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New Study

Before Submitting to the IRB

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Before Submitting to the IRB

Prior to submitting to the IRB, answer these questions.

Step 1. Does your research require IRB review?

Confirm that the proposed study is human subjects research ^[1] and needs IRB review. If your study needs IRB review, consider what level of review ^[2] it may require ? that is, full committee review, expedited review or exempt certification.

Step 2. Are you eligible to serve as PI?

The PI must be a UCSF faculty member who meets the eligibility requirements for PI status on grant applications [3]. Postdoctoral fellows, clinical fellows and residents are allowed to serve as PIs if certain conditions [4] are met. Students cannot serve as PI. See the PI eligibility section [4] for more info.

Step 3. Have you reviewed IRB guidance about your type of research?

There are special considerations for different types of research projects [5], such as those that involve:

- Social or behavioral research [6]
- Investigational drugs, biologics [7] or devices [8]
- Medical record reviews [9]
- Human biological specimens [10]
- Emergency setting research [11]
- Vulnerable populations [12]
- Human gene transfer/recombinant DNA [13]
- NIH Genomic Data Sharing (GDS) policy and Genome-Wide Association Studies (GWAS) [14]

Please review the IRB guidance while designing your study to ensure compliance.

Step 4. Does your research also require review by other committees or groups?

Depending on the location and type of your research, your study may require review or consideration by these committees/groups at UCSF or its affiliated institutions in addition to IRB review. **This is not an exhaustive list.** Your study also may require review by other groups and/or registration on ClinicalTrials.gov [15].

Some of these groups review the study before the IRB, while others will review it concurrently or after IRB approval. Please familiarize yourself with the group's review requirements, and contact the group directly with questions.

Committee or Group	Timing of Review
Conflict of Interest Advisory Committee [16]	Conflicts must be reviewed and approved before funding can be accepted and the research can begin.
CTSI Clinical Research Services (CRS) Advisory Committee [17]	Submission is routed to CRS via iRIS for scientific review before IRB review. Submit some forms directly to CRS.
Helen Diller Family Comprehensive Cancer Center Committees [18]	Approval is required prior to final IRB approval for cancer-related protocols. Attach the Cancer Center Protocol Review Committee (PRC) review in the Other Study Documents section in iRIS.

Patient Care Manager(s) ?Letter of Support [19]	Submit this letter with your IRB Application if the study takes place on a patient care unit. For more info, see the IRB Application and "Research on Patient Care Units" Medical Center policy [20] (see the HUB [21] for help accessing this site). Exceptions: Research at CRS sites, SFGH and SF VAMC.
San Francisco Department of Public Health (SFDPH) [22]	Review occurs before IRB review. SFDPH sites and clinics must adhere to the SFDPH HIPAA Policy [23], involve an SFDPH-approved investigator [22] and submit a signed SFDPH Research Proposal Approval [24].
San Francisco VA Medical Center Research and Development (R&D) Committee [25]	Study undergoes concurrent review. A copy of the initial submission is emailed to the R&D Committee via iRIS, but the R&D Committee reviews the study outside of the iRIS system. Include the required VA forms [25] in the Other Study Documents section in iRIS.
Zuckerberg San Francisco General Hospital and Trauma Center (formerly SFGH) [26]	PI submits directly to the Vice Dean's Office [26] after IRB approval.

Other UCSF Regulatory Committees:

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| <ul style="list-style-type: none"> • Animal Care and Use Committee [27] • Controlled Substance Program [28] • Institutional Biosafety Committee [29] • Radiation Safety Committee [30] • Radioactive Drug Research Committee [30] | <p>Concurrent review is allowed, but the IRB will not grant final approval until the other committee has issued an approval. Ideally, provide the relevant approval number on the initial IRB Application.</p> |
| | <p>Additional info is available in a help bubble in "Other Approvals and Registration" section of the IRB Application in iRIS.</p> |

More info on scientific or scholarly review of human research studies

Effective, June 15, 2015, UCSF PIs are no longer required to obtain scientific/scholarly review or feasibility analysis prior to submitting a research project to the IRB, unless it is required by the PI's division, department or organization. Upon review, the IRB will determine if the study has adequate scientific merit to comply with the following regulatory criteria for approval of research (45CFR46.111):

- Risks to participants are minimized by using procedures consistent with sound research design and which do not unnecessarily expose participants to risk.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

The IRB may still request a scientific review if it is unclear whether a study has adequate scientific merit. In such cases, the PI will be referred to the Clinical and Translational Science Institute (CTSI) CRS Protocol Services ^[31] at UCSF for scientific review.

Important Note: The IRB strongly recommends that scientific or scholarly review be conducted before greater-than-minimal risk investigator-initiated study without external funding is submitted to the IRB. This review will help assure the quality of the IRB submission and reduce turnaround time for review and approval.

