Emory IRB Criteria for Approval for VA Research

Use this in addition to the IRB Criteria for Approval Checklist

Consent:

- Consent will be documented through the use of VA Form 10-1086
- A witness to the participant's signature or the participant's legally authorized representative's signature will sign and date the consent document.
- The witness will sign and date both the short form and a copy of the summary, if applicable.
- The person actually obtaining consent will sign and date a copy of the summary, if applicable.
- A copy of the signed and dated consent document will be given to the person signing the consent document.
- If the sponsor or IRB requires a witness to the consenting process in addition to the witness to the participant's signature and if the same person needs to serve both capacities, a note to that effect was placed under the witness's signature line.

Should review be obtained more often than annually?

If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?

Does the medical record need to be flagged to protect the participant's safety by indicating participation in the study and the source of more information on the study? Yes No *If No, indicate the reason why:*

☐ Participation in the study involves only one encounter.
☐ Participation in the study involves the use of a questionnaire or previously collected biological specimens.
☐ Identification as a participant in a particular study will place the participant at greater than minimal risk.

Does this research involve?

☐ Non-veterans (If so, the PI must ensure that all recruitment methods have been exhausted to obtain veterans, and the PI can only perform the research with the inclusion of non-veterans)
☐ In vitro fertilization. (If so, the research cannot be approved)
Fetuses. (If so, the research cannot be approved)
☐ Prisoners. (If so, the research cannot be approved unless a waiver has been granted by the Chief Research and Development Officer.)
☐ Children. (If so, the research cannot be approved unless a waiver has been granted by the Chief Research and Development Officer and the research is conducted in accordance with DHHS Subpart D.)
☐ Pregnant women. (If yes, the research cannot be approved unless VHA Handbook 1200.5 criteria in APPENDIX D Items 4c (pg. D2-D3) and 4d (pp. D3-D4 are met.)
☐ Adults unable to consent. (If yes, the research cannot be approved unless VHA Handbook 1200.5 criteria in Item 11 (pp. 20-21) and APPENDIX D Item 6 (pp. D4-D5) are met.)

If the study addresses an issue related to biosafety or radiation safety, has the appropriate committee or subcommittee first approved the study?