



<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - VA Review ▾

Continue >>

Studies Conducted at Veterans Affairs (VA)

VA Records Requirements

☐ Yes

Is VHA Health Record flagging required for this study?

☐ No

The VA HRPP Administrator selected the following determination:

Clear

The health record must be flagged if the subject's participation in the study involves ONE OR MORE of the following:

1. Any invasive research procedures (e.g., muscle biopsy or bronchoscopy); OR
2. 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, treatment, or use of an investigational device); OR
3. Clinical services that will be used in the medical care of the subject (e.g., orders for laboratory tests or x-rays ordered as part of the study), of that could interfere with other care the subject is receiving or may receive; OR
4. 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 interest of the subject (e.g., an interview study of victims of sexual assault).

☐ Yes

May the requirement for maintaining a master list of all subjects be waived for this study?

☐ No

The VA HRPP Administrator selected the following determination:

Clear

The requirement for a master list may be waived if BOTH of the following conditions are met:

1. There is a consent signature waiver (i.e., a waiver of documentation of informed consent), AND
2. Including subjects on a master list poses a potential risk to the subjects from a breach of confidentiality.

☐ Yes

Have the applicable VHA and VA information security policies pertaining to research been applied to this study?

☐ No

The VA Information Security Officer selected the following determination:

Clear

- The VA Checklist for Reviewing Privacy, Confidentiality, and Information Security in Research can be found on the IRB Forms web page, under the heading VA Consent Documents: <http://irb.utah.edu/forms/health-sciences.php>
- Answer to this question must be 'Yes' in order to approve the study.

☐ Yes

Are veteran's Social Security Numbers (SSN) being used appropriately according to VA policy?

☐ No

The IRB review will confirm this.

☐ N/A

- N/A if the study does not propose to collect SSNs.
- Answer to this question must be 'Yes' or 'N/A' in order to approve the study.

Clear

The VA HRPP Administrator selected the following determination:

Social Security Numbers may be used if the following conditions are met:

- Investigators may obtain and use real Social Security numbers, scrambled SSNs, or the last four digits of SSNs only when required to meet the specific aims of the research protocol or to enter information into the subjects' health records.
- There are appropriate security measures in place to protect the SSNs.
- Research team members are prohibited from requesting Social Security numbers by telephone
- The use of SSNs is consistently described within the protocol, consent form, and/or HIPAA authorization/waiver.
- NOTE: This does not apply if the only use of SSNs is on the informed consent form or the HIPAA authorization as required by VHA Handbook 1907.01).

☐ Yes

For collaborative studies between the VA and University of Utah, are the VA activities clearly distinguished from University activities?

☐ No

☐ N/A

- N/A if the VA and University are not collaborating.
- Answer to this question must be 'Yes' or 'N/A' in order to approve the study.

Clear

VA Participant Consideration

☐ Yes

For vulnerable populations enrolled at the VA, have the following conditions been met:

☐ No

- **Pregnant women:** Complete the Board Member Checklist page for research involving this population

☐ No
☐ N/A
Clear

- **Pregnant women:** Complete the Board Member Checklist page for research involving this population.
 - Research directly on fetuses and neonates may not be conducted at the VA.
- **Persons with Cognitive or Decisional Impairment:** Complete the Board Member Checklist page for research involving this population.
- **Prisoners:** Complete the Board Member Checklist page for research involving this population. Then confirm that a waiver from CRADO is attached to the application.
- **Children:** Complete the Board Member Checklist page for research involving this population, and confirm that this study is minimal risk. Then confirm that a waiver from CRADO is attached to the application.

N/A if none of the vulnerable populations above will be enrolled at the VA

- Answer to this question must be 'Yes' or 'N/A' in order to approve the study.

☐ Yes
☐ No
☐ N/A
Clear

May non-veterans be enrolled at the VA site?

- N/A if the study does not propose for non-veterans to be enrolled at the VA site.

The VA HRPP Administrator selected the following determination:

Non-veterans may be enrolled at the VA site if BOTH of the following conditions are met:

1. *The study is relevant to veterans or active duty military personnel.*
2. *There is compelling argument for the inclusion of non-veterans (e.g., insufficient number of veterans; survey of VA employees; study of active duty military; study involving veterans' family members).*

☐ Yes
☐ No
☐ N/A
Clear

Is the payment of veterans for research participation appropriate?

- N/A if the study does not propose to pay veterans for research participation.
- Answer to this question must be 'Yes' or 'N/A' in order to approve the study.

Payment to veterans is permitted in the following circumstances:

- *If there is no potential for direct benefit to the participant*
- *If other subjects at other sites outside of the VA are being paid for participation*
- *When transportation expenses are incurred by the participant that would not be incurred in the normal course of receiving treatment and that are not reimbursed by any other mechanism*
- *In other comparable situations in which, in the opinion of the IRB, payment is appropriate*

Note that the following VA-specific requirements have been confirmed in other sections of the Board Member Checklist:

- VA HIPAA Privacy Requirements
- VA Informed Consent Requirements
- VA Tissue Banking Guidelines

Specific Concerns:

If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolutions to Concerns:

Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER:

If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).

Determination: Are the specific VA requirements met?

☐ Yes.

☐ Yes, if the above stipulation is met.

☐ No.

[Clear](#)

<< Back

Save | Exit | Hide/Show Errors | Print... | Jump To: - VA Review ▾

Continue >>