This AID highlights specific requirements applicable to research supported by, or otherwise subject to, the Department of Veterans Affairs (VA).

**Questions on VA requirements?** Contact VA Human Protections Administrator (650-493-5000 x67593)

## Protocol Application

**New applications and Modifications adding the VA:**
- Required Questions-VA Research (APP-1m) must be attached with eProtocol application
- **IRB Manager:** Complete checklist CHK-7 *VA Research* and attach in eProtocol; Assign VAPAHCS Human Protections Administrator as a reviewer in eProtocol

<table>
<thead>
<tr>
<th>Exempt determination</th>
<th>May be certified by IRB staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joint Stanford/VA studies</td>
<td>eProtocol Study Procedures should clearly delineate which procedures will occur at Stanford facilities, and which at VA</td>
</tr>
<tr>
<td>Unfunded Research</td>
<td>Need signed VA-R&amp;D <a href="#">Scientific Review Subcommittee – Initial Project Checklist</a> attached with eProtocol submission</td>
</tr>
</tbody>
</table>

### Vulnerable populations *eProtocol 8c*
- Where relevant, IRB must document:
  - **Why** an individual or population is vulnerable, and
  - **Adequate safeguards** are included to protect rights and welfare of participants likely to be vulnerable.
- Examples of participants that may be temporarily or permanently vulnerable: [VHA Handbook 1200.05](#)

### Adults with Impaired Decision-Making Capacity *eProtocol 8*
- Enrollment criteria: [VA Handbook 1200.05](#)
  - (see also *HRPP Ch. 12.2.1.: VA Research – Additional Requirements*)

### Data Storage & Reuse
- Protocol should describe where data will be stored.

### Records retention
- Record should be retained ‘indefinitely’ for now ([VHA Handbook 1200.05](#))

**NOTE:** The following are on **APP-1m Required Questions-VA Research**:

<table>
<thead>
<tr>
<th>Participation of non-veterans</th>
<th>Justification should be discussed in IRB meeting, and noted in Minutes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multi-site research <em>if VA investigator is multi-site PI for all participating sites</em></td>
<td>If any participating sites will have local differences in the protocol or informed consent, there must be a mechanism for ensuring that these differences are <em>justified by the local participating site investigator, and approved by the study PI before being implemented.</em></td>
</tr>
</tbody>
</table>

## Consent Form, HIPAA Authorization

- [VA Palo Alto Health Care System Consent](#)
- [VA HIPAA Authorization](#)
### Joint VA/Stanford study
- **Purpose** must include: “This study is being done by researchers at VA Palo Alto and Stanford University.”
- Separate consent forms may be needed (SU, VA), depending on the procedures.

### Tissue Banking or Storing for Future Research
Limitations on banking/storing of research specimens for future *undefined* uses. See red instructional text in [VA Palo Alto Health Care System Consent](#).

### Financial Considerations – Payment
- Must include one of these statements:
  - You may need to provide your social security number to receive payment, **or**
  - You will not be paid for taking part in this study.
- VA policy prohibits paying participants in some circumstances:
  - See red instructional text in [VA Palo Alto Health Care System Consent](#).

### Financial Considerations – Costs
- Veteran participants in VA research cannot be required to pay for care received during the study. Some veterans may be required to pay co-payments for routine medical care.
- Veterans’ *insurance* will never be billed for research-related costs

### HIPAA Authorization
- Must be separate from ICF (HIPAA does not need to be separated for studies started before March 31, 2011)

### Waivers and Alterations

**Consent**
For **VA/Stanford** studies, HIPAA waiver, ICF waiver, or alteration of consent should state to which institution it applies; “VA” (eProtocol section 16 “consent background”) should be checked when the waiver/alteration of consent applies to consenting procedures at the VA.

**HIPAA and the Short Form Consent Process**
*Alteration* of HIPAA Authorization is **not** permitted. For Short Form consent process a HIPAA *Waiver* must be requested.

### Reports

**Prompt reporting to the IRB**
VA researchers must report within 5 business days of becoming aware of UPs, possible noncompliance, any termination or suspension of research.

**Local unanticipated SAEs**
Local unanticipated SAEs must be reported to the IRB, via eProtocol Report item# 7 ➔ Assign to an IRB Member (preferably *medical* and VA-affiliated) for Expedited review: Review *within 5 business days* of report submission.
IRB Reviewer should determine if the event meets UP criteria.

### IRB Approvals, Determinations and Findings

**Approval with Conditions**
When approval is contingent on specific *minor* modifications:
- Review and approval must be by **IRB Chair**, or experienced **IRB voting member designated by Chair**
- Expedited review can be used.
Participation of non-veterans

Minutes document the justification for participation of non-veterans; any justification should be discussed in IRB meeting.

### Special Circumstances

<table>
<thead>
<tr>
<th>Certificates of Confidentiality</th>
<th>CoC process diagram</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conflict of Interest (investigators)</td>
<td>• <strong>Stanford-VA study</strong> or <strong>VA-only study</strong>: IRB Manager forwards CoI Action Report (for the VA investigator) to the VA Research Compliance Officer (<a href="mailto:Grace.Yeh@va.gov">Grace.Yeh@va.gov</a>).</td>
</tr>
<tr>
<td>International research</td>
<td>Research conducted at U.S. military bases, ships, or embassies is not considered international research.</td>
</tr>
<tr>
<td>Pilot studies</td>
<td>Pilot studies are full-fledged research studies that must be approved by the IRB, when human participants are involved. They are not considered <em>preparatory to research</em> activities.</td>
</tr>
<tr>
<td>Prohibited research</td>
<td>• Children, or pregnant women (unless restrictive conditions are met) • Planned emergency research • Research involving fetuses, or <em>in vitro</em> fertilization See CHK-7 <strong>VA Research</strong> for other prohibited research.</td>
</tr>
</tbody>
</table>

### Resources

| VA | • 38 CFR Part 16 • **VA Handbooks website** including: ○ **VHA Handbook 1200.05** - Requirements for the Protection of Human Subjects in Research ○ **VHA Handbook 1058.01** - Research Compliance Reporting Requirements • **VHA Forms, Publications & Records Management** • Contact the VAPAHCS **Human Protections Administrator** (650-493-5000 x67593) |
| Stanford | • APP-1m **Required Questions-VA Research** • CHK-7 **VA Research** |