VA PERSPECTIVE: CONDUCTING VA/STANFORD COLLABORATIVE PROJECTS

January 2010

Kristin Frazier
493-5000, ext. 67593
Kristin.Frazier@va.gov
Collaborative SU-VA Research

- Long-standing relationship between VA and Stanford
  - Stanford IRB is the IRB of record for Palo Alto VA
- Research is being conducted by people with dual VA and Stanford appointments
  - Many labs are at the VA
- VA has a large pool of potential research participants
But......additional and different rules that govern VA research

- Federal regulations
  - Privacy Act, Privacy Rule (HIPAA), 38 CFR 16 (VA version of the Common Rule)
- VHA Policies (Handbooks) & Directives
  - Humans Subject Protection, Privacy, Data Use and Security, Tissue Banking, International Research, Children in Research, Research Compliance & R&D Committee oversight
- Local policies
  - Local application of all applicable policies
Considerations.....before starting

- VA PI and VA study personnel
- VA Project
- VA Funding
- Sharing of Research data
- Prohibitions and Obstacles
VA Research

- Conducted completely or partially in VA facilities
- Conducted in approved off-site locations or facilities
- Conducted by VA employees while on official VA duty time
  - The research may be VA funded, funded from extra-VA sources or conducted without direct funding

Note: Referral of participants for a Stanford study is not listed
# Nutshell Requirements – VA Research

## Personnel
- Must have VA PI
  - Only select individuals have PI status
- VA research staff approved to conduct VA research
  - Clinical privileges at VA does not confer research PI status
  - Applies to residents/fellows
- Must have a VA appointment
  - VA employee
  - WOC (*without compensation*)
  - IPA (*interagency personnel agreement*)

## Project
- Submit project in RDIS
  - VA electronic database
- Subcommittee approvals
  - IRB, Scientific review, safety (if tissues, imaging, etc)
- Funding considerations
- Clinical impact statements
- Privacy and information security
  - Data storage and sharing
- R&D Committee approval
  - Annual project review required
Every person who wants to conduct research at the VA must register with the Research Administration Office
- RDIS – VA database of all researchers and research projects

A person may be approved to conduct research if:
- Employment status verified (VA paid or WOC)
- Passes background check and education verification
- Is credentialed (Vetpro), if possess (or are eligible for) a clinical license
- Takes required trainings
  - CITI (VA’s includes GCP), Information/Cyber Security, Privacy Awareness (all required annually) – other trainings may apply
- Completes a Scope of Practice
Personnel:
Scope of Practice

- Scope of Practice lists 15 categories of research duties
  - The PI and study staff sign it and ACOS/R approves it
- Scope sets forth the things a person can do on a study, including:
  - Obtain consent
  - Access VA data
  - Perform research activities (e.g. blood drawing)
- Research staff & duties are listed on a delegation log for each study
  - Audit of projects include ensuring personnel have an approved Scope and they are functioning within the duties listed on the scope
VA Research Project

- Submit project in VA electronic system – RDIS
  - Research must support the VA mission; benefit veterans

- Approval of project by R&D Committee
  - Cannot approve until project receives IRB approval
  - R&DC meeting – 3rd Wednesday of the month
    - Scientific subcommittee approval required before R&DC can approve the project
      - Scientific subcommittee meeting – 2nd Tuesday of the month

- Funding issues
  - Generally, each PI can only have 2 unfunded projects
  - If the project involves drugs, laboratory tests, imaging – there needs to be research funds to cover these
For projects funded by awards/contracts with to a Stanford PI, there needs to be a mechanism to get money to the VA to cover the research activities conducted at the VA

- Think of the VA as a separate site, not an extended SU site

- In the absence of a sub-award, subcontract or service agreement, etc to cover the VA’s involvement (costs, indemnity, IP, adverse events and data sharing), the VA cannot participate in these studies

- VA and SU can each have separate contracts with a sponsor for the same study
VA and SU:

Industry Sponsored Projects:

- If both SU and VA have separate contracts with the sponsor for the same study and the entire study will take place independently at VA and SU, then you need to have two separate IRB applications:
  - One for the SU PI and one for the VA PI
  - Generally, there is no exchange of data between various study sites, but between sites and the sponsor or CRO
  - Different contract terms
  - Different adverse event reporting obligations to the IRB
  - Different enrollment rates, one site could complete enrollment before the other

