Flagging Medical Charts of Patients Involved in Medical Research Studies

SOP HSP-005

VA Northeast Ohio Healthcare System
Cleveland, Ohio 44106

Service Line(s):
Research Service

Signatory Authority:
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Effective Date:
January 4, 2024

Responsible Owner:
Holly Henry, Administrative Officer

Recertification Date:
January 3, 2029

1. PURPOSE AND AUTHORITY

a. To establish policy for the flagging of medical charts of patients involved in medical research studies.

b. All non-exempt Human Subjects Research protocols will be reviewed to determine if the subject's medical record in the Computerized Patient Record System (CPRS) must be flagged to protect the subject's safety or quality of care by indicating the subjects' participation in the study and the source of more information on the study.

(1) The Veterans Affairs Northeast Ohio Healthcare System (VANEOHS) Institutional Review Board (IRB) will review all studies submitted for local review and approval.

(2) The VANEOHS Research and Development Committee (R&DC) will review all studies submitted to the Veterans Affairs Central Institutional Review Board (hereafter VA CIRB) or approved External IRB's. **NOTE: If VA CIRB has decided that flagging is required, R&DC will accept that determination.**

(3) Medical Records cannot be flagged unless required by the IRB or R&DC.

2. PROCEDURES

a. The IRB/R&DC will inform PI, via the study approval memo, of the requirement to flag patients enrolled in the approved research study.

b. The PI or designee will complete the PATIENT FLAG CREATION REQUEST FORM (Attachment A) and submit it via email to the PCAS designee, Kristian Wilson.

This form can be obtained from the Cleveland VA Research website https://www.clevelandvaresearch.org/research-sops

c. Upon receipt of the Research Flag Request, Kristian Wilson (Kristian.Wilson@va.gov) 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 Microsoft 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

(i) Important factors of the study with potential impact on the care of the subject

(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/research participant record 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***>.

The flag name WILL appear in the note. (The Study team can have this note made into a template – contact the Research Program Assistant, x 64660).

(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 CPRS.***

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) The participant has withdrawn from the study.

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

After completing the flag, a corresponding note documenting end of enrollment must be entered in CPRS. (See HSP-003 Documentation in CPRS.)

3. ASSIGNMENT OF RESPONSIBILITIES

a. The **IRB or R&DC will be responsible** for:

(1) Ensuring that studies are reviewed for flagging determination.

(a) Study specific factors considered during the review include, but are not limited to, the type of research, number of interventions, use of previously collected biological specimens, and/or risks involved with the research.

(b) Studies that may be appropriate for flagging are those that are invasive, including studies requiring surgery and/or utilizing investigational drugs or significant risk investigational devices as well as other interventions or clinical services used in the medical care of the subject or that could interfere with the subject's other medical care.

(c) The IRB/R&DC may choose not to require the medical record to be flagged or may consider lifting the flagging requirement for reasons including, but not limited to:

(1) The subject's participation in the study involves only one encounter, the use of a questionnaire, or the use of previously collected biological specimens.

(2) The identification of the patient as a subject in a particular study is not in the best interest of the subject (e.g., HIV status, study of victims of sexual assault).

(2) Notifying the Principal Investigator (PI) and the Study Coordinator in writing of the flagging determination, including the specific phase(s) of the study requiring flagging. The IRB/R&DC may require the flag to be maintained beyond the end of the subjects' involvement in the study (e.g., the subject has an implantable device that is not removed at the completion of the study). The determination of the specific phase(s) will be provided in the study approval letter. If the IRB/R&DC requires that records remain flagged beyond the standard duration stated in 3.d.(2) of this policy, this will be specified in the approval letter.

(3) The IRB or R&DC may review the flagging determination at post-approval actions, such as continuing review or modification, to determine if any changes should be made to the flagging requirement. The PI will be notified via the approval letter for the post-approval action of the current IRB or R&DC requirements for medical record flagging.

(4) The IRB Co-Chairperson or R&DC Chairperson, or designee, will be responsible for reviewing and approving requests for exceptions to any requirement in this SOP.

b. The **PI will be responsible** for

(1) Ensuring medical records of patients enrolled in the research study are flagged for the required phases of the study as directed by the IRB/R&DC in the approval memo.

(2) Ensuring the medical record flags are removed at the end of the subject's participation in the study (e.g., completion of the study procedures, subject voluntary withdrawal, or if subject removed from study by PI). If the PI feels the record should remain flagged at the end of the subjects' participation for the subjects' safety, when not initially required by the IRB/R&DC, a written request for exemption should be submitted to the IRB/R&DC with justification for continued flagging of the medical record. Flags may remain in place until the IRB/R&DC has reviewed the request and made a determination.

(3) Notifying the Patient Record Flag coordinator of any changes in research team members who manage the flagging.

c. The Study Coordinator will be responsible for

(1) Setting up the patient record flags

(2) Obtaining the appropriate VISTA menus

(a) Record Flag Assignment [DGPF RECORD FLAG ASSIGNMENT]

(b) Record Flag Reports Menu [DGPF RECORD FLAG REPORTS MENU]

(3) Maintaining an active VISTA account to receive alerts when the flags are due for review.

(4) Removing medical record flags at the completion of the subject's participation in the study.

4. DEFINITIONS

None

5. REFERENCES

Patient Record Flags (PRF) User Guide March 2019
https://www.va.gov/vdl/documents/Clinical/Patient_Record_Flags/patient_record_flags_user_guide.pdf

HSP-003 Documentation in CPRS https://www.clevelandvaresearch.org/research-sops

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 January 3, 2029. 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: 2024.01.22 15:46:24 -05'00'

Neal Peachey, Ph.D.
Associate Chief of Staff/ Research
Date Approved:

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

DISTRIBUTION: This will be posted on the Research Service website: https://www.clevelandvaresearch.org/