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**:<br>○ Required Questions-VA Research (APP-1m) must be attached with eProtocol application<br>○ *IRB Manager*: Complete checklist *CHK-7 VA Research* and attach in eProtocol;<br>Assign VAPAHCS Human Protections Administrator as a reviewer in eProtocol | |
| Exempt determination | May be certified by IRB staff |
| Joint Stanford/VA studies | eProtocol Study Procedures should clearly delineate which procedures will occur at Stanford facilities, and which at VA |
| Unfunded Research | Need signed VA-R&D Scientific Review Subcommittee – Initial Project Checklist attached with eProtocol submission |
| Vulnerable populations<br>*eProtocol 8c* | Where relevant, IRB must document:<br>• ***Why*** an individual or population is vulnerable, and<br>• ***Adequate safeguards*** are included to protect rights and welfare of participants likely to be vulnerable.<br>Examples of participants that may be temporarily or permanently vulnerable: VHA Handbook 1200.05 |
| Adults with Impaired Decision-Making Capacity<br>*eProtocol 8* | • Enrollment criteria: VA Handbook 1200.05<br>(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<br>[VHA Handbook 1200.05] |
| NOTE: The following are on **APP-1m** Required Questions-VA Research: | |
| Participation of non-veterans | Justification should be discussed in IRB meeting, and noted in **Minutes**. |
| Multi-site research<br>*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
- VA HIPAA Authorization

| | |
|---|---|
| Joint VA/Stanford study | • *Purpose* must include: "*This study is being done by researchers at VA Palo Alto and Stanford University.*"<br>• 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.<br>See red instructional text in VA Palo Alto Health Care System Consent |
| Financial Considerations – Payment | • Must include one of these statements:<br>○ *You may need to provide your social security number to receive payment*, ***or***<br>○ *You will not be paid for taking part in this study*.<br>• VA policy prohibits paying participants in some circumstances:<br>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.<br>• 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;<br>"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<br>➔ Assign to an IRB Member (preferably **medical** and **VA-affiliated**) for Expedited review: Review *within 5 business days* of report submission.<br>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:<br>• Review and approval must be by ***IRB Chair****, or experienced* ***IRB voting member designated by Chair***<br>• 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

| | |
|---|---|
| Certificates of Confidentiality | CoC process diagram |
| Conflict of Interest (investigators) | • **Stanford-VA study** or **VA-only study:** IRB Manager forwards CoI Action Report (for the VA investigator) to the VA Research Compliance Officer (Grace.Yeh@va.gov). |
| International research | Research conducted at U.S. military bases, ships, or embassies is not considered international research. |
| Pilot studies | 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. |
| Prohibited research | • Children, or pregnant women (unless restrictive conditions are met)<br>• Planned emergency research<br>• Research involving fetuses, or *in vitro* fertilization<br>See *CHK-7 VA Research* for other prohibited research. |

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