

CATEGORY II (MEDICAL RECORD) FLAG AND WAIVER POLICY

1. POLICY:

The VA requires that the health records of patients participating in research studies must be flagged in CPRS by a member of the study team if involving any one or more of the following:

- a) Any invasive research procedure (e.g., muscle biopsy or bronchoscopy).
- 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 (e.g., administration of a medication, device or treatment).
- c) Clinical services that will be used in the medical care of the subject (e.g., orders for laboratory tests or x-rays), or that could interfere with other care the subject is receiving or may receive.
- d) The use of a research survey or questionnaire that may provoke undue stress or anxiety.
- e) Other situations, whereby the IRB will determine if flagging is necessary.

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. The record must also contain information on the research study (ex. title, duration, study treatment) or identify where this information is available (ex. referencing the consent note).

The Medical Record Flag must be active for the duration of the study treatment, intervention, or clinical services that could interfere with other care. The flag should be entered at the start of the study treatment (randomization). The flag must be removed by a member of the study team when the patient discontinues treatment or completes their study participation.

ALL STUDIES THAT MEET THE ABOVE CRITERIA MUST EITHER FLAG SUBJECT'S MEDICAL RECORDS OR HAVE AN IRB-APPROVED MEDICAL RECORD FLAG WAIVER ON FILE.

The [Medical Record Flag \(MRF\) Waiver](#) must be submitted to the IRB for approval at either the Initial Submission or as an Amendment to the study. Once the MRF Waiver is approved, it should be stored in the study regulatory binder.

NO ACTION IS NECESSARY FOR STUDIES THAT DO NOT MEET THE ABOVE CRITERIA.

If there are questions as to whether a MRF or Waiver applies to your study, please contact the VA Research Compliance Office

REFERENCES

VHA Handbook 1907.01
VHA Handbook 1200.05