



**Department of Veterans Affairs  
Jesse Brown VA Medical Center  
820 S. Damen Avenue  
Chicago, IL. 60612**

R&D 537/151  
April 6, 2011  
Version 1.3

**SOP: Flagging Medical Records  
At the Jesse Brown VA Medical  
Center**

Please refer to IRB SOP Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (UIC IRB #4), Version 2.0, Dated 2/16/2011.

**PURPOSE**

To describe the policy and procedures for the flagging of research subjects' medical records to indicate participation in a research study at the JBVAMC.

**POLICY**

VA regulations require that the records of all VA research subjects enrolled in research at Jesse Brown VA Medical Center have a flag placed on the medical record (electronic) unless the requirement is waived by the Collaborative JBVAMC / NU/UIC IRB (UICIRB # 4). This determination is made on a protocol specific basis, taking into consideration the relative risks to the subjects of flagging the records.

**RESPONSIBILITIES**

- A. On February 1, 2009, the JBVAMC delegated to the UIC Collaborative IRB (IRB #4) the responsibility for determining which, and under what circumstances, JBVAMC patient medical records will be flagged in order to protect the research subject's safety in accordance with VA Handbook 1200.05, Paragraph 44. For JBVAMC patient medical records that have been flagged, JBVAMC will have the responsibility of ensuring compliance with VHA Handbook 1907.01, Paragraph 6.t.(10) and other applicable sections.
- B. The Principal Investigator, or designated research team member, must enter the term "Clinical Warning/Research Protocol" to document research related issues (not general medical care), into the record of each enrolled subject in the Computerized Patient Record System (CPRS).
- C. The Principal Investigator must provide a list of newly enrolled research subjects to the R&D Office every six months from the date of initial R&D approval of the research.

D. The R&D Office Program Support Assistant conducts bi-annual audits of the CPRS and telephone surveys of research subjects. The results of these audits are reported to the Research and Development Committee.

## **PROCEDURES**

### **Step 1: Collaborative JBVAMC/NU/UIC IRB (UIC IRB # 4) Determination of CPRS (flagging research subjects in electronic patient medical record)**

As of February 1, 2009, the Collaborative IRB at the time of initial review, as well as for amendments adding the JBVAMC as a performance site, determines if subjects' medical records must be flagged for expedited and convened protocols of all risk levels to meet the requirements of VA Handbook 1200.05 Paragraph 44 and VHA Handbook 1907.01, Paragraph 6.t (10 a, b).

The patient health record **MUST** be flagged if the subject's participation in the study involves:

- Any invasive research procedure (e.g., muscle biopsy or bronchoscopy);
- Interventions that will be used in the medical care of the subject, or that could interfere with other care the subject is receiving or may receive (e.g., administration of medication, treatment, or use of an investigational device);
- Clinical services that will be used in the medical care of the subject (e.g., orders for laboratory tests or x-rays ordered as part of the study), or that could interfere with other care the subject is receiving or may receive; or
- The use of a survey or questionnaire that may provoke undue stress or anxiety unless the IRB determines that mandatory flagging is not in the best interests of the subject (e.g., an interview study of victims of sexual assault);
- In other situations, the IRB determines if flagging is necessary.

If the IRB determines and documents that the patient health record must be electronically flagged in CPRS as participating in a research study, then in accordance with VHA Handbook 1907.01, the health record must:

- Identify the investigator, as well as contact information for a member of the research team that would be available at all times.
- Contain information on the research study of identify where this information is available.

. The investigator is notified of the determination for flagging with the IRB determination letter.