Researchers may also wish to contact the CTSI Consultation Services ^[32] for questions about study design and implementation, data management, biostatistics and scientific protocol development.

Division, department or organizational requirements

If the PI's division, department or organization require scientific review, below are some options for review:

External funding agency: Some external funding agencies conduct scientific review. A list of Funding Agencies that Conduct Acceptable Scientific Merit Review ^[33] is on the HUB.

If you wish to add another agency, please send an e-mail to IRB@ucsf.edu ^[34] and provide the name and address of the agency so that it can contact agency to inquire about its review process. If acceptable, the agency will be added to the list.

Internal scientific review committees: Committees include, but are not limited to the Comprehensive Cancer Center Protocol Review Committee (PRC), the Clinical Research Services (CRS) Advisory Committees, the Immune Tolerance Network (ITN) and the VAMC Clinical Research Subcommittee.

If an existing internal scientific review committee is not available, see below for guidance on establishing an internal scientific review committee.

Establishing an internal scientific review committee

An internal scientific review committee may be established within or among the department(s), division(s), organized research unit(s), or other appropriate groups. The following guidelines provide questions to consider when reviewing for scientific or scholarly merit. Please note that not all questions are relevant for every study and there may be additional questions to ask for any given study. The following are suggestions of what to consider.

Sound Scientific Basis and Rationale: Is the protocol scientifically sound and based on well-established scientific principles? Is there convincing clinical and/or preclinical evidence that the trial will have valuable results? Do preclinical studies demonstrate promising results regarding safety and potential efficacy? Is the technology/ understanding sufficiently advanced to warrant detailed clinical investigation?

Appropriateness of the Proposed Study Design: Are the primary and secondary objectives

scientifically sound? Is the study designed to meet the objectives? Has an appropriate study configuration been chosen? Does the protocol distinguish between standard and/or routine care and research? Are patient populations and associated criteria for inclusion/exclusion well defined? Are the sample sizes appropriate? Is the statistical design appropriate? Are the endpoints clearly defined?

Competency of Personnel and Adequacy of Proposed Resources: Does the principal investigator have the appropriate expertise and experience to conduct this study? Does the investigative team bring sufficient expertise to the project? Is there sufficient access to resources (e.g., appropriate personnel, equipment, facilities) for the successful and safe conduct of this study?

The Department or Collegiate Scientific Review Form ^[35] may be used to document the review, but do not submit it to the IRB.

These guidelines do not address administrative matters (i.e., how many people on a committee, who chairs, how to convey information to the researcher) for the Scientific Review Committee.

What, When and How to Submit via iRIS

What to Submit: You must complete an IRB Application in iRIS, as described below. Also submit and attach all applicable study materials listed on the **Initial Submission Checklist** ^[36], such as consent documents, advertisements, etc. Do not submit the checklist to the IRB.

Reminder: New greater-than-minimal-risk studies require a scientific protocol.

See the original announcement ^[37] for more info. This requirement affects you if your study meet the following criteria:

- Your new study (biomedical or behavioral) presents greater than minimal risk to study participants, AND
- Your study does not already have a study-specific scientific protocol from the study sponsor or cooperative group (e.g. industry-sponsored protocols, RO1 grants, investigator-initiated cooperative group protocols, and some funding grants that describe the scope of human subjects work).

When to Submit: There are submission deadlines ^[38] for studies that require full committee review ^[2]. We process expedited review ^[2] and exempt ^[2] studies on a rolling basis. See our Metrics page ^[39] for recent turnaround time data.

How to Submit: You will use the iRIS online application system to submit your new study and all subsequent submissions to IRB. Read the iRIS FAQs ^[40] and iRIS Accounts and Access page ^[41] for more info on the program. Technical assistance also is available by clicking on the Help icon in iRIS or at the iRIS Help website. ^[42]

1. Add a New Study in the IRB Study Assistant tab in iRIS

To submit a new study, click on the **Add a New IRB Study** link in the IRB Study Assistant tab iRIS. This will take you to the IRB Application.

2. Complete the IRB Application

The Application in iRIS is a smart form that builds and branches based on how you answer key questions. Click **Save and Continue to the Next Section** to progress through the Application. If you change any text boxes or radio buttons, click Save and Continue *through the rest of the sections* in case the change alters the branching. Most questions have help bubbles that offer guidance on how to respond.

Anyone with an iRIS account can fill out the IRB Application. However, you must be listed as an investigator, key study personnel or study contact in section 3 in order to access the study in iRIS later. Also, the PI must ultimately submit the new study.

3. Attach consent forms and other study documents in the Initial Review Submission Packet

After you complete the last section in the IRB Application, you will automatically enter the **Initial Review Submission Packet** after you save this section.

