Guide to the Submission of a Sponsor Monitoring Report

1. Login to iRIS.

2. From the main dashboard, access "Featured Study Operations." At this point, there are two options, click on "Start a Submission Form" or "View My Studies." Both will take you to the list of studies.

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

4. On the right hand side, under Actions, select "Forms" and select the "Sponsor Monitoring Report Form." Follow the steps indicated below starting with #7.

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

6. In the Submission Forms Column click on "Sponsor Monitoring Report Form."

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

8. Indicate the date and date of monitoring visit.

9. To add comments, click on the gray bar to access the text editor.

10. In the text editor, input comments and click "OK" when finished.

11. Attach the monitoring report, if the document is already uploaded under Other Study Documents, click

"Select or Revise Existing" and select the document from the list, otherwise

12. Click "Add a New Document."

13. Click "Browse" and locate the appropriate file from your computer and click "Open."

14. Enter the version number, and version date in the appropriate fields.

15. Select a category from the drop down menu.

16. Enter a description, if applicable.

17. Click "Save Document."

18. Repeat steps 10-15 for any other additional documents that need uploading.

19. Click "Save and Continue to the Next Section."

20. Click "Signoff and Submit."

21. Select "Approve" and enter your credentials.

22. Click "Save Signoff."

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