### **Step 2: JBVAMC R&D Committee is responsible for Compliance of this Policy**

When the Collaborative IRB has made a determination that a medical record must be flagged, JBVAMC will have the responsibility of ensuring compliance with VA Handbook 1200.05 Appendix C 3.c and VHA Handbook 1907.01, Paragraph 6.t.(10) with respect to such medical records by the JBVAMC research investigator and their research team. When notified of an IRB determination to flag the medical record, the

research investigator must include a clinical warning in the electronic patient medical record in the Computerized Patient Record System (CPRS) Graphical User of Interface (GUI) system to document research-related issues for veterans participating in research studies. The following research titles are to be used by Principal Investigators/ Research Coordinators or Research Assistants when entering data into CPRS GUI:

- Informed Consent / Research
- Clinical warning / Research protocol
- Research Progress note
- Research Protocol Completed

### **Step 3: Investigators found to be non-compliant with this policy**

Investigators failing to comply with the collaborative IRBs requirements for flagging will be considered in noncompliance with IRB and VA polices and subject to appropriate corrective action and reporting.

### **Step 4: CPRS Training at JBVAMC**

If you have any questions about progress note documentation or training on how to use CPRS, please page the CPRS Clinical Coordinators at 312-389-3644.

### **Step 5: Timeline for CPRS entry in electronic patient medical record**

The Principal Investigator, or designated member of the research team, must enter the protocol information into CPRS no later than three (3) business days after the subject has signed the informed consent documents.

If the research study protocol is flagged, the Principal Investigator must report the following information to the R&D office twice a year on June 1 and December 1.

- Full name of the research subject(s) including middle initial
- Last four digits of the SS#
- Subject signed consent form
- Home telephone number(s) of the research subject for telephone audit
- The total number of research subjects enrolled as of the requested date.
- Subject signed HIPAA document.

### **REFERENCES:**

VHA Handbook 1200.05, Appendix C 3.c: Requirement for the Protection of Human Subjects in Research, Department of Veterans Affairs, Veterans Health Administration, Washington, DC.

VHA Handbook 1907.01, Paragraph 6.t. (10)

Operating and Coordinating Procedures for the Administration of the Collaborative  
JBVAMC/NU/UIC IRB (UIC IRB #4), Version 1.3, Dated 4/10/09

**REVISION LOG:**

SOP: Flagging Medical Records at the Jesse Brown VA Medical Center

<b>Version (#, date)</b>	<b>Replaces (#, date)</b>	<b>Summary of changes</b>
1.3; April 6, 2011	1.2; March 23, 2010	

**Appendix A**

# **Progress Note Titles**

1. INFORMED CONSENT/RESEARCH
2. RESEARCH PROGRESS NOTE
3. CLINICAL WARNING/RESEARCH PROTOCOL
4. RESEARCH PROTOCOL COMPLETED

9/12/08

# 1. INFORMED CONSENT/RESEARCH

**Title: INFORMED CONSENT/RESEARCH**

This patient has been enrolled in a research trial titled:

IBB study #: \* [REDACTED]

Protocol Approval Period: \* [REDACTED]

VA RESEARCH CONSENT FORM (VA FORM 10-1086) completed on: \* [REDACTED]

