

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

1. Full Protocol Title:

IRB Number: HP-

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

3. Principal Investigator Name:

VAMHCS Service:

VA Appointment: VA Staff WOC Fee basis

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.

Name

Title

Date

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