The Initial Review Submission Packet ^{?packages?} the Application and documents together for submission. If there are any special processing instructions, list them in section 1.8.

As you progress through the packet, you will see the IRB Application form you just filled out in section 2.0. You then will be prompted to attach a) consent documents (if applicable) and b) other study documents. Refer to the Initial Review Submission Checklist ^[43] for a list of items that should be attached.

If the study involves the San Francisco Veterans Affairs Medical Center ^[25], you also will be prompted to attach certain **signed** VA forms ^[25]. A copy of the submission will be emailed to the VA R&D Committee, but that review will be done outside of the iRIS system.

4. The PI must electronically **sign off** on the initial submission

PI signoff occurs by following these steps:

- a) PI verifies that he/she is eligible to serve as PI in the "Principal Investigator Eligibility Statement" section.
- b) Click Approve.
- c) Click Save Signoff.

d) Once the PI signs off and submits the study, you may expect the following confirmation notice via email (for expedited/exempt studies):

This email is confirmation that your Expedited/Exempt study was successfully submitted on {Date of Submission}:

IRB# xx-xxx

Study Title

Study Alias

Submissions are screened in the order of receipt.* An analyst will be assigned when your submission is next in the queue. If you do not see an analyst assigned when you click on ?Track Location? this means we are working on items received before your submission.

Please review the interactive tutorial [iRIS 101: Homepage Orientation & Finding your IRB Forms & Documents \[44\]](#) for instructions how to track your study and identify the IRB analyst.

The IRB does try to accommodate requests in the Special Processing Instructions area of the Initial Review Submission Packet Form, but this is not always possible.

*If you checked use of CRS services in the Sites section of the Study Application, the submission will be routed to the IRB after completion of CRS review and will be screened in the order of receipt to the IRB.

5. Respond to pre-review corrections within 3 weeks and post-review corrections within 45 days

You may receive a request from the IRB to make changes to your study during the pre-review screening process or after formal IRB review ^[45]. Review the **Responding to Stipulations in iRIS page** ^[46] for help with your response.

To speed new clinical trials to enrollment, you must respond to pre-review corrections for a new full committee review ^[2] study within 3 weeks. New study submissions will be withdrawn if a response to request for corrections is not received within 21 days. Post-full committee review changes will be due within 45 days. Receiving responses sooner will lead to faster study approvals.

The level of review ^[2] the study requires determines how the IRB reviews the study (e.g. full committee studies are reviewed at a regular IRB meeting, while expedited and exempt studies are reviewed by 1-3 IRB reviewers outside of a meeting).

Minimum Submission Standards and Study Preparation Tips

Poorly-prepared submissions negatively impact the review and approval times of well-prepared submissions by diverting disproportionate time and resources to a small fraction of submissions. Consequently, we implemented consistent minimum submission standards, which enables the IRB staff to focus on well-prepared applications, resulting in faster

approvals overall (read the original announcement ^[47]).

The IRB will return new study applications that are Incomplete or do not meet the Minimum Submission Standards. Studies that are returned will not be further processed by the IRB staff until the submission is received complete and meets minimum standards. The IRB will process revised submissions in order of the date on which they are resubmitted to the IRB.

Return criteria for the ?Incomplete? or ?Submission Standards Not Met? determinations

?Incomplete? Submissions

Submissions will be sent back as ?Incomplete? for the following reasons:

- Missing study protocol (as required or available). All greater than minimal risk studies must have a scientific protocol ^[37].
- Missing Human Subjects Section of your federal grant if UCSF is awardee institution
- Missing investigator?s brochure (if required)
- Missing consent documents or consent in the wrong format ^[48]

?Submission Standards Not Met?

Submissions will be sent back as ?Submission Standards Not Met? if significant issues/ambiguities are identified prior to IRB review. The most common issues include:

- Incomplete, incorrect or unreadable responses to the IRB form/application
- Major inconsistencies within or between documents (e.g., consent form does not match protocol)
- Important attachments ^[36] are missing that are needed for the review (e.g. recruitment materials, non-standard instruments, etc.)

New study preparation tips

Please follow the IRB's preparation tips below. The IRB highly recommends PIs log into iRIS to review submissions in their entirety BEFORE study staff route to them for signoff in iRIS. Once routed for signoff, the submission has to be retracted before any changes can be made.

IRB Study Application

- Provide the requested information in an easy-to-read summary of the study.
- As much as possible, avoid the use of jargon, define acronyms and provide context for uncommon procedures to help the IRB members quickly understand what the research involves and assess risk.
- Use care when sourcing information from the sponsor?s protocol ? some protocols are well written and brief while others include too much detail for the IRB review. Most content will need to be edited down.
- Proofread the entire application, checking for clarity, completeness and consistency throughout.
- If you started with a copy of another study, pay careful attention to ensuring that any remnants of the original study have been removed and replaced with details about the new study. Leftover references to procedures and risks from other studies are a

- common cause for confusion and return by the committee.
- Address any potentially controversial or ethical issues upfront.

