

May 19, 2008

**DOCUMENTATION OF RESEARCH STUDY PROCEDURES
IN THE PATIENT'S HEALTH RECORD**

1. PURPOSE: To provide specific directions and procedures for the documentation of human research activities conducted at the South Texas Veterans Health Care system (STVHCS) in a patient's health record when a participant (research subject) is participating in a human research study.

2. POLICY:

a. A patient's health record includes the electronic medical record [Computerized Patient Record System (CPRS)] and any hard copy documentation located in Medical Records, combined, and is also known as the legal health record. Research files maintained by the Principal Investigator and/or research staff are not part of the legal health record.

b. A research subjects' health record must include documentation of informed consent, updated informed consents and addendums in a research study, research procedures or interventions that may impact a patient's clinical care, and disenrollment or study termination.

c. A research subject's health record must include information on investigational drugs used in the study.

3. ACTION:

a. The informed consent process must be documented by the use of an IRB-approved written consent form on VA Form 10-1086. It must be signed by (a) the participant or the participant's legally authorized representative, (b) a witness, and (c) the person obtaining the informed consent, unless an IRB waiver is approved. The consent form must be stamped with the date of the most recent IRB approval of the form. A copy of the signed research informed consent must be placed in the participant's health record. Investigators are to keep the original signed copy of the participant's research informed consent form in the participant's research record.

b. A "Research Consent/Enrollment Note" must be entered into CPRS after informed consent has been obtained. The following minimum information must be included in the note:

(1) Name of the study

(2) Name of the principal investigator

(3) IRB Protocol number

(4) Name of the person obtaining the participant's consent

(5) A statement that the participant, or the participant's legally-authorized representative, was capable of understanding the consent process

(6) A statement that the study was explained to the participant

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(7) A statement that the participant was given the opportunity to ask questions

(8) A statement that the participant was given a copy of the consent form

(9) A statement to indicate if the study involves the use of any investigational drugs

(10) Contact information for a member of the research team that is available at all times and from whom additional information concerning the study can be obtained

c. An approved member of the research team with approved CPRS access will document informed consent and enrollment in a research study in the patient's health record by completing the note template titled "Research Consent/Enrollment Note".

d. A copy of the signed and dated VA consent form (VA Form 10-1086), or a copy of the authorization for data use or disclosure if separate from the research informed consent, must be submitted to the Medical Records Office for scanning and electronic attachment to the "Research Consent/Enrollment Note".

e. A copy of the completed and signed Investigational Drug Information Record(s) (VA Form 10-9012) must be submitted to the Medical Records office for scanning and electronic attachment to the "Research Consent/Enrollment Note" if the study involves investigational drugs.

f. A "Research Consent Update Note" must be entered into CPRS after informed consent is obtained for any changes resulting in an informed consent addendum or an updated informed consent. The following minimum information must be included in the note:

(1) Name of the study

(2) Name of the principal investigator

(3) IRB Protocol number

(4) Name of the person obtaining the participant's consent

(5) A statement that the participant, or the participant's legally-authorized representative, was capable of understanding the consent process

(6) A statement that the study was explained to the participant

(7) A statement that the participant was given the opportunity to ask questions

(8) A statement that the participant was given a copy of the consent form

(9) Contact information for a member of the research team that is available at all times and from whom additional information concerning the study can be obtained

g. An approved member of the research team with approved CPRS access will document informed consent updates and addendums in a research study in the patient's health record by completing the note template titled "Research Consent/Update Note".

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h. A copy of the signed and dated updated VA consent form (VA Form 10-1086), or a copy of the signed and dated VA consent form addendum, must be submitted to the Medical Records Office for scanning and electronic attachment to the “Research Consent/Update Note”

i.. A “Research Progress Note” must be entered into CPRS to provide the following relevant information to providers participating in the care of that patient:

(1) Any research procedures or interventions that may impact a patient’s clinical care, including the indications and potential risks of physical or psychological adverse events.

(2) Any results, including laboratory studies, from the research study that are relevant to the medical care of the research subject.

(3) Any information regarding possible drug interactions and/or toxicity of the pharmaceutical agents administered as part of the research protocol.

j. A research progress note should be entered by the member of the research team who performed the procedure or intervention. Only a “Research progress Note” should be used to enter this information in CPRS.

k. Study procedure documentation should not be entered CPRS when it does not affect the medical care of the participant. Examples of study documents that should not be entered into the patient’s health record include case report forms, surveys, and questionnaires.

l. A “Research Disenrollment/Termination Note” must be entered into CPRS when the patient’s involvement in the study is discontinued or the study is terminated.

m. An approved member of the research team with approved CPRS access will document disenrollment or termination in a research study in CPRS by completing the note template titled “Research Disenrollment/Termination Note”.

n. It is the R&D Committee and the STVHCS Directors requirement that all medical records are flagged when a patient is enrolled and/or terminated from a research study. If the UTHSCSA IRB determines that flagging the medical record and scanning the informed consent document would increase the subject’s risk or compromise the study results, flagging the record and documentation in the subject’s health record may be waived.

o. Accountability:

(1) The STVHCS Research Office is responsible for:

(a) Informing the Principal Investigator of his/her responsibilities prior to the start of a study involving human subjects, and

(b) Providing updates, reminders, and ongoing education as needed to ensure that the Principal Investigators are fully informed of the policies and procedures related to documentation of research study procedures in the patient’s health record.

(2) The Principal Investigator is responsible to ensure that:

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(a) Informed consent and enrollment in a research study are documented in the patient's health record through a "Research Consent/Enrollment Note".

(b) Informed consent updates and addendums are documented in the patient's health record through a "Research Consent/Update Note".

(c) Research procedures, treatments, or interventions that may impact a patient's clinical care are documented appropriately in the patient's health record through a "Research Progress Note".

(d) A fully signed copy of the IRB-approved written consent form (VA Form 10-1086) and all updates and addendums are submitted to the Medical Records Office for scanning and placement in the patient's health record,

(e) A fully signed copy of the Drug Information Record(s) (VA Form 10-9012) is submitted to the Medical Records Office for scanning and placement in the patient's health record,

(f) Disenrollment of a patient in a research study or termination from a study are documented in the patient's health record through a "Research Disenrollment/ Termination Note"

(3) The Research Compliance Officer or designee is responsible for determining adherence to the policy and procedures related to documentation of research study procedures in the patient's health record through routine audits of research studies.

4. REFERENCES: VHA Handbook 1605.1: Privacy and Release of Information; VHA handbook 1907.01: Health Information Management and Health Records; VHA handbook 1200.5

5. RESPONSIBILITY: Associate Chief of Staff for Research (151)

6. RESCISSION: Policy Memorandum 151-07-08 dated September 8, 2007

7. RECERTIFICATION: May 2011

//signed//
RICHARD J. BALTZ, FACHE
Director

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