The principal investigator may delegate the development and processing of the revised consent form, or any other written information. Any such revisions need to receive IRB approval prior to use.
- 4.4. Informed consent will be obtained for each research subject prior to altering a subject's care for the purpose of research. The consent must be obtained according to IRB and GCP requirements.
- 4.5. Upon identification of a potential study subject, the principal investigator or designee will be responsible for identifying who is legally authorized to give consent. If the subject is physically or mentally unable to provide consent, then the legally authorized representative may be approached to give consent. Careful attention should be given to reviewing the subject's medical history to alert the researcher to any potential impairment to informed consent.
- 4.6. If the subject or the subject's legally authorized representative is unable to read, then the IRB-approved consent form must be read in its entirety in the presence of an impartial witness. This

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should be documented directly onto the consent form and signed by the witness accordingly [ICH GCP 4.8.9].

- 4.7. If the subject or the subject's legally authorized representative is unable to speak or understand English, then the IRB-approved consent form must be translated verbally in its entirety and so documented in the subject's record and/or directly onto the consent form. The IRB shall determine whether or not the written consent form itself needs to be translated into any other language. Translators or sign language interpreters should be contacted for ongoing communication throughout the research study.
- 4.8. The principal investigator or designee will fully inform the subject or the subject's legally authorized representative of all pertinent aspects of the study including the written information as approved by the IRB. The process includes:
 - 4.8.1. Giving the subject adequate information concerning the clinical investigation in language that is as non-technical as possible.
 - 4.8.2. Providing ample time and opportunity for the subject or the subject's legally authorized representative to inquire about the details of the clinical study and to decide whether or not to participate in the study as well as to consider other available options, if any.
 - 4.8.3. Responding to subject's questions. All questions about the study should be answered to the satisfaction of the subject or the subject's legally authorized representative.
 - 4.8.4. Ensuring that the subject has comprehended this information.
 - 4.8.5. Obtaining the subject's voluntary consent or consent of their Legal Authorized Representative.
 - 4.8.6. Ensuring that no study procedure occurs prior to signing of the consent.
- 4.9. Informed consent will be documented by using the current written consent form as approved by the IRB. The written consent should be signed and personally dated by the subject or subject's legally authorized representative, and by the person who conducted the informed consent discussion [ICH GCP 4.8.8].
- 4.10. The investigator or designee will file the original signed consent form with the subject's case report forms or regulatory binder. A copy of the consent form will be provided to the person signing the form at the time of consent. A copy of the signed consent form may be provided to the pharmacy if required for study randomization. A copy will also be provided to the IRB only if requested.
- 4.11. Prisoners may only be consented and enrolled in clinical trials if specific written approval is obtained from the IRB.
- 4.12. The investigator or designee will document in the subject's case history that informed consent was obtained prior to participation in the investigation [21 CFR 312.62].
- 4.13. The investigator and all site personnel are responsible for continuing the informed consent process throughout the subject's participation in the study. The subject or the subject's legally authorized representative should be informed in a timely manner if new information becomes

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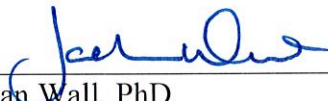
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available that may be relevant to the subject's willingness to continue participation. The communication of this information should be documented [ICH GCP 4.8.2].

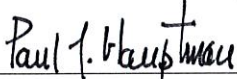
- 4.14. If the written consent form is revised during the course of a subject's participation in the trial, then the subject shall be re-consented by the principal investigator or designee with the revised IRB-approved consent form. The investigator or designee will file the newly obtained original signed consent form in the subject's study file. A copy of the consent form will be provided to the person signing the form as soon as possible after the consent has been signed, usually in person, but sometimes this is accomplished by mail.

APPROVED:



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9/23/21
Date



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