

TITLE: **INFORMED CONSENT**

1.0 OBJECTIVE:

- 1.1 This Standard Operating Procedure (SOP) describes the methods and policies for:
- Informed Consent Document (ICD) generation
 - Review and approval of the ICD
 - Obtaining informed consent
 - Documentation of the informed consent process

This SOP ensures that adequate and legal informed consent has been properly obtained and documented for each study subject participating in a study at MCG, MCGHI and satellite locations affiliated with MCG and/or MCGHI.

- 1.2 This procedure is intended to meet FDA and DHHS regulations, GCP guidelines and MCG and MCGHI regulations regarding informed consent for clinical studies while recognizing that these regulations may override the procedure.

2.0 DEFINITIONS:

- 2.1 Principal Investigator (PI) - an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the subject related activities occur and the drug or device is administered or dispensed to a subject).
- 2.2 Sub-Investigator: The term Sub-Investigator (Sub-I) - may include any other individual member of the research team. [21CFR 312.3] It is generally understood to mean those individuals engaged in the informed consent process.
- 2.2 Institutional Review Board (IRB)- any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research.

Study Coordinator- person representing the investigator and study site that is responsible for the accuracy and management of data and overall organization of the day-to day activities of the study.

- 2.3 Informed Consent Document (ICD)- document between the investigator and the study participant (or an authorized representative) which describes the subject's role in a clinical research study.

- 2.4 Children's Assent Document (CAD)- Document used to obtain informed consent from children between the ages of 7-17. It is written on a much lower reading level than the adult informed consent document.
- 2.5 Source Document- Location where information is first recorded

3.0 RESPONSIBILITIES:

The PI is responsible for:

**The PI may delegate certain responsibilities to another qualified member of the research team. The delegation of responsibility should be clearly documented.*

- 3.1 Preparing the protocol, ICD/CAD, subject recruitment materials, subject instructions, and other study related material for submission to the IRB.
- 3.2 Submitting the ICD/CAD to the IRB for review and approval, and for ensuring that all ICDs/CADs contain the required elements of informed consent.
- 3.3 Ensuring that the IRB approves the study protocol, subject recruitment materials, and the informed consent document.
- 3.4 Retaining a copy of the IRB approval of the protocol, approved ICD/CAD, and approved recruitment materials and subject instructions in the investigator's site files.
- 3.5 The PI and the IRB are responsible for providing a complete and adequate ICD/CAD to the study subject, and for ensuring that it meets all Federal, State, and local requirements.
- 3.6 Investigators (PI and Sub-Is) approved by the IRB to obtain informed consent are responsible for discussing the elements of the ICD/CAD with the study subject, providing a copy of the ICD/CAD to the study subject.
- 3.7 Ensuring that potential study subjects are properly informed regarding study events, risks/benefits, and other information detailed in the elements of informed consent.

3.8 Providing a copy of the ICD/CAD to the study subject for their records.

3.9 Documenting in the source document that informed consent was obtained, by whom, and when.

4.0 PROCEDURES FOR ICD/CAD GENERATION AND APPROVAL

4.1 The site must use the MCG-Office of Human Research Protections ICD/CAD template when developing an ICD/CAD.

4.2 The ICD/CAD must be approved by the IRB before it is used.

4.3 The IRB approval stamp indicating the IRB approval and expiration dates should be indicated on the IRB approved ICD/CAD. This documentation ensures that the approved version is used when obtaining informed consent from study subjects.

5.0 PROCEDURES FOR OBTAINING INFORMED CONSENT

5.1 The Investigator (PI or Sub-I) will discuss the elements of the ICD/CAD with the potential study subject and ensure that the potential study subject understands the content and meaning of the ICD/CAD.

5.2 The discussion of the ICD/CAD should occur in a private location before the initiation of any study-related procedures.

5.3 The Investigator will give the potential subject sufficient time to read the ICD/CAD and ensure that all of the subject's questions have been answered before they sign the ICD/CAD.

5.4 A research subject must be legally and individually competent to give informed consent. For incompetent subjects, a surrogate whose primary interest is the subject's welfare may give informed consent. The guidelines for consent by individuals other than the subject are defined in Code 31-9-2 of the Official Code of Georgia, and in VHA 1200.5, as appropriate to the site of study conduct.

5.5 A witness must be present during the entire informed consent process. A witness is generally defined as an individual who is not affiliated with the protocol and who can attest to the ***informed consent process***. It is recommended that the witness be a family member or friend of the potential subject, not the research coordinator or investigator.

- 5.6 After the potential subject reads and reviews the ICD/CAD the following parties must sign and date the ICD (in blue or black ink) **before** the initiation of any study related activities:
- Study Subject (or legally authorized representative)
 - Parent/Guardian (if subject is a minor)
 - Witness
 - Investigator (approved by the IRB to obtain consent)

- 5.7 The subject must be given a copy of the ICD/CAD. The original signed ICD/CAD should be kept in a secure location in the principal investigator's area. The subject and/or the subject's representative must be given a copy of the ICD (a signed copy is recommended).

