

## VAMHCS Collaborative Studies Checklist

All CICERO protocols prior to IRB review will be administratively reviewed by a member of the Research Service for their completeness and presence of the following:

- SECTION I.** Project information (for all studies)  Investigator-Initiated Study (check if applicable)  
 Multi-Site  Single-Site (select one)  
 CRADA
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1. Full Protocol Title:

IRB Number: HP-

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2. Type of project (check all that apply):  Human Subjects  Animal  Laboratory

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3. Principal Investigator Name:

VAMHCS Service:

VA Appointment:  VA Staff  WOC  Fee basis

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4. Point of Contact Name:

Email:

### Section II.

1. Protocol: Clear delineation of research related activities conducted at VA and other institutions that includes:

- |                                     |                                    |                             |                              |                                 |
|-------------------------------------|------------------------------------|-----------------------------|------------------------------|---------------------------------|
| a. Recruitment                      | <input type="checkbox"/> Not Clear | <input type="checkbox"/> VA | <input type="checkbox"/> UMB | <input type="checkbox"/> Other: |
| b. Advertisement                    | <input type="checkbox"/> Not Clear | <input type="checkbox"/> VA | <input type="checkbox"/> UMB | <input type="checkbox"/> Other: |
| c. Study procedures                 | <input type="checkbox"/> Not Clear | <input type="checkbox"/> VA | <input type="checkbox"/> UMB | <input type="checkbox"/> Other: |
| d. Data Coordinating Center         | <input type="checkbox"/> Not Clear | <input type="checkbox"/> VA | <input type="checkbox"/> UMB | <input type="checkbox"/> Other: |
| e. Data collection,                 |                                    |                             |                              |                                 |
| f. use access, storage, disclosure  | <input type="checkbox"/> Not Clear | <input type="checkbox"/> VA | <input type="checkbox"/> UMB | <input type="checkbox"/> Other: |
| g. Visits, clinics, labs, etc.      | <input type="checkbox"/> Not Clear | <input type="checkbox"/> VA | <input type="checkbox"/> UMB | <input type="checkbox"/> Other: |
| h. Data registry                    | <input type="checkbox"/> Not Clear | <input type="checkbox"/> VA | <input type="checkbox"/> UMB | <input type="checkbox"/> Other: |
| i. Tissue/specimen banking          | <input type="checkbox"/> Not Clear | <input type="checkbox"/> VA | <input type="checkbox"/> UMB | <input type="checkbox"/> Other: |
| j. Dispensing of study drugs        | <input type="checkbox"/> Not Clear | <input type="checkbox"/> VA | <input type="checkbox"/> UMB | <input type="checkbox"/> Other: |
| k. Future use of data and specimens | <input type="checkbox"/> Not Clear | <input type="checkbox"/> VA | <input type="checkbox"/> UMB | <input type="checkbox"/> Other: |

l. VA specific criteria:  Completed  Enrolls Veterans  Enrolls Non-Veterans

If enrolling non-Veterans, non-Veteran enrollment was justified:  N/A

2. Informed Consent and HIPAA Authorization:

Yes  No  N/A

Clear delineation and completeness of research related activities conducted at VA and other institutions.

Yes  No  N/A

VA required elements or language on both documents. (Refer to Informed Consent Checklist).

3. Study Personnel:

VA Study Staff have VA appointment (Staff, WOCs, IPA)

Training complete

4. ISO/PO checklist:  Complete  Followed up with ISO/PO

5. VA Cooperative Research & Development Agreement (CRADA):  Yes  N/A

6. VA Data location:

**This is not a collaborative study (VAMHCS only)**

**This is a collaborative study**

**I have reviewed this protocol and it meets VA requirements.**

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Name

Title

Date

**The following revisions are suggested in order for the protocol to meet VA requirements:**