Research at the SF VA Healthcare System

Special Considerations for Conducting Clinical Research at the SFVAHCS

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Research at the SFVAHCS

The San Francisco Veterans Affairs Health Care System (SFVAHCS) has an institutional affiliation with UCSF and provides researchers access to additional research opportunities. The UCSF IRB is the IRB of record for SFVAHCS, but there are additional requirements to obtain permission to conduct research at the VA. While SFVAHCS and UCSF are affiliated institutions, they are separate legal entities.

National VA Policy (new revision published January 7, 2019): VHA Directive 1200.05 [2] is

the national policy that describes the requirements for the protection of human subjects in VA research. Please review this policy if you are interested in engaging VA in your research project.

When is VA Approval Required?

VA research is research that is conducted by VA investigators (serving on compensated, WOC , or Intergovernmental Personnel Agreement appointments) while on VA time. If you wish to enroll patients at the VA, or use VA personnel, facilities or medical records, you must secure prior approval of the SFVAHCS Research & Development Committee (R&DC).

Please complete this form [3] for UCSF research projects where SFVAHCS is an administrative site only. SFVA is considered an administrative site if no VA patients or employees are enrolled, no identifiable data or specimens are collected from or used at SFVAHCS, and no VA funding is used. This also applies when local VA resources such as SFVAHCS property, office/la, computer, server, or email are used, and/or VA time is used.

Note: If you *only* wish to inform VA patients about a non-VA study by posting/distributing recruitment materials on the premises of a VA facility, R&DC approval *may not* be required. Please consult the VA Clinical Research Office to discuss how this can be approved.

How to Apply to the VA and Required Forms

On the IRB Study Application, check ?SF VA Medical Center (SF VAMC)? under UCSF and Affiliated Sites and ensure that all VA-specific sections of the Application are completed. Note that the **VA Research Data Privacy and Security (RDSA) Form** is no longer required.
If you ?are not affiliated with SFVAHCS, you will need to identify a SFVAHCS-approved PI who will be responsible for the conduct of the work at the VA.

The VA distinguishes between projects (a cohesive body of work usually tied to one major funding source) and protocols. Ensure that you submit the necessary forms for each, as you need ***protocol*** approval before VA R&D Committee ***project*** approval will be granted.
You cannot begin a new research project without a signed ACOS/R&D letter giving you authorization to do so.

SFVAHCS Forms (for all new PROJECTS):

- **Request for R&D Approval (aka ?pink sheet?) [4]:** List all the protocols attached to this funding source. You must obtain your Service Chief?s signature, but the Research Office will obtain the ACOS signature once the project has been approved.
- **Research Protocol Safety Survey (RPSS) [5]:** Used to identify which VA research subcommittees or workgroups must review and approve the project. Here are instructions for completing the RPSS [6].

SFVAHCS Forms (if applicable for a given protocol):

- **Consent form 10-1086 template [7]:** This document is just the header and footer. For content, refer to UCSF consent form guidelines and suggested wording. All consent forms and verbal consent scripts must contain the required elements of consent as described in VHA Directive 1200.05 [8]. You may use the VA Informed Consent checklist [9] as a guide.

Please include the following in the VA consent form:

SFVAHCS-approved PI?s name in the template header field: You may include the UCSF PI name, if different, in the text of the VA consent form. ?

All consent forms must include a person to contact in case of research-related injury, and a statement that VA will provide treatment for research-related injury in accordance with VA regulations.

- If the study is greater than minimal risk, include the VA treatment and compensation for research-related injury paragraph (updated March 2018).

For greater than minimal risk studies, this paragraph must be used verbatim in the VA consent form:

If you are experiencing a medical emergency, please call 9-1-1. If you incur an injury or illness as a result of being in this study, the Department of Veterans Affairs (VA) will ensure that treatment is made available at a VA medical facility or non-VA facility, as appropriate. If you were following study instructions, the costs of such treatment will be covered by the VA or the study sponsor (if applicable). If you were NOT following study instructions, the costs of such treatment may be covered by the VA or the study sponsor (if applicable) or may be billed to you or your insurer just like any other medical costs, depending on a number of factors. The VA and a study sponsor do not normally provide any other form of compensation for injury or illness. For further information about this, call the study team at the number(s) provided.

