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

Effective Date: September 7, 2017

SOP Title: Submission of Informed Consent Documents and other Signed Authorizations

SOP Number: Human Research – HSP-020

SOP Version: .03

1. Purpose. To establish policy for the submission of authorizations of research documents to the Research Compliance Office and Medical Records.

2. Policy. If the research study meets the requirements for documentation in the VHA health record (SOP HSP- 003 Documentation in the Patient's Health Record-of Research Enrollment Contact, Actual Enrollment, and End of Study Participation), VHA regulation requires the following documents be a part of the research subject's electronic VHA health record:

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

(b) A copy of the signed and dated HIPAA authorization

(c) A copy of the signed and dated VA Form10-9012, Investigational Drug Information Record,

(d) A copy of any authorizations (such as release of information, DPOA and Picture/Voice 10-3203),

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

Research staff will work with Patient Care Administrative Service (PCAS) staff to ensure these documents are scanned into the research subject's electronic VHA health record.

3. Definition.

4. Responsibility.

a. Principal Investigator (PI) or designee will ensure research documents required to be scanned into the research subject's electronic VHA health record are forwarded to the Research Compliance Office.

b. Patient Care Administrative Services (PCAS) staff will ensure the research documents are picked up from the Research Compliance Office, scanned into the

research subject's electronic VHA health record and associated with the appropriate research note.

5. Procedure.

a. If the IRB has determined that a written informed consent, HIPAA authorization, VA form 10-3203 and/or VA form 10-9012 is required a copy of the signed and dated document must be submitted to the Research Compliance Office within five business days of obtaining the signature(s). This also includes re-consents, assents and surrogate consents.

b. The above documents may be personally submitted and/or placed in the secured Research Compliance Office mailbox outside the Research Compliance Office.

c. After obtaining documentation of informed consent, the PI or designee will create a consent note in the research subject's electronic VHA health record. (SOP HSP- 003 Documentation in the Patient's Health Record-of Research Enrollment Contact, Actual Enrollment, and End of Study Participation).

d. In order to assure the documents are appropriately linked with the consent note, all authorizations must be accompanied by a cover sheet with the PI or Study Coordinator's name and contact information. The cover sheet must include the research participant's name, research participant (s) last 4 of social security number, research participant(s) research ID number and date of consent and reconsent if applicable.

e. The cover sheet must be an accumulative list of research participants.

f. The PI or designee will maintain the original documents for their files.

g. PCAS Record Room staff will pick up the research documents from the research Compliance Office. PCAS staff will scan research documents into patient medical record and link the authorizations to the Research Study Note.

h. Other documents such as research result that are used for medical care, release of information, note(s) to file, DPOA and other authorizations may be scanned using the same process.

6. Reference. HSP 003 Documentation in the Patient's Health Record of Research Enrollment Contact, Actual Enrollment and End of Study Participation; SOP HSP 005 Flagging Medical Charts of Patients Involved in Medical Research Studies.

7. Rescission. Review date for this policy is August 17, 2020

8. Follow up Responsibility. Research Clinical Coordinator