

IRB SUBMISSION LOG INSTRUCTIONS

PURPOSE

This log assists with the tracking and status of IRB submissions. It is used to record the dates the documents became active (using either signature dates or completion dates) so that qualification documentation attributed to specific staff members can be easily updated and verified.

HOW TO USE

- Complete the form header by adding the Short Study Title, and the Principal Investigator's name.
- Complete the IRB status portion of the log as follows:
 - IRB# - The tracking number the IRB has assigned to your protocol/study
 - Initial IRB approval date – The date your protocol/study was initially approved by the IRB. This date can be found on your IRB approval letter.
 - Current IRB approval start and end dates – The date your protocol/ study approval was renewed by the IRB after continuation review. Be sure to update this section annually at continuation review.
 - IRB Close date – The date your protocol/study was closed with the IRB.
 - Serial # - The tracking number assigned to an IRB submission.
 - IRB Reply – The date the IRB responded to your submission. This may be an approval or a formal request for additional information.
 - Date to Sponsor – The date the IRB approval was forwarded to the study sponsor. If the study is PI initiated, this column can be marked N/A or deleted.
 - Date to Grant Manager – The date the IRB approval was forwarded to the grant manager. Approvals forwarded to the grant manager generally include IRB initial, continuation review and final review approvals as well as protocol amendments.
 - Subject – A summary of contents of the IRB submission, with enough detail to provide an effective overview of any changes made
- Update the study status portion of the log as information becomes available

GOOD PRACTICE RECOMMENDATIONS

- If reviewed and updated regularly, this log can function as an effective roadmap for the study.
- Using a serial or tracking number to identify IRB submissions is a great organizational tool - consider using the following system:
 - Start your numbering system by assigning 000 to your initial submission

- If the IRB requests revisions in addition to those initially submitted, assign 001 FU1 to the submission. This allows for traceability back to the original submission while keeping the documentation separated by request.
- After receiving initial IRB approval subsequent submissions would follow the same pattern 001, 002, 002FU1 (if additional requests for information were made), etc.
- Consider including the date the submission was sent to the IRB on the log for example 000-05/04/18 so that you can follow-up on any submissions that you've not received a response on in a timely fashion
- Consider including the same content that is in the subject line of the log in your IRB approval letter so that the items reviewed and approved by the IRB are documented on the approval letter. Preface the content with the type of submission for example:
 - MR, updated study personnel removing Jones, adding Smith
 - PV, participant 01-2000

Note: The content can be added to your approval letter in the "Approval Letter Details" section of the Additional Information portion of your e-IRB application.

- Highlighting certain types of submissions can make them easier to locate on the log, for example
 - 2018 Continuation Review
- Be sure to customize the template to make it study-specific.