UCSF IRB

Initial Review Submission Checklist

Please include all applicable items in the designated sections of the **Initial Review Submission Packet**, which automatically appears after you complete the IRB Application. You may see the following sections in the Initial Review Submission Packet:

- Initial Review Submission Packet,
- IRB Application Form (in which the application you just completed will be attached),
- Consent Documents,
- Other Study Documents and
- VA Forms.

Initial Review Submission Packet, Section 1.9:

☐ Notes on difficult ethical issues, special considerations for review or requests for special handling (*optional*)

Consent Documents Section:

☐ Consent form, including any parental consent forms
☐ Assent form
☐ Information sheet and/or verbal script
☐ VA-specific consent form

Reminder: For each consent form, include at least a 1.25" top margin and no text in the upper right-hand corner.
Do not submit the Experimental Subject's Bill of Rights.

Other Study Documents Section:

☐ Tables, charts, diagrams referenced in the IRB Application – paste these items into a Word document(s) and reference the attachment in the relevant application section(s).
☐ Sponsor's or multicenter protocol
☐ Scientific protocol for greater-than-minimal-risk-studies that don't have a sponsor's or multicenter protocol
☐ Investigator's drug/device brochure
☐ HIPAA authorization form (UCSF, SFVAMC or other) if HIPAA authorization is required
☐ Recruitment materials, including copies of ads, notices, flyers, etc.
☐ Telephone scripts
☐ Pamphlets and study handouts
☐ Questionnaires and survey instruments (excluding standard questionnaires, such as the PHQ-9)
☐ Focus group or interview guides
☐ Federally funded studies only: Human Subjects section of grant, proposal or progress report
☐ Data collection sheets
☐ IRB approval letters and/or letters of support from collaborating or cooperating sites
☐ Letter of support from the patient care manager if study takes place on a patient care unit (not VA, ZSFG or CRS)
☐ If the PI is a Postdoctoral Fellow, Clinical Fellow or Resident: a letter of support from the Faculty Advisor

VA Documents Section (if applicable):

Current versions of the forms are available on the Research at the SFVAMC webpage or by clicking on the Help icon in iRIS. The uploaded VA forms must be signed.

Additional Information

Research at ZSFG: If you are enrolling patients at ZSFG or using ZSFG personnel, resources, facilities, or data, submit the ZSFG Research Protocol Application directly to the Vice Dean's office – do not attach this form in iRIS.

Univ. of California IRB Review Reliance and Other IRB Reliances: Register all UC IRB reliance requests in the UCOP IRB Reliance Registry. If UCSF is the reviewing IRB, submit the PDF NOITR form generated by the IRB Reliance Registry in iRIS. Learn more about relying on other IRBs.