When to use a VA consent form

Examples of when a VA consent document must be used:

- The study for which you are obtaining informed consent has VA funding of any type (including, but not limited to Career Development Awards, Merit Review Awards, Cooperative Studies Program). You must use the VA consent form for VA-funded studies even when informed consent is obtained at UCSF or other outside (non-VA) site.
- An individual from whom you are obtaining consent was identified by reviewing VA records (medical or research) and/or screened for study eligibility and consented at VA, but sent to UCSF for all subsequent study procedures. Note the participant *may need to sign both* VA and UCSF consents.
- Study procedures are conducted at both the VA and UCSF?participant signs a VA consent and a UCSF consent (if such is required by UCSF).
- VA or NCIRE employees (on their VA or NCIRE time) go to UCSF to obtain informed consent from UCSF patients for VA studies.
- You (or your study staff) are on your VA time when you obtain informed consent from an individual on UCSF premises.
- The participant typically receives care at UCSF, but you are seeing him/her at the VA for a study procedure (including obtaining informed consent).
- Informed consent is obtained at VA or on VA-leased property ? regardless of:
    - participant?s Veteran status

- the location(s) at which study procedures will be performed, or
- whether the individual obtaining informed consent is employed by VA, NCIRE, UCSF, or elsewhere. (Please note: Any individual who obtains informed consent on VA premises MUST be VA-employed or have WOC status.)

Examples of when a VA consent document mustNOT be used:

- VA clinician informs Veteran patient of a UCSF-based treatment study, then refers patient directly to UCSF study team and consent process is conducted at UCSF.
- All data is UCSF data (obtained either through direct interaction or records review) and the role of VA is limited to data analysis.
- Upon seeing a flyer recruiting for a UCSF-based study, a prospective participant contacts the UCSF study team and incidentally discloses that he/she happens to be a Veteran.

- **Authorization for Use & Release of Protected Health Information for Research Form (HIPAA form): [10] (Please open this document on Internet Explorer)** This VA form must be used for VA research subjects for which written HIPAA authorization is required. *SFVAHCS Privacy Officer must review and approve the VA HIPAA form for each study prior to implementation (this also applies to modifications to the HIPAA).* Upload the HIPAA form in Other Study Documents in iRIS?DO NOT upload in Consent Document section. If you have questions, please contact the VA Privacy Officer at v21SFCPOstaff@va.gov [11].
- **VHA Directive 1200.05 [2] Privacy Officer duties (Page 42) states:**

  If a study includes information covered under 38 U.S.C. 7332 (DRUG, ALCOHOL, HIV AND SICKLE CELL ANEMIA INFORMATION) that will be disclosed outside of VA, **the study must include written assurance from the VA researcher, e.g. within the protocol**, that the purpose of the data is to conduct scientific research and that no personnel involved in the study will identify, directly or indirectly, any individual patient or subject in any report of such research, e.g. manuscript or publication.

  38 U.S.C. Section 7332 makes all VA records that contain the identity, diagnosis, prognosis or treatment of VA patients or subjects for drug abuse, alcoholism or alcohol abuse, infection with human immunodeficiency virus (HIV/AIDS), or Sickle Cell Anemia strictly confidential. This statute applies to information regardless of whether it is recorded in a document or a Department record.

  PARTICIPATION OF NON-VETERANS AS RESEARCH SUBJECTS The following guidance applies to Non-Veteran participants *receiving clinical care or treatment* as part of the research. The following language must be included in the IRB Study Application when the study population includes non-Veteran subjects:

Please add the following language in the Inclusion Criteria section of the Study Application:

The recruitment of non-Veterans in VA research is not for the sake of convenience for this study. The objective and justification for enrolling non-Veterans in VA research is:_____. (for example, there are not enough Veterans available to reach the sample size needed to draw meaningful conclusions). Although non-Veterans subjects will be

recruited in VA research, we believe the results will be generalizable to the Veteran population. The approximate number of non-Veterans to be enrolled in VA research is _____.