- 5.7.1 If the subject is a patient of MCGHI, the procedures listed below must be followed.

- A copy of the ICD/CAD must be placed in the subject's medical record
- The subject and/or the subject's representative must be given a copy of the ICD (a signed copy is recommended)
- One copy of the signed ICD must be sent to the Investigational Pharmacy if drugs are dispensed from the MCGHI Investigational Pharmacy
- The original signed ICD must be kept in a secure location in the principal investigator's area

- 5.8 Subjects must be reconsented when there is a change in the risk to benefit ratio that will increase the risks of participation

6.0 PROCEDURES FOR DOCUMENTATION OF THE INFORMED CONSENT PROCESS

- 6.1 The investigator must make a notation in the patient's medical record or healthy subject's source document that informed consent was obtained prior to participation in the study. [21CFR 312.62(b)].
For VA studies, the original signed VA Form 10-1086 must be placed in the subject's record. The investigator will keep a copy of the signed VA Form 10-1086.

- 6.2 Informed consent is a continual process and should take place at each study visit. The investigator must document (in the subject's medial record or healthy subject's source document) the

subject's consent to continue participation in the research study at each study-related visit.

6.2.1 If a subject is unable to read or write, it must be documented on the informed consent document and should be noted in the medical record or visit note.

6.3 The investigator must inform the subject of any new significant findings that develop during the course of the study, which may relate to their continued willingness to participate. This may require a revision to the ICD and may also require re-consenting previously enrolled subjects.

6.4 Signed ICDs must be retained by the investigator for at least three years past completion of the research activity or at least three years after termination of the last IRB approved period for research activity, whichever is later.

6.4.1 The PI should consult with the sponsor/funding agency to determine their record retention requirements, which may be longer than the requirements stated in Section 6.3

7.0 PROCEDURES FOR EXCEPTIONS TO THE REQUIREMENT OF OBTAINING INFORMED CONSENT

7.1 IRB Waiver of the Need for Informed Consent

7.1.1 The IRB may waive the requirement that the study subject sign the ICD/CAD if the study protocol meets the following specific criteria found in 45 CFR § 46.116(d): The research involves no more than minimal risk to the subjects if;

- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate (generally, when there is a health justification), the subjects will be provided with additional pertinent information after participation.

7.2 Oral Informed Consent

- 7.2.1 The IRB may approve research in which informed consent is obtained orally from subjects under limited circumstances.
 - 7.2.2 A script must be prepared and approved by the IRB before it can be used. Ideally, some written study information is provided to the subject during his/her participation in the research.
 - 7.2.3 Oral consent and/or authorization should be documented by the Investigator. If obtaining oral consent/authorization, researchers should ask subjects if they wish to receive a copy of the Privacy Notice and provide the Notice if requested.
 - 7.2.4 The researcher must assure, in writing, that the subject's protected health information (PHI) will not be reused or wrongly disclosed by the researcher. Practically, this item may be satisfied by the Investigator stating that the information will only be used as described in the approved protocol, or in an amendment approved in writing by the IRB.
 - 7.2.5 The IRB must also receive a "brief description" of the information to which access is requested. A proper and clearly written protocol should fulfill this requirement.
- 7.3 Remote Consent
- 7.3.1 IRB approval for obtaining informed consent from a remote site is considered on a case- by-case basis.
 - 7.3.2 A protocol utilizing remote consent must obtain prior written IRB approval.
 - 7.3.3 The IRB approved ICD should be sent to the site via facsimile (fax).
 - 7.3.4 The subject must have possession of the IRB approved ICD before the informed consent process is initiated. If duplicating facilities are not available, send multiple documents to ensure that the subject retains a copy.
 - 7.3.5 The subject and/or subject's representative should read and receive explanation of the ICD and the study over the

telephone line. *Note: Informed consent cannot occur over a cell phone while the potential subject and/or the parent/guardian/legal representative is driving.

- 7.3.6 The subject should discuss the ICD over the telephone with the investigator authorized to obtain consent via telephone, with an identified witness present with the subject during the telephone discussion.
- 7.3.7 Subject and witness must sign the ICD at the time informed consent is obtained.
- 7.3.8 The subject must be given a copy of the ICD.
- 7.3.9 The signed ICD should be sent to the PI via facsimile.
- 7.4.0 The original of the faxed ICD must be remitted by mail to the PI.
- 7.4.1 Upon receipt, the person obtaining consent must sign both copies.
- 7.4.2 A copy of the ICD, signed by the investigator authorized to obtain consent, is sent to the subject with a self-addressed, stamped receipt acknowledgement card for the subject to return to the PI.
- 7.4.3 The study may proceed once the PI receives the (faxed, when applicable) consent.

APPENDIX I

Basic Elements of Informed Consent (45 CFR 46.116)

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise

entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional Elements of Informed Consent

- (b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
 - (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
 - (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - (3) Any additional costs to the subject that may result from participation in the research;
 - (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
 - (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
 - (6) The approximate number of subjects involved in the study.