

**UCSF HRPP
Initial Submission Checklist**

| Before you start your submission: | |
|--|--------------------------|
| • Refer to the guidelines for levels of review and new study guidance before you start your submission. | <input type="checkbox"/> |
| • Ensure the Informed Consent document is on the current UCSF consent template | <input type="checkbox"/> |
| • Use the current UCSF Research HIPAA Authorization document | <input type="checkbox"/> |
| • If your research involves a Device, App, or other technology, please review: <ul style="list-style-type: none"> ○ Device and Technology Guidance ○ UCSF Device Checklist for determining what regulatory determinations your use of a medical device needs | <input type="checkbox"/> |
| • If research involves data sharing, please review the IT security risk assessment guidance . | <input type="checkbox"/> |
| • Ensure CITI training requirements are completed for all key research personnel | <input type="checkbox"/> |
| • Ensure the appropriate Contract and/or agreements are in place. | <input type="checkbox"/> |
| • The UCSF IRB strongly encourages enrollment of diverse participants. UCSF's Clinical & Translational Science Institute (CTSI) Participant Recruitment Program and the CTSI Integrating Special Populations Core offer tools, services, and consultations to support recruitment of underrepresented populations. For more information and to request a consultation, see: Bit.ly/UCSFORAGE | <input type="checkbox"/> |
| • Please use these redacted copies of well-prepared IRB applications (MyAccess login required) as a reference for how the application can be filled out, and as a guide to some of the different branching paths that the application can take for different types of studies. We will add to this library over time to include a greater variety of research models. | <input type="checkbox"/> |

All study materials must be submitted in iRIS. For new studies, fill out the IRB application form in iRIS. Once the application is completed, iRIS will automatically bring you to a form called “Initial Review Submission Packet.” This form prompts you to upload all the study materials needing IRB review (*e.g.*, consent forms, recruitment materials, HIPPA forms, etc.). Depending on the information you provide in the IRB application, the following sections may appear in the Initial Review Submission Packet:

- [IRB Application Form](#)
- [Consent Documents](#)
- [Other Study Documents](#)
- [VA Forms](#)

Here are the types of documents to include in each section, as applicable to your specific study:

| | |
|--|--------------------------|
| IRB Application Form (This will already be attached to the Initial Review Submission Packet) | |
| Consent Documents* | |
| • Consent Form, including any parental consent forms | <input type="checkbox"/> |
| • Assent form | <input type="checkbox"/> |
| • Information sheet and/or verbal script | <input type="checkbox"/> |
| • VA-specific consent form | <input type="checkbox"/> |
| <p><u>Reminder</u>: 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.</p> | |
| Other Study Documents* | |
| • 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). | <input type="checkbox"/> |
| • Sponsor's or multicenter protocol | <input type="checkbox"/> |
| • Scientific protocol for greater-than-minimal-risk-studies that don't have a sponsor's or multicenter protocol | <input type="checkbox"/> |
| • Investigator's drug/device brochure | <input type="checkbox"/> |
| • HIPAA authorization form (UCSF, SFVAMC or other) if HIPAA authorization is required | <input type="checkbox"/> |
| • Recruitment materials , including copies of ads, notices, flyers, etc. | <input type="checkbox"/> |
| • Telephone scripts (note: these are not verbal consent documents) | <input type="checkbox"/> |
| • Pamphlets and study handouts | <input type="checkbox"/> |
| • Questionnaires and survey instruments (do not submit standard instruments unless they are revising the standard instrument) | <input type="checkbox"/> |
| • Focus group or interview guides | <input type="checkbox"/> |
| • Determination Letters and/or letters of support from collaborating or cooperating sites' IRBs or appropriate officials as applicable. | <input type="checkbox"/> |
| • Letter of support from the patient care manager if study takes place on a patient care unit (not VA, ZSFG or CRS) | <input type="checkbox"/> |
| • If the PI is a Postdoctoral Fellow, Clinical Fellow or Resident : a letter of support from the Faculty Advisor | <input type="checkbox"/> |
| • If available, approval letters from ancillary review committees (e.g. Radiation Safety Committee/Radiation Drug Safety Committee, Laser Safety Committee, Protocol Review Committee, Site Committee) (Note: Ancillary review can occur concurrently with IRB review; however, final IRB approval is contingent on receiving documentation of approval from ancillary review committees.) | <input type="checkbox"/> |
| • <i>If applicable</i> , documentation of the IND or IDE (e.g., study may proceed letter from the FDA, IND or IDE number noted on a sponsor protocol or letter). | <input type="checkbox"/> |
| • <i>If applicable</i> , rationale for IND or IDE exemption status of any investigational drugs/devices or investigational uses of approved | <input type="checkbox"/> |

| | |
|---|--------------------------|
| drugs/devices (e.g., completed checklists, FDA or sponsor correspondence, etc.) <ul style="list-style-type: none"> • IND Worksheet • Investigational Device Checklist | |
| <ul style="list-style-type: none"> • <i>If applicable</i>, compliance with General Data Protection Regulation (GDPR) | <input type="checkbox"/> |
| VA Forms (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. | <input type="checkbox"/> |

*[Translating Study Documents](#): Certified translations are **required** for all Greater than Minimal Risk Studies. Certified translations are **encouraged** for minimal risk studies, but not required by the IRB.

Additional steps to take if the following scenarios apply:

- Special processing/information
- Research at ZSFG/SFDPH
- University of California IRB Review Reliance and Other IRB Reliances

| | |
|---|--------------------------|
| Initial Review Submission Packet “Special processing instructions or information about the submission” Section | |
| Complete this section of the Initial Review Submission Packet if you want to notify the IRB of difficult ethical issues, special considerations for review, or requests for special handling <i>e.g.</i> , NIH JIT, student research projects (<i>optional</i>) | <input type="checkbox"/> |
| Research at ZSFG/SFDPH | |
| Research at ZSFG/SFDPH: Review this link for more information and contact information for SFDPH questions. | <input type="checkbox"/> |
| University of California IRB Review Reliance and Other IRB Reliances | |
| All requests to rely on UCSF’s IRB must be submitted using the form(s) found here prior to submitting to the IRB: https://irb.ucsf.edu/when-ucsf-can-serve-irb-record . You will receive all instructions to set up the reliance after you receive a consultation. Most reliances will be set up as modifications after the initial approval. We will inform you when an exception to this process is allowed. | |