- Should have only one IRB, if parts of the study are at both SU and VA, but separate sponsor contracts with SU and VA:
  - List both contracts in the Funding section of eProtocol – one through PAIRE and other SU (this will be rare)

Multi-site Projects

Collaboration
eProtocol needs to cover the entire project, include both VA and SU specific issues

Indicate in the procedures section what procedures will take place at the VA and SU

Privacy and confidentiality section needs to account for storage and sharing of data between the VA and SU

Continuing review, needs to account for status of entire study; including enrollment at the VA

Separately list number of people enrolled at the VA
VA-SU Collaborations: HIPAA
Sharing Research Data Outside the VA

- VA and Stanford are two separate covered entities from a privacy (HIPAA) standpoint
  - To share identifiable data/specimens with Stanford for research purposes, you need the participant’s permission via a signed HIPAA authorization that:
    - Lists SU as an entity who will get the data/specimens
    - Data to be shared is listed in the authorization
  - In the absence of a signed authorization, only de-identified data/specimens can be shared outside the VA as part of a collaborative project
    - Privacy Officer review and approval is needed, which is part of the R&D approval process
VA-SU Projects: Data Sharing with SU
VA Consent/HIPAA Template

- Consent form; include something like the following:
  - *This study is being done together by investigators at Stanford University and Palo Alto VA*

- HIPAA authorization:
  - List VA PI and VA research staff as persons who may use and share data that is collected
  - List Stanford collaborating investigators and research staff and Stanford University as persons/entities who may receive, use and share data received by the VA
    - Keep as general as possible, don’t list individual study staff – this allows new staff to have access to the information
VA-SU Projects: Separate VA and SU Consents?

- Ideally, the VA consent should only include the procedures that will be done at the VA or by VA personnel
  - Consent should note what procedures will be performed at SU and by SU personnel and that the participant will be asked to sign a separate SU consent to cover those procedures
  - The risks associated with the procedures to be done at SU will be considered
- One consent must include the procedures and risks for entire study
All VA sensitive research data must be stored appropriately:

- Electronic data stored at the VA must be on a VA approved computer
  - You cannot use your personal or Stanford laptop at the VA, unless it has been approved for use here by the ISO

- Only VA issues thumb drives can be used
  - Cannot use other non-VA approved removable storage devices (i.e. hard drives, iPod, iPhone, USB connected devices)

- Paper data must be subject to double lock storage (locked cabinet in a locked room)
Now for the good news!

VA Recruitment Assistance

- VA colleagues can assist in informing their patients about a Stanford study
- **No VA project is needed** provided recruitment is limited to the following during a clinical interaction at the VA:
  - Informing prospective subjects about the availability of the research;
  - Provide prospective subjects with information about the research (which may include a copy of the relevant informed consent form) but do not obtain subjects’ consent for the research or act as representatives of the investigators;
    - Cannot post a flyer at the VA for non-VA research
  - Provide prospective subjects with information about contacting investigators for information or enrollment;
  - and/or
  - Seek or obtain the prospective subjects’ permission for investigators to contact them
So...if you only want VA patient referrals....

- You don’t need a VA project (if recruitment is limited to information in prior slide)
- In eProtocol
  - Do not check VA in the Study Location section
  - Answer no to all the VA questions in the General Checklist
    - The recruitment question is for VA only projects
  - Include in eProtocol question 8(g) that participants will be identified at the VA by colleagues and referred to the SU investigators for possible enrollment

Remember: None of the study can take place at the VA if you go this route
VA Research: Prohibitions and Waivers

- **Alteration of Authorization** is not permitted
  - As part of a request for a waiver of consent documentation for (oral consent), request a full waiver of authorization (not an alteration)
  - The IRB may request you still present the authorization elements orally or in writing

- **Tissue banking at for-profit institutions** (i.e. industry sponsors) is not permitted
  - Can bank samples at a non-profit institution (i.e. Stanford) with a waiver from VA Central Office

- Research involving children and international research are not permitted unless a waiver from VA Central Office is granted
FAQs

- The participant’s veteran status does not dictate the type of consent to be used
  - VA consent should only be used when VA staff consents a participant for a VA study
    - Many veterans do not receive health care from the VA – if encounter a veteran at a SU clinic, use a SU consent to enroll participant, even if for a SU-VA study and separate SU and VA consents

- A VA PI can obtain consent from a participant with a VA consent while at Stanford
  - We consider this activity is being done on VA time

- A SU-VA clinician can inform their VA clinical patients about a SU only study that the PI may be involved in at SU
Questions?