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

Effective Date: April 7, 2022

SOP Title: Flagging Medical Charts of Patients Involved in Medical Research Studies

SOP Number: 005

SOP Version: .06

1. PURPOSE: To establish policy for the flagging of medical charts of patients involved in medical research studies.

2. POLICY: The Institutional Review Board (IRB) will determine if the subject's medical record in the Computerized Patient Record System (CPRS) must be flagged to protect the subject's safety by indicating the subject's participation in the study and the source of more information on study. In making this determination, the IRB may consider type of research, number of interventions, use of previously collected biological specimens, and/or risks involved with the research.

3. DEFINITIONS: None

4. RESPONSIBILITIES

a. The **IRB** will be responsible for ensuring that studies are reviewed for flagging determination and notifying the Principal Investigator (PI) and the Research Clinical Coordinator.

b. The PI will be responsible for ensuring medical charts of patients enrolled in the research study are flagged appropriately.

c. The Research Clinical Coordinator will be responsible for training users.

d. The Study Coordinator will be responsible for setting up the patient record flags and obtaining the appropriate VISTA menus.

5. PROCEDURE:

a. The IRB will inform PI in writing of the requirement to flag patients enrolled in VA approved research study.
b. The PI or designee will complete the PATIENT FLAG CREATION REQUEST FORM (Attachment A) and submit it to the PCAS designee, Larry Foote.

This form can be obtained from Larry.Foote2@va.gov .

c. Upon receipt of the Research Flag Request Larry Foote (or PCAS designee) will:

(1) Set up Research Flag and associated mail group.
(2) Request Flag Menu be added to designees VISTA profile.

d. Actual Flagging of medical chart is as follows:

(1) In word or some word-processing program type the following information:

(a) This patient is enrolled in a RESEARCH STUDY
(b) This is an INVESTIGATIONAL DRUG STUDY if applicable
(c) This is an INVESTIGATIONAL DEVICE STUDY if applicable
(d) NAME OF RESEARCH STUDY
(e) Principal Investigator: *type principal investigator's name*
(f) Contact: *type contact's name and extension if there are questions.*
(g) See progress note RECORD FLAG CATEGORY RESEARCH STUDY for study information
(h) Enrollment date

(2) In Vista choose the menu: RECORD FLAG ASSIGNMENT

(3) At the prompt "Select action:Quit//" enter " SP select patient

(4) At the prompt "Select PATIENT NAME:" enter patient name or number

(5) At the prompt "Select action:Quit//" enter " AF assign flag

(6) At the prompt "Select a flag for this assignment:" *enter the first few letters of the flag name*

(7) At the prompt "Approved by:" *enter the first few letters of the principal investigator's name*

(8) At the prompt "enter Narrative Text for this record flag" copy and paste the text you set up in (1) above.

(9) To move past the narrative section, on your computer keyboard strike the NUM LOCK key then the 'E' key.

(10) At the prompt: "Would you like to file this new record flag assignment? YES//" enter YES, You will see: Filing patient's new record flag assignment ... **Assignment was filed successfully**.

e. When a patient participant is flagged a corresponding progress note must be entered in CPRS.

(1) The note is listed as: RECORD<***PATIENT RECORD FLAG CATEGORY II - FLAG NAME***>. **Your flag name WILL appear in the note. (You can have this note made into a template – contact the Research Program Assistant, x 4660).**

(2) The progress note can be used as the enrollment note and documentation of informed consent note. ***To meet the criteria for an enrollment note, it must include information noted in HSP-003, Documentation in the Patient's Health Record-of Research Enrollment Contact, Actual Enrollment, and End of Study Participation***

f. Flag assignments must be reviewed at certain intervals. This interval is determined when the flag is set up.

(1) At the determined interval the associated mail group will be prompted via an email message in VISTA to review the flag assignment.

(2) If the patient is still active in the study, you will need to complete a Progress Note in CPRS.

(3) Use the RECORD FLAG CATEGORY II RESEARCH STUDY note.

(4) In the note document that the patient is still enrolled in the research study and the flag is still appropriate.

(5) This must be done each time you receive a notice requiring the flag to be reviewed.

g. When the subject's participation in the study has been completed the Flag must be removed

(1) In Vista choose the menu: 'RECORD FLAG ASSIGNMENT'

(2) At the prompt "Select/action:Quit// enter “SP” select patient

(3) At the prompt "Select PATIENT NAME:" enter patient name or number

(4) At the prompt "Select/action:Quit//” enter "EF" edit flag

(5) At the prompt "Select one of the following" Choose 'I' Inactivate Flag Assignment

(6) At the prompt "Approved by" Enter the PI

(7) Enter the reason for removing the flag. This should include something like:

(a) This patient was enrolled in the VA approved research study,<insert study title>.

(b) The patient's participation has ended because:

(i)The Study has ended

(ii) has withdrawn from the study.

(iii) The Physician has withdrawn the patient from the study.

(8) After the flag a corresponding note documenting end of enrollment must be entered in CPRS. (See HSP-003 Documentation in patient's medical record of Enrollment Contact, Actual Enrollment and End of Study Participation.)

6. REFERENCE: Patient Record Flags (PRF) User Guide March 2019 PRF document (va.gov)

7. RESCISSION: The review date for this SOP is April 6, 2025.

8. FOLLOW UP RESPONSIBILITY: Administrative Officer/Research