West Virginia Clinical and Translational Science Institute
Clinical Trials Center of Excellence

STANDARD OPERATING PROCEDURE

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Informed Consent Process: Development and Implementation	Page 1 of 7	
	Date of Issuance: 16 APR 2021	Date Effective: 17 MAY 2021
	Supersedes: N/A	

Prepared by: 09 APR 2021	Reviewed by: 09 APR 2021	Approved by: 17 APR 2021
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Purpose:
This standard operating procedure (SOP) describes the operations guidelines followed by the Morgantown, West Virginia University (WVU) Health Science Center (HSC) campuses and affiliated health systems for the informed consent process to ensure that the regulatory and ethical requirements are performed.

Scope:
This SOP describes procedural pathways for the informed consent process utilized at this site for all human subject research. It describes the steps for the design, approval, presentation and follow up suggested according to applicable regulations, institutional policies, GCP (Good Clinical Practices) ethical principles of human subjects' protection.

An investigator may not begin the informed consent process with subjects until the IRB reviews and approves the clinical investigation, consent form, and the information to be given to subjects as part of the consent process. In addition, for clinical trials, the consent process may not be initiated until the clinical trial is registered with the COE and COE approved. Refer to COE SOP 'Registration of Clinical Trials' for more information on this process.

Definitions:
Assent: A child's affirmative agreement to participate in a clinical investigation

Legally Authorized Representative: 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.

Materials:
NA

Responsibility:
This SOP applies to the HSC Institutions and associated clinical departments actively engaged in clinical research involving human subjects.

Procedure:
Note: The Principal Investigator (PI) shall identify which members of the research team will be obtaining the informed consent. The individual obtaining the informed consent must be qualified by education and/or experience, trained on the protocol and delegated by the PI.

Ensure that the most recent version of the IRB-approved consent form is used.

A. Designing an Informed Consent Form

1. The design or development begins with obtaining a template from either WVU IRB, IRB of record or collaborating with the sponsor/CRO/lead site on a pre-designed template. The ICF should be appropriate to the study, contain the regulated requirements provided in 21 CFR Part 50 and adhere to federal, state and local laws.

    a. Utilizing the WVU IRB provided template

    Obtain a template from the WVU IRB and apply the appropriate language from the protocol, investigator brochure and additional information, as applicable.
    OR

    b. Utilizing the Sponsor/Clinical Research Organization (CRO) provided template

    Obtain a template from the sponsor/CRO/lead site and apply clinical site information according to the WVU guidelines and in accordance to WVU's IRB requirements.

    Collaborate with the sponsor/CRO/lead site and submit the draft informed consent for review. Once it is approved by the sponsor/CRO/lead site then it is ready to submit to the IRB for approval.

2. Prepare and submit the IRB required documents, including the informed consent form and all information that will be used in the informed consent process (e.g. proposed informed consent method, recruitment, HIPAA statement) to the IRB for approval. If modifications to the consent form are required, consult with the sponsor/CRO/lead site and revise as requested by the IRB.

    Once IRB approval has been received file the documents appropriately and send copies of the required documents to the sponsor/CRO/lead site.

    If applicable, IRB approved consent form may be built/loaded to a 21 CFR Part 11 and HIPAA compliant platform such as REDCap.

    Note: Protocols may change throughout the study and the informed consent may need revised and resubmitted to the IRB for additional approval.

B. Obtaining Consent

1. Written Consent from the Subject or Legally Authorized Representative (LAR) – In Person

   Review the informed consent form with the subject in its entirety by discussing all of the elements, such as but not limited to, an overview of the study, explain its purpose, procedures, risks and benefits, drug and comparative agent (if applicable), alternatives, research-related procedures and the right to decline or withdraw. Provide the potential subject with adequate information that allows the subject to make an informed decision about the voluntary participation in the study.

   Allow the subject adequate time to read and review 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 legal authorized representative (LAR). Refer to IRB of record for LAR requirements.

   After consenting to participate in the clinical study, ensure that the subject/LAR and investigator/delegated study staff have personally signed, dated and timed (if applicable) the document.

