Documentation in CPRS

SOP HSP-003

VA Northeast Ohio Healthcare System
Cleveland, Ohio 44106

Service Line(s):
Research Service

Signatory Authority:
Neal Peachey, Ph.D. ACOS/Research

Effective Date:
July 13, 2023

Responsible Owner:
Holly Henry, Administrative Officer

Recertification Date:
July 12, 2028

1. PURPOSE AND AUTHORITY

a. This policy will outline requirements for research study documentation in CPRS, the VHA electronic medical record.

b. A CPRS record must be created or updated for all research subjects (Veterans or non-Veterans) who receive research procedures or interventions as inpatients or outpatients at VA medical facilities that are either used in or may impact the medical care of the research subject. NOTE: Any study that is reviewed by the IRB as 'greater than minimal risk' will meet this standard. If the greater than minimal risk study involves a minimal risk cohort, the participants enrolled in the minimal risk cohort, may not need documentation in the CPRS.

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

d. Additionally, the following information must be included in CPRS:

1. A copy of the signed and dated, VA Research Consent Form.

2. A copy of the HIPAA authorization 10-0493 if required.

3. The initial enrollment progress notes and other research progress notes of relevance to the patient's medical care or safety, as determined by the clinician PI or Co-I.

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

5. A copy of any research results that are used for medical care, as determined by the clinician PI or Co-I.

6. Information on all research and experimental interventions relevant to patient's medical care, as determined by the clinician PI or Co-I, including potential risks, indications, and applicable progress notes.

e. There are three types of progress notes for documenting participation in CPRS. 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 entered into the study, and

3. a progress note when a human subject's participation is completed or otherwise terminated.

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

2. PROCEDURES

a. If the IRB has determined that the study requires special flagging of the CPRS 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 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) can understand 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 subjects 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. 64660

3. ASSIGNMENT OF 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 Computerized Patient Record System (CPRS) if documentation in the CPRS is required by VA policy (see above).

b. The Institutional Review Board (IRB) may stipulate that a progress note in CPRS 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 CPRS when it is not required by policy or IRB stipulation.

4. 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 everyone 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.

a. Collaborative Research. Collaborative Research is research collaboration involving investigators from VA and other institutions, with VA investigators having a substantive role in the design, conduct, and/or analysis of the research.

5. REFERENCE

VHA Directive 1907.01 VHA Directive 1907.01 Health Information Management and Health Records

VHA Directive 1200.05 VHA Directive 1200.05 Requirements for the Protection of Human Subjects Research,

6. REVIEW

At recertification or when there are changes to the governing documents.

7. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of July 13, 2028. In the event of contradiction with national policy, the national policy supersedes and controls.

8.SIGNATORY AUTHORITY

Neal Peachey 411157

Digitally signed by Neal Peachey 411157
Date: 2023.08.03 16:06:51 -04'00'

Neal Peachey
Associate Chief of Staff/ Research
Date Approved:

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

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