UCSF IRB Initial Submission Checklist

Before you start your submission	
• Read new study guidance	☐
• Determine level of review	☐
• Review IRB Submission Standards	☐
• Use the current UCSF informed consent template and Companion Document to create the informed consent document	☐

• If the study involves a Device, App, or other technology:
  ○ Read Device and Technology Guidance
  ○ Complete UCSF Device Checklist to determine if it's a medical device, and if so, IDE Exempt, Non-significant Risk or Significant Risk
  ○ Contact UCSF FDA Regulatory Support for a free consultation
	☐

• If the study involves radiation, submit to the Radiation Safety Committee (RSC). Review these RSC instructions	☐
• If the study involves data sharing, review the IT security risk assessment guidance	☐
• Ensure CITI training requirements are completed for all key studypersonnel	☐
• Ensure the appropriate Contract and/or agreements are in place	☐
• 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/UCSFRAGE	☐
• Review 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.	☐

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, HIPAA forms, etc.). Depending on the information you provide in the IRB application, the following sections may appear in the Initial Review Submission Packet:

- Study Application
- 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 Study Application Form (This will already be attached to the Initial Review Submission Packet)	
Consent Documents*	
• Consent Form, including any parental permission 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*	
Note: Some types of documents are not compatible with the iRIS system (*e.g.,* password-protected, XML code). Follow this guide before submitting your study: Other Study Documents: Check for (and Fix) Corruptible Files	
• 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).	☐
• Scientific protocol for greater-than-minimal-risk-studies and studies where UCSF will be reviewing for other sites	☐
• Investigator's brochure for drug or device	☐
• HIPAA authorization form (UCSF, SFVAMC or other) if HIPAA authorization is required	☐
• Recruitment materials, including copies of ads, notices, flyers, etc.	☐
• Telephone scripts (note: these are not verbal consent documents)	☐
• Pamphlets and study handouts	☐
• Questionnaires and survey instruments (do not submit standard instruments unless they are revising the standardinstrument)	☐
• Focus group or interview guides	☐
• Determination Letters and/or letters of support from collaborating or cooperating sites' IRBs or appropriate officials as applicable.	☐
• 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	☐
• 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.)	☐

• *If applicable*, 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). • *If applicable,* rationale for IND or IDE exemption status of any investigational drugs/devices or investigational uses ofapproved drugs/devices (e.g., completed checklists, FDA or sponsor correspondence, etc.) • IND Worksheet • Investigational Device Checklist	☐
• *If applicable*, compliance with General Data Protection Regulation (GDPR)	☐
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.	☐

*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 *e.g.,* NIH JIT, student research projects (*optional)*	☐
Research at ZSFG/SFDPH	
Research at ZSFG/SFDPH: Review this link for more information and contact information for SFDPH questions.	☐
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.	☐