   Document the informed consent process in the subject's records including, the date and time (if applicable) of informed consent, the ICF was signed after all questions answered, consent was obtained prior to initiation of any study-related activities, and a copy of the signed ICF was given to the subject/LAR.

   Provide a copy of the signed and dated informed consent form document to the subject or LAR. The signed original ICF must be filed within the study record and a copy placed into their medical record.

   Additional Considerations:

- 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 of record. This information must be included in the documentation of the consent process.
- For subjects that are unable to read, oral presentation of the information contained in the consent form is especially important.
- A person who is physically challenged (for example, physically unable to talk or write or has hearing or visual loss) can enroll in a clinical investigation if competent and otherwise able to communicate consent when consistent with applicable IRB state and regulatory standard. The subject's case history shall include a description of the specific means by which the prospective subject communicated agreement to take part in the clinical investigation and how questions were answered.

2. Electronic Informed Consent (eIC)

   Note: The electronic informed consent (eIC) process may be used to supplement or replace paper-based informed consents and must meet both the same regulatory 21 CFR 50.25 and institutional requirements as an in person-paper based informed consent and 21 CFR Part 11.

   Discuss the consent process with the subject and verify that the plan is acceptable and provide contact information for the study staff to the subject.

If using an electronic informed consent process, a clear description of the electronic media, confidentiality protections, and timing of the consent process should all be included in the IRB submission.

Any eIC should be easy to navigate, allowing the user to proceed forward or backward within the system and to stop and continue at a later time. Hyperlinks may be provided where helpful. The eIC may also incorporate electronic strategies to encourage subjects to access all of the consent material before documenting their consent.

a. In Person eIC

Subjects should be given the opportunity to use either paper based or electronic informed consent method, or assistance may be required by the study staff to navigate through the eIC.[1]

Review the informed consent form with the subject in its entirety, including hyperlinks associated with the study.

Allow the subject or the subject's legal authorized representative (LAR) time to read and review the document and ask questions. Encourage input from family members and other care providers, if appropriate. Refer to IRB of record for LAR requirements.

Provide a copy of the signed and dated informed consent form to the subject or LAR and maintain a copy and the hyperlinks within the study file.

Document the informed consent process in the subject's records including, the date and time of informed consent, the ICF was signed after all questions answered, consent was obtained prior to initiation of any study-related activities, and a copy (paper or electronic) of the signed ICF was given to the subject/LAR.

b. Remote eIC

Note: If procedures other than a face-to-face consent interview are proposed, such as by telephone, the IRB must approve the informed consent process.

The consent process may be performed electronically and remotely (e.g. subject is at their home) as long as it:

a. allows adequate exchange of information and documentation
b. a method is in place to ensure that the signer of the consent form is the person who plans to enroll as a subject in the clinical investigation or is the legally authorized representative of the subject.

For example, the information may be provided to the subject or LAR by means of a fax, email or an eConsent application for review prior to the actual consenting process. This will allow the subject time to review and consider whether or not to participate.

The consent review process may be performed by telephone or video media with access to conversation when the subject or subject's legally authorized representative can read the consent form during the discussion. A witness shall be present during the telephone or video media consent process.

Review the informed consent form with the subject in its entirety by discussing all of the elements, such as but not limited to, an overview of the study, explain its purpose, procedures, risks and benefits, drug and comparative agent (if applicable), alternatives, research-related procedures and the right to decline or withdraw.

After the consent discussion, the subject or the subject's legally authorized representative shall sign and date the consent form and if in paper format, return the document to the clinical investigator either by fax, mail, secured email or alternatively, the subject may bring the signed and dated consent form to his/her next visit to the clinical site. If an electronic signature is applied this must meet both the same regulatory 21 CFR 50.25 and institutional requirements as an in person-paper based informed consent and 21 CFR Part 11, if applicable.

The signed document should be filed with the subject's study file and the person signing the consent form must receive a copy of the consent form. Although FDA regulations do not require the subject's copy to be a signed copy, FDA recommends that a copy of the signed consent form be provided.

