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 Scientific Review Subcommittee – Initial Project Checklist attached with eProtocol submission</td>
</tr>
<tr>
<td>Data Storage &amp; Reuse</td>
<td>Protocol should describe where data will be stored.</td>
</tr>
<tr>
<td>Records retention</td>
<td>Record should be retained as specified by the VA Records Control Schedule. [VHA Handbook 1200.05]</td>
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</table>

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

- Multi-site research if VA investigator is multi-site PI for all participating sites
- 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 justified by the local participating site investigator, and approved by the study PI before being implemented.

### Consent Form, HIPAA Authorization

- **VA Palo Alto Health Care System Consent with HIPAA**
  - **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.
  - 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**
    - May be combined with the consent form as long as clearly separate. If separate HIPAA Authorization is used, must use the VA Form 10-0493
**Waivers and Alterations**

<table>
<thead>
<tr>
<th>Consent</th>
<th>For <strong>VA/Stanford</strong> 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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIPAA and the Short Form Consent Process</td>
<td>Alteration of HIPAA Authorization is <strong>not</strong> permitted. For Short Form consent process a HIPAA Waiver must be requested.</td>
</tr>
</tbody>
</table>

**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. |

**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 or VA-only study</strong>: CoI Action Report (for the VA investigator), if applicable, is documented in eProtocol</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 preparatory to research activities.</td>
</tr>
</tbody>
</table>

**Resources**

| VA | • 38 CFR Part 16  
• VA Publications website including:  
  o VHA Directive 1200.05 - Requirements for the Protection of Human Subjects in Research  
  o 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 |