

# Flagging the Medical Record: Collaborative IRB



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# Introduction

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What Does “Flagging the Medical Record” Mean?

- In the context of research trials, “flagging” means:
  - As determined by the IRB, patients enrolled in a research trial will have their medical record (electronic or paper) indicate they are enrolled in that research trial.
  - The medical record will also link to the title of the trial and to information about the trial.



# Two Exceptions:

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Two Exceptions as to when the medical record should be flagged:

1. The “One Encounter, Only a Questionnaire, Previously Collected Biological Specimens” Exception
2. The “Identification Creates Greater than Minimal Risk” Exception

More later...



# Responsibility

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Who Makes the Determination to Flag the Medical Record?

-This has previously been the responsibility of the R&D Committee.

However-

-The IRB became responsible for this requirement on February 2, 2009.



# Transition Process

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Why is there a transition of the responsibility to the Collaborative IRB?

- VHA Handbook 1200.05 provides that the IRB is responsible for the flagging determination.

But-

- The Collaborative IRB had limited permission from a federal regulatory agency to delegate this responsibility to the R&D Committee until the IRB was fully functioning.
- Now that the Collaborative IRB is fully functioning, the limited permission is no longer effective and the responsibility has been transferred to the Collaborative IRB.



# Timeline:

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When is the flagging determination made?

- Made by the IRB at **initial review only** for both expedited and convened review protocols and
- for both minimal risk and greater than minimal risk protocols.



# Timeline:

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Why isn't the flagging determination made at continuing review or for amendment submissions?

- The Office of Research and Development informal opinion:
  - Most relevant studies (interventional studies) will be captured and flagged at initial review.
  - As a result, this removes a need for the flagging determination for amendments or continuing review applications.
  - It is unlikely that research involving a questionnaire will become interventional through an amendment or at continuing review.



# Purpose: Why is a flagging determination made? (Slide 1 of 2)

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To protect subject safety when seeking treatment outside of the research trial at the JBVAMC by indicating subject participation in a research study:

- The health care professional is able to use the research study information to develop the patient's treatment plan and to adjust standard of care treatment if necessary
- Assists in the determination of medical necessity
- Reduces duplication of administration of items and services



# Purpose: Why is a flagging determination made? (Slide 2 of 2)

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- Reduces medical errors
- Reduces improper drug combinations
- Provides a source of more information about the subject's health care treatment
- Greater communication and coordination among health care professionals of different discipline



# Flagging Determination Should be Outcome Based:

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The Collaborative IRB should first query whether the desired outcome of this regulatory requirement will be met by voting to flag the medical record.

- The desired outcome is similar to the purpose:
  - To protect subject safety when seeking treatment outside of the research trial at the JBVAMC
    - Guidance does not exist as to specific criteria for the flagging determination.
    - Industry relies on an outcome based determination.



# Two Exceptions

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The Collaborative IRB should query whether the two exceptions apply:

**First Exception:** “One Encounter, Only a Questionnaire, Previously Collected Biological Specimens” Exception:

- IRB may not want to require the medical record to be flagged if the subject participation in the study involves:
  - a. “Only one encounter,
  - b. Only the use of a questionnaire, or
  - c. The use of previously collected biological specimens.” (VHA Handbook 1200.05).
- In theory and on paper, this exception applies to both minimal risk studies and greater than minimal risk studies.
- In practice, greater than minimal risk studies are unlikely to fall within this exception.



# Exception

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**Second Exception:** The “Identification Creates Greater than Minimal Risk” Exception:

- “The identification of the patient as a subject in a particular study (if the study is not greater than minimal risk) would place the subject at greater than minimal risk.” (VHA Handbook 1200.05).
  
- For minimal risk studies:
  - Apply this exception.
  - Be sure to document the reasoning one way or the other on the review guides.
  
- For greater than minimal risk studies:
  - This exception does not apply.



# Current Industry Interpretation

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- The Office of Research and Development informal interpretation is that, generally, all interventional research studies must be flagged.
- Given that:
  - The “One Encounter, Only a Questionnaire, Previously Collected Biological Specimens” exception very rarely will be applicable to greater than minimal risk studies; and
  - The “Identification Creates Greater than Minimal Risk” exception does not apply to greater than minimal risk studies.
  - The Office of Research and Development interprets the practical application of the exceptions as creating a general rule of thumb (unless the exceptions apply).



# Application

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What is an interventional study?

Interventional studies include:

- Drug studies;
- Device studies; and
- Mental health interventions.



# Application

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Does the IRB make a flagging determination for each subject or a global determination for each protocol?

- One flagging determination is made per research trial.
  - The single determination applies to all subjects in a particular research trial in a uniform manner.
  - If the IRB determines that the medical record should be flagged for a research trial, the medical record of each subject in the trial is flagged.
  - A particular subject cannot be separated from the IRB determination to flag the medical record.



# Congressional Focus

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- The Office of Research and Development stated that Congress has placed a premium on the area of medical record flagging to ensure that unnecessary complications or side effects do not occur due to the VA medical center lack of knowledge about the enrollment of the patient in research trial.
- The Office of Research and Development stated that the industry interpretation at this time is to flag most interventional studies, with the exception of the very few, which would fall within the first exception.



# Procedure: Expedited Review (Collaborative IRB)

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The expedited review determination will be made in the JBVAMC Review Guide:

- IRB reviewer as delegated by the IRB Chair answers a question as to whether they would like the medical record flagged on the JBVAMC review guide during expedited review of initial submissions only.



# Procedure: Convened Review (Collaborative IRB)

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- Convened review determination will be documented in the meeting minutes.
  - AD will:
    - Prompt the convened IRB to discuss whether flagging is appropriate or not; and
    - Assist the IRB with the regulatory nuances of this determination.
  - The convened IRB should include, as part of the protocol deliberation and determination, whether the medical record should be flagged.
  - The determination is documented in in the meeting minutes.
  - The AD (or designee) will also maintain a spreadsheet that indicates the overall outcome.



# Procedures for Notifying R&DC of IRB's Flagging Determination:

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Note: Same procedure for expedited and convened review-

- AD of IRB or designee will compile the outcome in a spreadsheet.
  - This information is delivered to the R&D Office on a monthly basis in accordance with the Collaborative IRB SOP, which then ensures that the appropriate medical records are flagged by the R&D Office.
  - The UIC IRB is not permitted to access the JBVAMC medical records and cannot perform the actual flagging.
    - Therefore, the R&D Office is ultimately responsible for implementation of the IRB determinations.



# Link to Applicable Policy

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Policy: Operating and Coordinating Procedures for the Administration of the Collaborative JBVAMC/NU/UIC IRB (UIC IRB #4)

Link:

<http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0292.pdf>

Applicable Pages: 6, 7 and 12



# Question and Answer Period

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- Questions?
- Comments?
- Other?