Non-Veteran participants enrolled in VA research will be provided the VA Notice of Privacy Practices in accordance with VHA Handbook 1605.04 found here: http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/notice%20of%20privacy%20practices.pdf [12]

Include any of the following language applicable to this study:

[Required for greater than minimal risk studies] For VA research related injuries: For any non-Veteran injured because of participation in a VA research activity for this study, immediate care will be provided as described in the VA research consent form.

For a multisite study only: In this study it is/is not anticipated that any VA inpatient care will be needed however, we have made arrangements with the study site(s) for the provision of care if needed. The study budget was reviewed and funding will be reserved to accommodate the enrollment of non-Veterans in VA research.

For a DOD/VA joint study: Active duty will be recruited for enrollment in VA research and agreements are in place that all VA research related injuries of an active duty enrolled in this protocol will be treated (either inpatient or outpatient) by the DOD. In the event that an active duty person is within a VA medical facility when emergent care is needed, the emergency treatment will occur within VA until the subject is stabilized and then the active duty member will be transferred to the nearest DOD medical facility that is capable of caring for the injury/problem.

- **VA Investigational Drug Information Report (10-9012) [13]:** This form is required for studies involving investigational drugs. An investigational drug is defined as a new chemical compound, which has not been approved by the FDA, or an approved drug that is being studied for an approved or unapproved use, dose, dosage form, administration schedule, or under an IND application, in a clinical investigation. The 10-9012 must indicate who may prescribe the research medications and include any safety information that may not be available in published references. Please ensure this form is signed by VA PI, IRB Chair, and R&D Chair.
- VA Form 10-9012 is not required if package insert is available (i.e., for studies involving approved drug(s) being used according to its/their approved labeling). Authorized prescribers should be described as such in the key study personnel section of the Study Application

Study Application Guidance

Unless the research is conducted at VA only, the following sections of the IRB Application MUST dintinguish the VA vs non-VA research elements:

Inclusion/Exclusion Criteria

VHA Directive 1200.05 [8] requires explicit justification for including non-Veterans in VA research that involves VA outpatient or VA hospital treatment (e.g. research occurring at VA facilities). Include this information in the inclusion criteria of the IRB Application.

Qualifications of Key Study Personnel

Clearly distinguish VA personnel from non-VA in the Qualifications of Key Study Personnel section. Describe whether personnel will have access to identifiable VA data.

Study Procedures

Identify all research-related procedures to be conducted at VA. If any procedures are not being done at VA or any study populations are not included at the VA, describe in this section.

Recruitment

Distinguish which recruitment methods will be unique to the VA and which methods will NOT be conducted at the VA.

Confidentiality

Describe how VA data/specimens will be stored (e.g., de-identified, coded or identifiable), where data will be stored (e.g., VA server, UCSF server, Sponsor), and who will have access to the data. Specify whether non-VA personnel will have access to identifiable VA information. If you plan to transmit VA data outside the VA, describe how the data will be transferred (e.g., encrypted email) AND whether VA data will be combined with non-VA data. This information must also be included on the VA consent and VA HIPAA forms. Note that the complete record (original or copy) of all data obtained in VA research must be retained at VA.

Include the following verbatim in the Confidentiality section of the Study Application: **VA research records will be retained and disposed in accordance with the VHA Records Control Schedule (**RCS 10-1 [14]**).**

Research Records Storage. Refer to VHA Records Control Schedule (RCS 10-1) Section 8300.6 Research Investigator Files for research records maintenance. Contact the Research Office for assistance for off-site record storage.

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Review VHA Directive 1200.05 for specific requirements for conducting human research at the VA

In particular, please review the following paragraphs of VHA Directive 1200.05 [8] (version date January 7, 2019):

- 5g -- VA Investigators' Responsibilites
- 13 ? Collaborative Research

- 17 ? General Requirements for Informed Consent (refer to Informed Consent Checklist)
- 18 ? Documentation of Informed Consent
- 19 ? Research Involving Pregnant Women, Human Fetuses, and Neonates as Subjects
- 20 ? Research Involving Prisoners (restricted by the VA)
- 23 ? HIPAA Authorization

There are additional requirements in VHA Handbooks 1058.01 [15], 1200.01 [16],1605.1 [17], and 6500 [18] and SFVAMC MCM 11-19 [19]. Contact the SFVAHCS Clinical Research Office for assistance in interpretation of these policies.

