

## VAMHCS RESEARCH SERVICE HOT TOPIC

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### Informed Consent Forms: Scanning, Enrollment Notes and “Flagging” of Research Charts

Have you wondered what the IRB’s recent requirement to “flag” the medical record is all about\*? Do you even know what we (VAMHCS) mean as the “flag”\*\*? Do you continually get consent forms sent back to you by Research Service staff because of problems with scanning them?

[\*Answer: the VA says that the IRB must make a determination on whether charts need to be flagged ([VHA Handbook 1200.05](#), Appendix C Par. 3.c (p.C-6)]

[\*\*Answer: Within the VAMHCS, “flagging” is the “Research Subject Clinical Warning (RSCW)”]; see #8-10 below.]

From observations gained through the recent audits of informed consent forms, a review of Research Service procedures on scanning, and new VA requirements, we have concluded that an UPDATE on this topic is in order.

1. ENROLLMENT NOTES AND “FLAGGING” (RSCWs) ARE TWO SEPARATE ISSUES. See #2-7 below for updates on ENROLLMENT NOTES. See #8-10 for information on FLAGGING.

### **ENROLLMENT NOTES AND SCANNING OF RESEARCH CONSENT FORMS**

2. REMINDER: All signed informed consent forms AND HIPAA authorizations must be scanned into CPRS unless certain exemptions apply or unless the IRB decides otherwise. The exemptions are:
  - The study involves only a single visit / one encounter
  - The study involves the use of a questionnaire or previously collected biological specimens

- ▣ Identification as a participant in a particular study would place the participant at greater than minimal risk,
  - ▣ NEW CLARIFICATION: The participant is an individual who does not already have a VA medical chart AND who does not need medical or other VA services as part of the research study (see #8 below).
3. Scanned informed consent forms and “Research Subject Clinical Warnings” (RSCW) (see #8 below) help to preserve the rights and welfare of participants AND help to preserve the integrity of your studies:
- ▣ They provide medical staff with important information about the study AND contact information for the PI/study staff.
  - ▣ For clinical decisions, this can enable safe withdrawal of an investigational drug, safe addition of medications for clinical reasons, etc.
  - ▣ For the study staff, being contacted when a participant has been admitted, or has exhibited a new medical problem can help to prevent adverse events, expedite the reporting of adverse events, and to maintain accurate study records.
4. REMINDER: Enrollment notes MUST be entered into CPRS when a participant is enrolled in a study (except for the participants excluded in #1 above).
- ▣ The VHA has requirements for the content of enrollment notes. These are listed in [VHA Handbook 1200.05](#), p. C-5.
  - ▣ REMINDER: If you use the template already accessible in CPRS for [Research Enrollment Notes](#), you will meet all requirements. See Hot Topics [Vol1.No2](#), [Vol1.No3](#), [Vol1.No4](#) for details on how to access the template, personalize it, and save it to your personal templates for easy use for your individual studies.
  - ▣ Ms. Johnson cannot scan consent forms unless there is an enrollment note present in CPRS. (Ms. Johnson is the Research Service staff person who is responsible for the scanning of consent forms.)
  - ▣ If the enrollment note does not meet all requirements, this may delay scanning until the note can be amended (by you).
5. NEW: The Research Service is reinstating the use of a “Scanning Cover Sheet”. The new and improved version is attached and will be available on the Research Service website shortly:

[http://www.maryland.research.va.gov/research/human/forms/scan\\_informed\\_consent\\_cover\\_letter.pdf](http://www.maryland.research.va.gov/research/human/forms/scan_informed_consent_cover_letter.pdf)

