SFVAHCS local guidance for reliance on commercial IRBs

Initial Review Submissions

Commercial IRBs SFVAHCS can rely on (as of 3/10/2021):

1. Western Institutional Review Board (WIRB)-Copernicus Group (WCG)
2. Advarra

The sponsor selects the commercial IRB to use, not VA. If the sponsor has selected a commercial IRB not listed above, please contact HRPP (V21SFCHRPP@va.gov) to discuss options.

The sponsor will also have to pay the commercial IRB directly for the review of our VA site. VA and NCIRE cannot pay them.

The VA Facility site liaisons to the commercial IRBs are Gregory Green (Gregory.Green@va.gov) and Jennifer Ransom (Jennifer.Ransom@va.gov). The UCSF IRB does not have a role in this arrangement. Therefore, there is no need to submit anything via iRIS.

There are three main steps to project approval: 1) VA pre-review, 2) commercial IRB protocol approval, and 3) R&D Committee project approval.

Documents needed for pre-review:

1. IRB Study Application, including application for waiver of HIPAA authorization (if applicable)
    a. These forms will likely be provided to you by the sponsor, especially if VA is not the lead/coordinating site.
    b. If not provided by the sponsor, please visit WIRB Forms (HRP-212 and VA Addendum to Initial Review Form) or follow the Advarra IRB Instructions to set up an account and use their website to generate the forms.
2. VA consent form (on the sponsor's template w/ VA language added). For both the consent form and HIPAA authorization, please review this ORPP&E guidance to ensure that both documents are in compliance before requesting pre-review.
3. VA Form 10-0493 (stand-alone VA HIPAA Authorization, unless you are using a combined consent/HIPAA authorization form) **Note:** Authorization language may only be combined with the informed consent to be approved by the IRB if both conditions are met:
    a. No optional banking of identifiable data or biospecimens is involved, and
    b. The IRB does not approve the use of subject's legally authorized representatives (LARs) to consent for the subject.
4. VA Facility Commercial IRB endorsement letter (completed but not signed)
5. VA Form 10-250 (research privacy review checklist; page 1 completed only)
6. Enterprise Research Data Security Plan (ERDSP)
7. Research protocol

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VA pre-review

1. Email all of the documents above to the HRPP mail group (V21SFCHRPP@va.gov) with the subject "**Request for commercial IRB submission pre-review – [PI LAST NAME]**"
2. Once all documents are received, HRPP will coordinate the pre-review with the Privacy Officer (PO) and Information Systems Security Officer (ISSO).
3. HRPP will send back any pre-review comments. Once all comments are addressed, please re-send the corrected documents to HRPP.
4. HRPP will confirm that the comments are addressed and obtain the signature on the VA Facility endorsement letter and send back to you.

Note: Work with the sponsor to determine who will submit documents to the commercial IRB.

Commercial IRB approval

5. You or the sponsor submits the pre-reviewed documents to the commercial IRB—do not submit R&D Committee forms to the IRB.
    a. WIRB submission website: https://gov.irbnet.org/
    b. Advarra submission website: http://www.cirbi.net/
6. Once the commercial IRB approves SFVAHCS's site documents, forward the approval letter and documents to HRPP (V21SFCHRPP@va.gov).
7. HRPP will obtain the final PO and ISSO reviews and clear the study for R&DC approval.

R&DC Project Approval

8. As with any other project, submit the Request for R&D Approval form (pink sheet) and Research Protocol Safety Survey (RPSS) to the appropriate Grants Manager. If enrolling non-Veteran subjects at SFVAHCS, include the Request for Non-Veteran Approval Form and send a copy to V21SFCHRPP@va.gov.
9. The Grants Manager will send the project for SRS and any other required sub-committee review(s).
10. You will receive a signed ACOS memo when the project is approved, at which point you may begin working on the project.

UCSF IRB Acknowledgement:

If UCSF (including the UCSF CTSI site located at SFVAHCS) or ZSFGH are also sites for the research, you will also need to submit an initial review submission to the UCSF IRB through iRIS and indicate in the Study Application that you wish to rely on a commercial IRB. The UCSF IRB will provide an acknowledgement letter.

Additional information about the commercial IRBs can be found on ORPP&E's Single IRB website.