Guide to the Submission of a Response Form

- 1. Log in to iRIS.
- 2. On the home page, you will see a Submission Response form pending under All Tasks Outstanding, but this can also be shown under "Forms Pending Submission".
- 3. Click to open the study.
- 4. Save and continue until you get to the stipulation section.
- 5. Click "Save and Continue to the Next Section" until you get to the stipulations.
- 6. For each stipulation that indicates "revise existing" on the right-hand side, click on it, and it will create a revision of the form that needs to be revised. For Word documents, make sure to turn on "track changes" prior to making revisions. For the study application, highlight any changes that are within text editor boxes.
- 7. Once you have revised the document and saved it, you will be returned to the stipulation section.
- 8. For each stipulation, indicate Yes, No, N/A, along with an explanation of the changes that were made.
- 9. For each explanation, click on "complete action" to indicate that you are done with the stipulation.
- 10. The stipulation status should change once this is complete.
- 11. If there are multiple stipulations for one document, for example, the study application, all revisions may be made when revising it the first time. Once all changes have been made, you return to the response form and address each stipulation as indicated in the steps above.
- 12. Repeat for each stipulation, as needed.
- 13. Click "Save and Continue to the Next Section."
- 14. Under *Response Comments,* add any information that you think would be helpful for review. This is also where it should be indicated that additional documents, not listed in the stipulations, have been revised.
- 15. Click "Save and Continue to Next Section."
- 16. If there are any additional documents that were requested to be added, click on "Click here to view the revised copy of the submission form," which will take you to the original submission. The response should indicate that this has been done.
- 17. Attach the additional document under the section it pertains to. Once attached, the document(s) will display under the respective section of this form.
- 18. Please note that only documents that have been requested may be uploaded. The addition of any new documents that have not been previously reviewed may require an additional full board review.
- 19. Click "Save and Continue to Next Section."
- 20. Exit the form.
- 21. Review the response form and make sure that all revised documents needed have been attached. If they are not attached, please review the steps to attach documents.
- 22. At this point, you can exit the form and return at a later time, or sign off and submit.
- 23. Click "Save and Continue."
- 24. The entire submission, including all attached and revised documents, should be displayed above the approval section. This includes the initial review form, application, protocol, consent form, etc. Please make sure that all required documents are attached before signing off. The version numbers should no longer be 1.0 for any documents that have been revised. If any documents are missing, please do not sign off. If you do not see the documents needed for review listed here, please go back to attach them.
- 25. Click "Save Signoff."
- 26. Please allow enough time for this approval process and to meet IRB submission deadlines.
- 27. When the item has been placed on an agenda for review, an iRIS notice is sent to the PI and study contact. If a notice is not received, you may also track the submission on your dashboard.