\* Indicates a Required Field

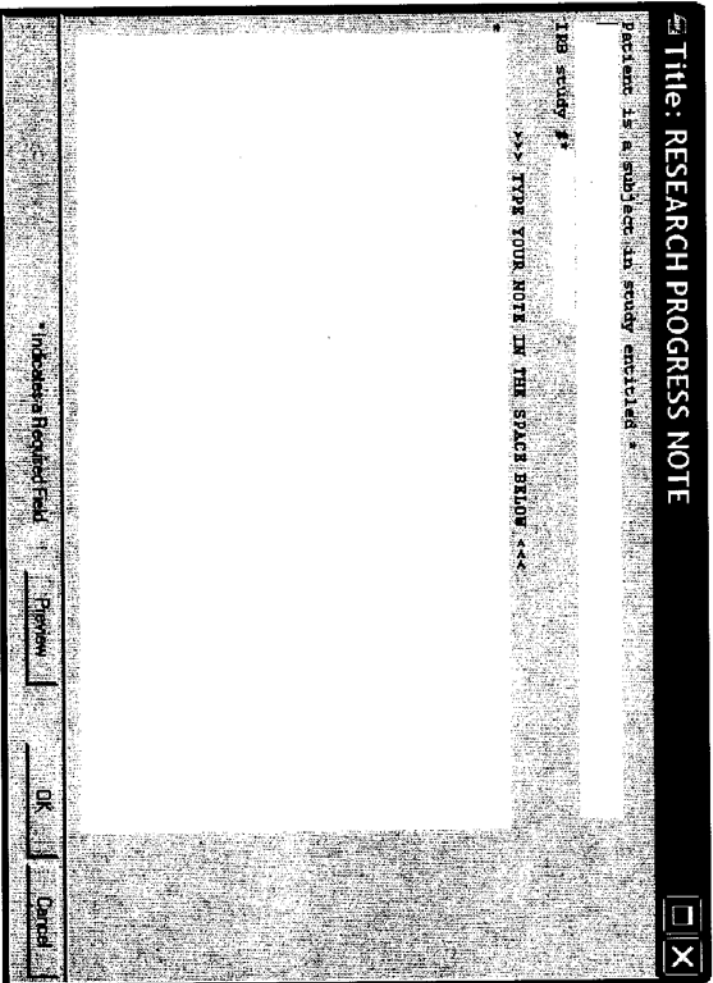
Print

OK

Cancel

9/12/08

## 2. RESEARCH PROGRESS NOTE



9/12/08

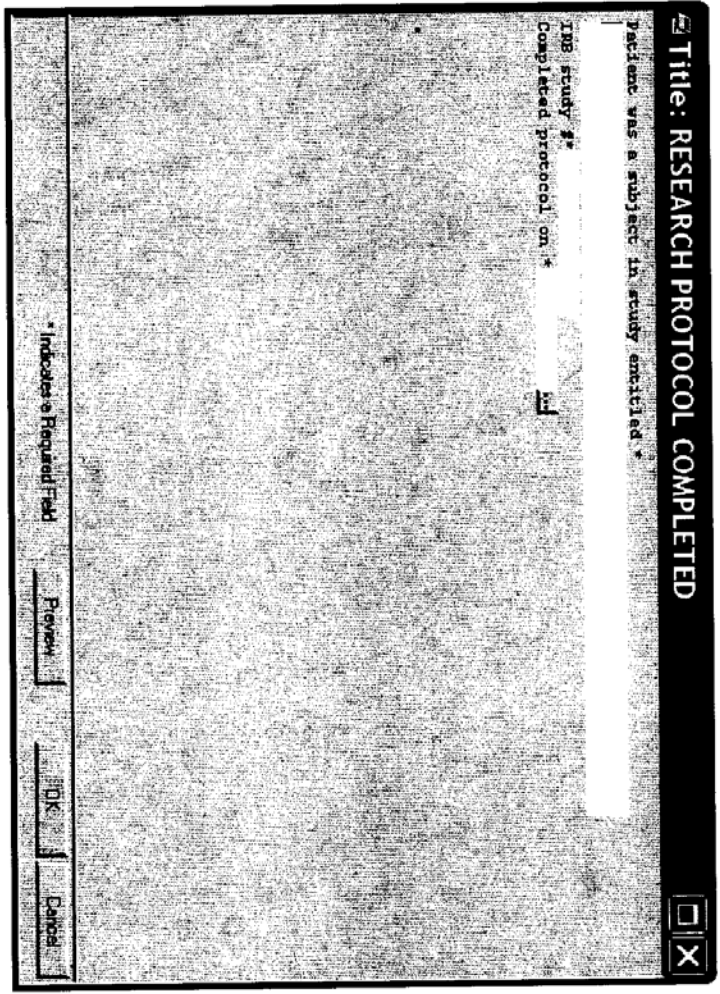
### 3. CLINICAL WARNING/RESEARCH PROTOCOL

Patient IS or HAS BEEN on research protocol(s).

Reference is made to documentation in progress notes titled as follows:  
INFORMED CONSENT/RESEARCH  
RESEARCH PROGRESS NOTE  
RESEARCH PROTOCOL COMPLETED

9/12/08

# 4. RESEARCH PROTOCOL COMPLETED



9/12/08

# ***SIGN your progress notes!!***

If you do not:

1. Nobody but you will be able to read them
2. They will be **deleted** 60 days after being written (then even you will not be able to read them!)

9/12/08