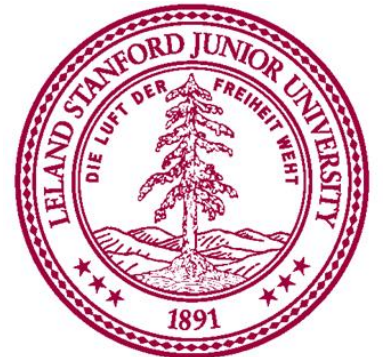


# VA and IRB Review

Research Compliance Office  
Stanford University



<http://researchcompliance.stanford.edu>



# Program Review

- Office of Research Oversight (ORO) Veterans Health Administration (VHA) CPR at VAPAHCS from April 8 to 19
- CPR will include a review of:
  - Research documents
  - Interviews with key individuals
  - Inspection of facilities



# Stanford IRB and VAPAHCS

- Stanford University has a Memorandum of Understanding (MOU) with the VA Palo Alto Healthcare System (VAPAHCS)
- Stanford IRB serves as the reviewing IRB for the VA
- VA member representation on IRB Panels
- VA has access to IRB approved minutes and protocol approval lists



# What is VA research

- Conducted by VA researchers
- Conducted on VA time or on VA property
- Research may be funded by the VA, by other sponsors, or is unfunded.
- All VA research is federally conducted and supported; therefore, all federal and VA requirements apply.



# Reviews and Approvals

- VA Privacy and Information System Security Officer conducts privacy and security review
- Financial Conflict of Interest (COI) disclosures reviewed by VA COI committee and outcome provided to IRB
- VA Scientific Review Subcommittee reviews unfunded VA research
- VA research must have Research and Development (R&D) Committee approval prior to commencing



# Special Populations and Research

Additional requirements for certain types of research may apply, including:

- Research with Prisoners
- Research with Pregnant persons and Neonates
- Research with Children
- International Research

VA also has a separate definition for Legally Authorized Representative (LAR)



# VA Consent Requirements

- Consent must be obtained by the Protocol Director (PD) or the PD must delegate responsibility to research staff
- Separate Stanford and VA consent forms required for joint SU/VA studies, depending on where the research procedures occur
- VA consent template includes VA required language and elements
- VA DocuSign, not Stanford DocuSign, used for electronic consent



# HIPAA Authorization

- VA HIPAA Authorization is used [VA Form 10-0493]
- Combined consent and HIPAA authorization is permitted in some cases (as long as it is separated with separate signature)
- Reviewed by the VA Privacy Officer
- Alteration of HIPAA Authorization is not permitted for VA studies
  - Waiver of HIPAA Authorization must be requested





# References

- AID-27 [VA - Reviewing VA Research](#)
- CHK-07 [Research Involving VA Studies](#)
- [VHA Directive 1200.05\(2\) Requirements for the Protection of Human Subjects in Research](#)
- [VHA Directive 1058 Research Compliance Reporting Requirements](#)
- [VHA Program Guide 1200.21 VHA Operations Activities That May Constitute Research](#)
- Department of Veterans Affairs [38 CFR 16](#)



# Questions?



<http://researchcompliance.stanford.edu>

