LOUIS STOKES CLEVELAND DVA MEDICAL CENTER
Medical Research Service
Standard Operating Policy and Procedure (SOP)

Effective Date: July 9, 2015

SOP Title: Documentation in the Patient's Health Record-of Research Enrollment Contact, Actual Enrollment, and End of Study Participation

SOP Number: Human Researchers - HSP-003

SOP Version: .04

1. PURPOSE. This policy will outline requirements for research study documentation in the VHA medical health record.

2. POLICY

a. A VHA health record must be created or updated for all research subjects:

(1) Who are admitted as in-patients, treated as outpatients, or when research procedures or interventions are used in the medical care of the research subject.

(2) When the research requires the use of any clinical resources, such as radiology, cardiology (e.g., EKG, stress test), clinical laboratory, and pharmacy.

(3) When the research intervention may lead to physical or psychological adverse events.

b. If documentation in the VHA health record is required as noted in a. above, a progress note documenting the informed consent process must be placed in the health record

c. Additionally, the following information must be a part of the subject's VHA health record:

(1) A copy of the signed and dated VA Form 10-1086, VA Research Consent Form.

(2) A copy of the HIPAA authorization for data use or disclosure.

(3) The initial enrollment progress note and other applicable progress notes.

(4) Information on possible drug interactions and/or toxicity of the pharmaceutical agents that are being administered to the patient-research subject because of the research (i.e., investigational drugs as defined in VHA Handbook 1200.05).

(5) VA Form 10-9012, Investigational Drug Information Record, or superseding forms for investigational drugs as required VHA policy.

(6) A copy of any research results that are used for medical care.

(7) Information on all research and experimental interventions including potential risks, indications, and applicable progress notes.

d. There are three types of progress notes for documenting a participation in the VHA health record. The three types are as follows:

(1) a progress note documenting the informed consent process,

(2) a progress note documenting when a human subject is actually entered

into the study, and

(3) a progress note when a human subject's participation is completed.

The first two progress notes can be combined if consent occurs at the same visit as when the subject is entered into the study.

3. DEFINITIONS.

a. **Case History.** A case history is a record of all observations and other data pertinent to the investigation on each research subject. An investigator is required to prepare and maintain adequate and accurate case histories. Case histories include the case report forms and supporting data including signed and dated consent forms, any medical records including, but not limited to: progress notes of the physician, the individual's hospital chart(s), and nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.

b. **Health Record.** A health record includes the electronic medical record and the paper record, combined, and is also known as the legal health record.

4. RESPONSIBILITIES

a. The Principal Investigator (PI) must ensure that documentation of the informed consent process, entry into the study, and termination of participation in the study is entered into the participant's health record in the Computerized Patient Record System (CPRS) if documentation in the health record is required by VA policy (see above).

b. The Institutional Review Board (IRB) may stipulate that a progress note in the medical record is required where it is not required by VHA policy.

c. The PI must use his/her judgment regarding entering a progress note in the medical record when it is not required by policy or IRB stipulation.

5. PROCEDURE

a. If the IRB has determined that the study requires special 'flagging' of the medical record, follow the medical research policy, HSP-005 "Flagging of Medical Research Subjects."

b. In CPRS there are two research note templates entitled, **"Research Informed Consent Note" and Research progress note. These templates may be used** when:

(1) A patient is contacted to participate in a research study but declines to participate.

(2) A patient is consented to participate in a research study.

(3) A patient is actually entered into a research study.

(4) A patient's participation in a study has ended.

When enrollment and consent occur at the same time, one note can be entered.

c. If a research study coordinator chooses to enter their own informed consent note, or chooses to develop their own CPRS template when documenting the informed consent process they must include the following in the note or template:

(1) The name of the study.

(2) The person obtaining the subject's informed consent.

(3) The date the subject signed the informed consent

(4) A statement that the subject or the subject's legally-authorized representative (LAR) was capable of understanding the informed consent process.

(5) A statement that the study was explained to the subject or the subject's LAR.

(6) A statement that all risks, benefits and alternatives were explained to the subject or the subject's LAR.

(7) A statement that the subject or the subject's LAR was given the opportunity to ask questions.

(8) A statement that the subject met the inclusion and exclusion criteria.

(9) A statement that the subject or the subject's LAR consented before participation in the study began.

(10) A statement that a copy of the signed and dated Consent Form and HIPAA was given to the subject or subject's LAR.

d. For assistance with CPRS, or to request a CPRS template contact the Research Clinical Coordinator in the research office, at (216) 791-3800, ext 4660.

6. REFERENCE: VHA Handbook 1200.05 Requirements for the Protection of Human Subjects Research, VHA Handbook 1907.01 Health Information Management and Health Records," Human Research Protection Program Standard Operating Procedures,

7. RESCISSION: Medical Research Service Standard Operating Procedure HSP-003.00 dated August 1, 2007 was rescinded. Review date for this policy is July 8, 2018.

8. FOLLOW UP RESPONSIBILITY: Research Service, Research Clinical Coordinator