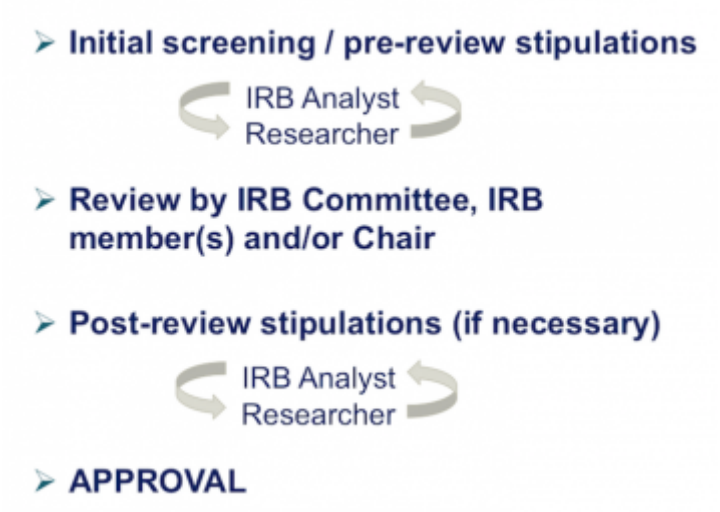
IRB Review Process

Review Process

The IRB office utilizes an initial pre-review screening process, during which an IRB analyst reviews each submission for completeness and compliance.

The analyst may ask the PI to make changes to the submission before it is reviewed by the IRB (pre-review). The IRB reviewer(s) may also ask for changes or clarifications, which the IRB analyst will communicate to the research team after IRB review (post-review). See Responding to Stipulations in iRIS [1] for more information.



Notes:

- New studies must meet minimum submission standard requirements [2] before they undergo the pre-review screening process.
- The number of IRB reviewers varies based on the level of review [3] the submission requires. Full committee review studies are reviewed by the IRB committee at a convened meeting, while expedited and exempt studies are reviewed by a small number of IRB reviewers outside of an IRB meeting.

Review Outcomes

One of the following review outcomes is applied to each IRB submission.

Approval Letter Is Issued and Study Can Begin

1. Straight Approval or Approval with Comments

- The criteria required by federal regulations for IRB approval have been met.
- Granted when the IRB has no questions about the submission.
- The IRB members may, however, make comments about this approval or recommendations for future submissions. Such comments will be included in the approval letter.

2. Approved with Comments That Must Be Addressed

- A submission approved with comments that must be addressed is an approved submission. However, issues outlined in the comments must be addressed before those items may be implemented.
    - Example 1: A survey under revision may not be administered to participants until the final version of the survey is approved.
    - Example 2: In a study where findings from the first arm of the study will inform some portion of the implementation of a second arm, the second arm may not be implemented until the associated issues are addressed.

Study Cannot Begin Until PI Addresses IRB Reviewer Concerns or Required Changes are Addressed by the PI and the Response is Approved by the IRB or the IRB Meets Its

Own Criteria for Review

The PI and study contact(s) will receive an email and task in iRIS that identify the review outcome. The Review Response Submission Form in iRIS will list the IRB's requested stipulations or comments (changes or clarifications). Review our tips for responding to post-review stipulations [1].

1. Revisions Requested

- The criteria required by federal regulations for IRB approval have been met, although specific, non-substantial revisions may be required. The IRB approves the submission in principle.
- The members require a written response from the investigator to directive stipulations or simple concurrences or specific non-substantive changes in the protocol and/or the recruitment and Informed Consent Documents.
- The investigator will be issued a Review Response Submission Form that will list the IRB's stipulations and comments [1].
- The investigator's response is normally reviewed by the Chair, another IRB member and/or qualified IRB staff, although the reviewer has the option of sending the response to the full committee or a select number of IRB members. Note that the IRB does not normally raise additional issues at the time of response unless, in rare cases, federal requirements or an important matter of human subject protection was overlooked.
- No approval letter is issued until the questions and/or concerns of the committee have been satisfactorily addressed and approved by the Chair or designated reviewer(s).

2. Returned to Full Committee for Additional Information

- The criteria required by federal regulations for IRB approval have not been met. The committee is not prepared to approve the submission without additional information and review.
- Requested when concerns are raised about the risk/benefit ratio or other federal criteria required for IRB approval (i.e., risks to subjects are minimized, selection of subjects is equitable provisions for monitoring collected data are adequate) or other issues of human subject protection. The members determine that additional information, justification, or changes are needed before approval can be reconsidered. The IRB members have explicitly asked that the submission be returned to full board for additional review.
- The investigator's response to the IRB's stipulations and comments will be reviewed by the full committee. Usually, the revised submission is granted contingent, conditional, or straight approval at the time of the second review. However, the submission may be returned again if the members request it.

