

# Flagging of VHA Health Record

# IRB Determination for VA Studies

- The IRB may determine that the patient health record must be flagged to protect the subject's safety by indicating the subject's participation in the study.

# Mandatory Flagging

- (1) The patient record **MUST** be flagged if the subject's participation in the study involves:
  - (a) Any invasive research procedure;
  - (b) 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;
  - (c) Clinical services that will be used in the medical care of the subjects;
  - (d) 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).

# Mandatory Flagging (cont.)

- (2) In other situations, the IRB determines if flagging is necessary.

# AAHRRP Element

## II.5.B

- The IRB or EC documents discussions and decisions relevant to a research protocol or plan in accordance with legal and regulatory requirements, Sponsor requirements, if any, and organizational policies and procedures.

# eIRB Smartforms

- Revised eIRB smartforms to provide VA investigators with:
  - an easy way to request waiver.
  - education on when medical records must be flagged.
  - examples of circumstances when flagging may be waived.

# Document the Decision

- The IRB's determination of whether medical records need to be flagged or whether to waive the requirement must be documented in the IRB minutes.

# Questions?

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