Consent Documents

- Write the consent forms in UCSF's format [48].
- Use simple 8th-grade-level language [49].
- Define all medical and technical terms and acronyms [49].
- Do not alter the treatment and compensation for injury language [50] (see restrictions on changes).
- Proofread the consent forms carefully. The IRB will no longer ask you to fix typos.

Study Documents

- Use easy-to-interpret document names and categories so reviewers can quickly see what the document is.
- Proofread the attachments and make sure they are consistent with the IRB Application.

Before You Submit

- Review the Initial Review Submission Checklist [36] prior to submitting to make sure the submission includes all the required components.
- Proofread the submission to ensure there aren't inconsistencies between sections or between the application and attachments.

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Source URL: <http://irb.ucsf.edu/new-study>

Links

- [1] <http://irb.ucsf.edu/research-needing-irb-review>
- [2] <http://irb.ucsf.edu/levels-review>
- [3] <http://osr.ucsf.edu/content/pi-status>
- [4] <http://irb.ucsf.edu/research-needing-irb-review#eligibility>
- [5] <http://irb.ucsf.edu/guidance>
- [6] <http://irb.ucsf.edu/social-and-behavioral-research>
- [7] <http://irb.ucsf.edu/investigational-new-drugs-and-biologics>
- [8] <http://irb.ucsf.edu/investigational-devices>
- [9] <http://irb.ucsf.edu/medical-record-review>
- [10] <http://irb.ucsf.edu/research-using-human-biological-specimens>
- [11] <http://irb.ucsf.edu/research-emergency-settings>
- [12] <http://irb.ucsf.edu/special-consent-requirements-vulnerable-populations>
- [13] <http://irb.ucsf.edu/human-gene-transferrecombinant-dna-research>
- [14] <http://irb.ucsf.edu/nih-genomic-data-sharing-gds-policy-and-genome-wide-association-studies-gwas>
- [15] <http://hub.ucsf.edu/clinicaltrials.gov>
- [16] <http://coi.ucsf.edu/conflict-interest-research>
- [17] <http://accelerate.ucsf.edu/research/crs>

[18] <http://cancer.ucsf.edu/itr/itr-about-more>
[19] <https://ucsfpolicies.ucsf.edu/Nursing%20Manual/AdministrativePolicies/ResearchonPatientCareUnits.pdf>
[20] <http://ucsfpolicies.ucsfmedicalcenter.org/default.aspx>
[21] <http://hub.ucsf.edu/med-center-researcher-policies>
[22] <http://irb.ucsf.edu/ucsf-affiliated-institutions>
[23] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/dph-hipaa-compliance.pdf>
[24] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/dph-research-proposal-approval.pdf>
[25] <http://irb.ucsf.edu/research-sfvamc>
[26] <http://sfgh.ucsf.edu/protocol-applications-zsfg>
[27] <http://iacuc.ucsf.edu/>
[28] <https://ehs.ucsf.edu/controlled-substances-program>
[29] <https://ehs.ucsf.edu/IBC>
[30] <https://ehs.ucsf.edu/RSC>
[31] <mailto:crsprotocolservices@ucsf.edu>
[32] <http://accelerate.ucsf.edu/consult>
[33] <http://hub.ucsf.edu/funding-agencies-scientific-merit>
[34] <mailto:IRB@ucsf.edu>
[35] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/scientific-review-approval.doc>
[36] <http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/initial-submission-checklist.pdf>
[37] <http://irb.ucsf.edu/news/new-greater-minimal-risk-studies-require-scientific-protocol-starting-5115>
[38] <http://irb.ucsf.edu/irb-rosters-meeting-dates>
[39] <http://irb.ucsf.edu/irb-metrics>
[40] <http://irb.ucsf.edu/iris-online-application-system-info-and-faqs>
[41] <http://irb.ucsf.edu/iris-accounts-and-access>
[42] <https://iris-help.ucsf.edu/irb-iris>
[43] <http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/initial-submission-checklist.pdf>
[44] <https://courses.learning.ucsf.edu/?eCourse=347463>
[45] <http://irb.ucsf.edu/irb-review-process>
[46] <http://irb.ucsf.edu/responding-stipulations-iris>
[47] <http://irb.ucsf.edu/news/minimum-submission-standards-implemented>
[48] <http://irb.ucsf.edu/consent-and-assent-form-templates>
[49] <http://irb.ucsf.edu/consent-form-guidelines-and-suggested-wording>
[50] <http://irb.ucsf.edu/treatment-and-compensation-injury>