If a written informed consent is needed, once the informed consent is received by the study team, the investigator/delegated staff shall sign the informed consent in the appropriate area with the current date (date that they received the informed consent).No research activities may occur prior to the receipt of the signed informed consent.

C. Consent – **Special Circumstances** (remotely or with limited contact)

Circumstances (e.g. pandemic) may occur causing an impact on the conduct of clinical trials and the process for obtaining informed consent. Refer to 21CFR Part 50 and any issued specific regulatory guidance (for example FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency) to ensure the safety of trial participants, maintain compliance with good clinical practice (GCP), and minimize the risks to the trial integrity during an unforeseen circumstance. The IRB of Record should be consulted for any specific guidance as needed.

D. Exceptions from general requirements for informed consent

1. Consent of children

Consult with the IRB of record, regarding regulatory, state and local laws for the consent and assent of minors.

If the subject is considered to be a legal minor, consent must be obtained either from one or both parents or legal guardian.

As indicated by age, develop an assent form to be used by children for written consent for their participation in the study that describes the risks and benefits in age-appropriate language.

Follow all procedures for obtaining and documenting the informed consent process outlined above. Provide a copy of the informed consent and/or assent form to the child and parent(s) or legal guardian(s).

2. Waiver of informed consent in emergency situations

Establish that informed consent cannot be obtained from the subject for **all** the following reasons:

a. The subject is in a life-threatening situation requiring the use of the investigational product,
b. Informed consent cannot be obtained from the study subject,
c. There is insufficient time to seek consent from the subject's legal authorized representative,
d. No appropriate alternative therapy is available or recognized as being effective.

Obtain verbal/telephone approval from the IRB to administer the investigational product and maintain the communication record.

Within 5 working days of the emergency use of the investigational product, provide the IRB with documentation from the investigator and the second physician.
Notify the sponsor as soon as possible of the above actions.
Refer to the IRB of record for emergency use for waiver of informed consent in emergency situations.

3. Exception from informed consent for Emergency Research

Establish that a licensed physician not participating in this study, who is an IRB member or a consultant to it, determines that the clinical investigation cannot be conducted with prior informed consent from subjects for all the following reasons:

a. The subjects are in a life-threatening situation, where available treatments are unproven or unsatisfactory, and scientific knowledge gained from the study will be used to determine the efficacy and safety of the investigational product,
b. Informed consent cannot be obtained from the study subjects or legal representatives prior to initiating the experimental treatment,
c. The clinical investigation could not be carried out without waiver of consent.

In addition, the investigator must:
a. Assure that risks to the study subjects are reasonable and subjects may directly benefit from the research study,
b. Document all attempts to obtain consent from the subject as soon as possible, or to contact the subjects' legal representatives to obtain informed consent (pre-approved by the IRB) within the pre-established protocol duration,
c. Ensure that family members have been afforded the opportunity to object to the subject's participation
d. At the earliest feasible opportunity, obtain consent from the subject or legal authorized representative (LAR)
e. Comply with all other mandates for the waiver of consent as required by the IRB of record and federal regulations.

E. Revisions to the Informed Consent Form/Communication of Modification

The written informed consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent.

Any revised written informed consent form, and written information should receive IRB approval prior to use. The subject or the subject's legally acceptable representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial, as directed by the IRB of record. The communication of this information should be documented.

The study team should work with the PI to determine who needs to be reconsented according to internal process and with 21 CFR Part 50.

Follow all procedures for obtaining and documenting re-consent as outlined above for the original consenting process.

References

Use of Electronic Informed Consent, Questions and Answers, FDA Guidance for Institutional Review Boards, Investigators, and Sponsors
International Conference on Harmonisation; Good Clinical Practice Consolidated Guidelines, Section 4.8
Code of Federal Regulations: 21 CFR Part 11
Code of Federal Regulations: 21 CFR Part 50, 56
Code of Federal Regulations: 21 CFR Part 312.60 General Responsibilities of Investigators
Office for Human Research Protections: 45 CFR 46.116 General Requirements for Informed Consent
Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects

History of Revisions to SOP

Effective Date	Nature of Revision
17 May 2021	New SOP