Quick Guide to the Submission of Continuing Reviews

1. Log in to iRIS.

2. You have a few options. First, from your homepage, you will see "**Continuing Review Due**" under the outstanding tab of the tasks widget. You can click on this task to start the Continuing Review Form. Go on to #9.

3. Secondly from the main dashboard, you can access "**Featured Study Operations.**" Click on either "**Start a Submission Form**" or "**View My Studies**." Both will take you to the list of studies.

4. Find the study that you want to create the form for.

5. On the right hand side, under Actions, select "**Forms**" and select the "**Continuing Review Form**." Follow the steps indicated below starting with #8.

6. You may also access the form using the previous format by clicking on the "**Open**" button.

7. In the "**IRB Submission Forms**" column, click on "**Continuing Review Form**" if you are submitting a renewal.

8. Click the icon under the "**Start a new Submission**" column to add a new form.

9. The first section is pre-populated.

10*. Click "**Save and Continue**" to go to the next section, *Enrollment.*

11. For Section 2.1, indicate the current status of the study. If it is a chart review, check off "*Research involves only PHI.*"

12. For Section 2.2, indicate the number of approved subjects. This information can be found in the summary section or in your approval letter. This may pre-populate, but please confirm the approved number.

13. For Section 2.3, indicate the total number of subjects reported at last continuing review. Refer to the previous form, if needed. If this is the first continuing review, enter 0.

14. For Section 2.4, indicate the number of subjects enrolled during this review period. If this is the first continuing review, this will be since the approval. ***If the study includes a consent form, any subject who signed a consent form is counted for purposes of the continuing review. If this is a chart review, each record is counted as a subject.***

15. For Section 2.5, indicate the total subjects enrolled. **This is the sum of 2.3 and 2.4.**

16. For Section 2.6, of the total indicated in 2.5, state how many are currently active in the study, (i.e., screening is ongoing, research procedures have not been completed, chart review is ongoing, etc.)

17. For Section 2.7, of the total indicated in 2.5, state how many have completed the study (i.e., all research procedures have been completed, chart review has been completed, etc.)

18. For Section 2.8, indicate whether any subjects have been withdrawn during this review period. If yes, access the text editor and state the number and reasons for withdrawal. Click "**OK**" when finished. A withdrawal can include voluntary subject withdrawal, withdrawn by the researcher, lost to follow up, screen failure, etc. This number is then included in section 2.9 for a running total.

19. For Section 2.9, indicate the total number of subjects withdrawn for any reason noted above, since the study began.

20. Please note: the numbers indicated in sections 2.6, 2.7, and 2.9 need to add up and total the number indicated in 2.5.

21. Once the subject numbers section has been completed and the numbers add up, click "**Save and Continue**."

22. For Section 3.0, indicate whether there have been any local adverse events. Click "**Save and Continue to the Next Section**."

23. For Section 4.1, indicate whether there have been any external adverse events. Click "**Save and Continue to the Next Section**."

24. For Section 5.1, indicate whether there have been any protocol deviations. Click "**Save and Continue to the Next Section**."

25. For Section 6.1, indicate whether there have been any complaints. Click "**Save and Continue to the Next Section**."

26. For Section 7.0, complete the fields and click "**Save and Continue**."

27. For Section 8.0, complete the fields and click "**Save and Continue**."

28. For Section 9.0, complete the fields. If you are maintaining PHI, additional questions will populate that you will need to complete. Click "**Save and Continue**."

29. For Section 10.0, access the text editor and include a summary of all study activity since the last continuing review.

30. Click "**Save and Continue**."

31. If you are not ready to submit, click "**Exit Form**," and you can return to sign off when ready.

32. If you are ready to submit, click "**Signoff and Submit**".

33. Select "**Approve**" and enter your credentials.

34. Click "**Save Signoff**."

35. You will then be routed to "*Studies Submission Status*."

36. You can expand the + under "Task Status" for details on the submission history and to track its location/status.

37. If changes are needed, click "**Retract Submission**" to release the form for editing. This will only work as long as the submission has not been processed by the IRB.