Research pharmacy requirements

All investigational drugs and devices used at the SFVAHCS MUST be shipped directly to the VA Research pharmacy, not to the PI or study staff. If your research needs do not permit participants to obtain medications directly from the pharmacy, this should be addressed in your application. The pharmacy charges researchers a modest fee for its services; researchers are encouraged to discuss dispensing issues and fees with the research pharmacist before the budget is finalized.

When the study is conducted at SFVAHCS, the following additional obligations must be met by the researcher:

- Ensure the local Pharmacy Service or Research Service Investigational Pharmacy receives:
  - A copy of VA Form 10-9012 [13] (if applicable).
  - A copy of the consent document for each participating participant with all appropriate signatures.
  - Copies of Sponsor-related correspondence specific to the drug(s) if applicable.
  - Copies of all correspondence addressed to the Researcher from the FDA specific to the investigational drugs or devices if applicable.
- Inform the chief of pharmacy service, the research pharmacy when applicable, and the IRB in writing when a study involving investigational drugs or devices has been suspended, terminated, or closed.
- Comply with all documentation requirements and make relevant records accessible to the investigational drug pharmacist when requested.

VA employment or ?WOC? status required

All personnel working in research at the VA, including volunteers, must be paid by the VA or have completed a federal background check and have Worker Without Compensation (WOC) status. These personnel must be registered in the VA Research and Development Information System [20] (RDIS) which is only accessible behind the VA firewall.

VA-specific training mandatory for research staff, including residents and fellows

All research staff, including residents and fellows, must complete the following trainings which

are specific to the VA (UCSF training is not sufficient):

- **CITI Training** [21] in the protection of Human Subjects?CITI account must be affiliated with **VA San Francisco, CA-662**. This training must be renewed every three years. Review the CITI FAQs [22] for more information.
- **VA Privacy and HIPAA**: Available online at VA TMS [23] training website. For TMS access, please contact the VA Clinical Research Office.
- The **Scope of Practice (in RDIS)** lists research duties delegated to research team members and may be signed only by the VA PI. Access to the VA?s electronic medical record (CPRS) must be indicated in the Scope of Practice along with the level of access requested (read-only or read/write).

VA Privileges required for Research Personnel

Licensed practitioners must have appropriate privileges from the VA?s Professional Standards Board or Nurse Credentialing Committee prior to working on research or prescribing research medications at SFVAHCS.

Adverse Events/Incident Reports/Unanticipated Problems: VA has a shorter timeline (5 days) and different definitions for reporting

The VA has a shorter timeline (5 business days) and different definitions than UCSF for reporting certain categories of post-approval events. See VHA Handbook 1058.01 [15] for specific examples. Please consult with the VA and review the following VA decision charts to determine if your adverse event report or protocol violation or incident needs to be reported to the IRB.

- Examples and Reporting Guide for Apparently Serious or Continuing Noncompliance in VA Human Research [24]
- Decision Chart for Reporting Local Deaths, SAEs, and Serious Problems Involving Risk in Research [25]

Note: The VA requirements dictate that some types of *apparent* serious or continuing noncompliance be reviewed at a convened IRB meeting for determination of whether they constitute *actual* serious or continuing noncompliance. See section 6.f [15] in VHA Handbook 1058.01.

Reporting privacy/information security incidents

- For privacy incidents, email the VA Privacy Office at v21sfcpostaff@va.gov [26] or call 415-750-2135. For data security incidents, email the VA Information Security Office at v21sfcpostaff@va.gov [26].
- If the privacy or data incident also involves UCSF participants, contact the UCSF Privacy Office, 415-353-2750

- **Monitoring of research:** All outside monitors must register with VA Police Services for

a badge, check in with the Clinical Research Office [27] and file a brief report before they leave.

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Source URL: https://irb.ucsf.edu/research-sfvamc

Links
[1] mailto:v21SFCHRPP@va.gov
[2] https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171
[3] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/ucsf%20studies%20using%20SFVAMC%20resources%209-22-2016%20%28Non-engaged%29.pdf
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[26] mailto:v21sfcpostaff@va.gov
[27] https://irb.ucsf.edu/research-sfvamc#contact