- At first glance, the cover sheet may seem cumbersome. However, ALL of the items on the sheet are VERY common problems that our scanner staff CONTINUALLY find.
    - Suggestion: save a template containing your study and contact info and then fill in the blanks for specific forms as needed.
  - Beginning in June, Ms. Johnson will perform and document an audit of each consent form and HIPAA authorization before it is scanned into CPRS. This will enable you to correct problems quickly and will facilitate the annual mandatory consent form audits that must be done by the VAMHCS compliance staff.
6. Common problems found by Ms. Johnson almost every day:
- Headers on the consent forms are not filled out
  - Validation dates (footers) are cut-off on the copies sent to the Research Service
  - Copies are very crooked on the page
  - Enrollment notes can't be found
  - Enrollment notes contain incomplete or inaccurate information (for example, the template has not been updated with new validation dates of the renewed consent forms)
  - Double-sided copies of ICFs are sent for scanning. This slows down the scanning process INCREDIBLY. PLEASE send single-sided copies.
7. FORMAL INTRODUCTION: Ms. Angelus “Angel” Johnson is the Research Service individual who is responsible for scanning your consent forms and HIPAA authorizations into CPRS. She can be reached at x3147 or [angelus.johnson@va.gov](mailto:angelus.johnson@va.gov). She is on duty in 3A-125 on Mondays, Wednesdays and Fridays. She will generally be the person who contacts you when there are problems with scanning your forms.

### **“FLAGGING” OF RESEARCH CHARTS**

8. NEW CLARIFICATION, “Flagging” of research charts: Flagging of research charts has always been a VHA requirement ([VHA Handbook 1200.05](#) Par 3.c). The VAMHCS method of complying with it has always been through Research Subject Clinical Warnings” (RSCWs).

- a. During the past year or so, the IRB formally votes on whether or not flagging of research records is required. This is because VHA Handbook 1200.05 requires that the IRB vote on whether a record needs to be flagged to protect participants' safety. In general, the UMB IRB confirms our VAMHCS SOP that states that all records need to be flagged unless they are exempt as in # 1 above.
  - b. In practice, the IRB notifications about flagging of records really should not be any change to what you already should have been doing. If you have been entering RSCWs into CPRS when a participant is enrolled in a study, then you have been in compliance with the "flagging" requirement.
  - c. For details on RSCWs, including the template in CPRS, how to insert one into CPRS and how to remove one, go to Hot Topic [Vol1.No3](#).
  - d. If you feel that there is a reason not to flag your participants' records, you must contact the IRB with your justification.
9. NEW CLARIFICATION (CONTINUED) from Bullet # 2 above, further explanation about the need for a medical record. If a participant does not have or need a VA medical record for clinical reasons, then a medical record for research purposes DOES NOT need to be created (and therefore there is no record to "flag", no record to have ICFs scanned into, etc.).
- a. For example, in an observational study (therefore not requiring VA medical services) or a study of veterans' non-veteran family members (therefore not requiring VA medical services), the veteran and the family members all DO need to sign the study's consent forms and HIPAA authorizations, but only the veteran's ICF and HIPAA authorization needs to be scanned and only his record would need to be flagged (because only the veteran has a VA medical record).
  - b. In other words, CPRS medical records DO NOT need to be created for research participants if the research does not involve VA medical services. And if a CPRS record DOES already exist, the ICF and HIPAA authorizations DO need to be scanned and enrollment notes written for research that is not exempted in bullet 1 above.
  - c. Whether scanned or not, the PI/designee must ALWAYS obtain a signed informed consent form and HIPAA

authorizations (unless waivers have been granted by the IRB), and must ALWAYS maintain the ICF and HIPAA authorization in the study files.

10. Still confused? Please feel free to contact Jessica Mendoza or other members of the Office of Research Compliance with any questions.

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

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Can't put your finger on a past Hot Topic you know would solve your problem? No problem. Check the Hot Topics archive on the Research Service website:

[http://www.maryland.research.va.gov/hot\\_topics.asp](http://www.maryland.research.va.gov/hot_topics.asp)

For comments, complaints or suggestions regarding the Research Service or Office of Research Compliance, contact:

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