3. Tabled

- Criteria for a convened full board meeting are not met (e.g., loss of quorum, or a required member is not present?VA representative, non-scientific member not present)

and/or appropriate expertise for a particular study (e.g., pediatrician) is not available at the meeting.
- Study will be reviewed at the next available full board meeting.

Study Cannot Be Approved by the UCSF IRB

1. Disapproved?

- The criteria required by federal regulations for IRB approval have not been met. The committee disapproves the submission in principle.
- Only the full board may disapprove a study. The IRB action to disapprove a study may not be overturned or reversed except by the IRB itself.
- Decided very rarely, disapprovals occur in one of two ways:
    - After multiple attempts (i.e., typically after two or more reviews) have been made to resolve the issues, the full board and the investigator reach an impasse. Though not required to attend a meeting, the investigator must be invited to present his or her justifications to the members before the project can be denied approval.
    - The study is disapproved outright because the full board determines that:
        - The research is unethical or inappropriate,
        - The resources to conduct the study are not available, and/or
        - The science is inadequate. In this latter case, the IRB may ask the PI to seek scientific review [2]and redesign the project which may then be resubmitted as a new study.

2. Denial of Review

- The IRB will not review the submission because the submission does not qualify as human subjects research [4] or the UCSF IRB does not have jurisdiction over the study.
- The IRB will issue a Denial of Requested Review letter on which the IRB will list the rationale for denying review of the submission.

Study Statuses ? The overall study has a status in iRIS. A description of these statuses is located in the iRIS FAQs [5]. After the study is submitted, the status is manually updated by the assigned IRB analyst.

Post-Approval Event Review Outcomes

The committee occasionally is asked to make determinations on post-approval events, including internal adverse events or protocol violations and incidents. The committee must determine if the event qualifies as one or more of the following:

- An unanticipated problem involving risk to participants or others
- Noncompliance
- Serious noncompliance
- Continuing noncompliance

More information about these determinations, the review process and reporting/submission

guidelines is available on the Adverse Event or Safety Information [6] and Protocol Violation or Incident [7] pages.

The IRB may request additional corrective action plans or request that the QIU conduct a directed site visit [8]. The committee may also suspend or terminate IRB approval, among other actions.

Conditions of Approval and Approval Documentation

Expiration dates

When applicable, an expiration date is clearly listed on the approval letter. More information on how the IRB calculates expiration dates is available on the Study Expiration Dates and Extended Approval Criteria page [9]. Although the iRIS system sends courtesy renewal reminders prior to the expiration date, it is the investigator's responsibility to keep track of the expiration date and initiate the continuing review [10] process sufficiently early.

Approval letters

The UCSF approval letters issued via iRIS are not signed by a member of the IRB. However, these letters and other available information comply with all regulatory requirements. Similar letters are in use at other institutions and the letters comply with past guidance we received from the Association for Accreditation of Human Research Protection Programs (AAHRPP). We will not issue separate letters complying with additional requests from sponsors.

The IRB approval letter does not list the items that were approved with the submission. Investigators can obtain a list of these items by following the instructions listed below.

iRIS a closed system and falls under FDA 21 CFR Part 11 (Electronic Records; Electronic Signatures).

We have additional information for sponsors about the UCSF Federalwide Assurance (FWA) [11] and IRB membership [12].

Approved versions of consent documents and other study document**s**

To obtain a list of documents that were approved with a particular submission, follow these steps: Go to My Studies and open the study ? Click on Submissions History ? Go to Completed Submissions ? Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study ? Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

Approval stamps on consent documents

Approved consent documents in iRIS will receive an approval stamp. To accommodate the stamp, each consent document should have at least a 1.25" top margin and the upper right-hand corner should be blank.

Other study documents will not receive an approval stamp.

Note: Prior to the implementation of iRIS in early 2010, the IRB did not stamp consent forms but instead listed the approved versions on the approval letter.

Page last updated:
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Links
[1] https://irb.ucsf.edu/responding-stipulations-iris
[2] https://irb.ucsf.edu/new-study
[3] https://irb.ucsf.edu/levels-review
[4] https://irb.ucsf.edu/not-human-subjects-research
[5] https://irb.ucsf.edu/iris-online-application-system-info-and-faqs
[6] https://irb.ucsf.edu/adverse-event
[7] https://irb.ucsf.edu/protocol-violation-or-incident
[8] https://irb.ucsf.edu/routine-site-visits-and-directed-investigations
[9] https://irb.ucsf.edu/study-expiration-dates-and-extended-approval-criteria
[10] https://irb.ucsf.edu/continuing-review
[11] https://irb.ucsf.edu/federalwide-assurance
[12] https://irb.ucsf.edu/irb-rosters-meeting-dates