



University of California
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Responding to Stipulations in iRIS

Stipulations, Comments and the Review Response Submission Form Revising the Submission Components

Making Unrequested Changes

Stipulations, Comments and the Review Response Submission Form

You may receive a request from IRB to make changes to your submission during the pre-review screening process or after formal IRB review ^[1].

To receive IRB approval in the shortest possible time, follow the guidelines below in preparing your response to the IRB's request for revisions or more information. For additional help, read the Submission Correct quick guide ^[2] (also available in the Help section of iRIS).

The PI and study contact(s) will receive a Review Response Submission Form in iRIS that lists the IRB's request for revisions or more information. If you do not respond to the request for submission corrections within the specified timeframe, the IRB will withdraw your submission.

Categories of Changes, Clarifications or Comments Requested by the IRB

Stipulations that must be addressed

Issues or revisions that need to be addressed before the submission can go forward in the review process and approval can be granted.

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.

Comments

Suggestions, comments, or observations that you may wish to incorporate, but do not necessarily require follow-up or action.

Filling Out the Form

Accept (or reject) the stipulation and describe how you addressed the stipulation

You will be asked if you accept each stipulation or comment ? e.g. do you agree to make the suggested change or provide the requested information? You must respond either Yes, No or N/A to each question. Then describe how you addressed the stipulation in the text box.

Provide rationale if you disagree with the stipulation

If you disagree with the IRB's recommendations and do not wish to make a certain change, provide rationale for not making the change. Without an explanation, the response will not be complete and approval may be delayed.

Make general comments about the response (optional)

If you have any general comments about the response, include them in the "Response Comments" section at the bottom of the form.

Revising the Submission Components

If you need to revise any portion of your study or submit new documents, you must attach the revised or new items. When revising consent forms or other study documents, do NOT highlight or track your changes.

See the the Submission Correct quick guide ^[2] (also available in the Help section of iRIS) for more information and screenshots. If you need additional help or have questions about the stipulations, contact the IRB analyst ^[3] assigned to the submission.

Reminder: Use standard treatment and compensation for injury consent form statement

If research-related injury is possible in research that is more than minimal risk ^[4], you must

include the standard Treatment and Compensation for Injury wording in the consent form [5] verbatim. Your response cannot be approved if different wording is used.

Making Unrequested Changes

If you want to make new *minor* changes to the study when responding to the IRB's comments, describe the modifications clearly and separately in the "Response Comments" section of the Review Response Submission Form.

New major modifications that were not requested by the IRB will require full Committee review, which will delay approval.

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Links

[1] <https://irb.ucsf.edu/irb-review-process>

[2] <https://iris-help.ucsf.edu/irb-iris>

[3] <https://irb.ucsf.edu/contact-us>

[4] <https://irb.ucsf.edu/levels-review>

[5] <https://irb.ucsf.edu/treatment-and-compensation-injury>