

Clinical Research Support Office (“CRSO”)

Protocol Close Out CFI-WI-4006
Work Instructions

Need Help?
Contact the CRSO at: ctms.support@uky.edu

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IRB Review Information

The assigned regulatory or protocol manager will enter the IRB closure information after IRB approval.

1. Click **PC Console**.
2. Search for and select your protocol.
3. Click **Reviews**.
4. Click the **IRB** tab.
5. Click **Add**.
6. Enter the following:
 - a. Review Date
 - b. Submit Date
 - c. Committee
 - d. Review Reason: **Study Closure**
 - e. Action
 - f. Action Date
 - g. Expiration Date

Update IRB Review ?

Protocol No.: CR50-FINANCERUNTHROUGH1 Library: CCTS Biospecimen PI: Sponsor: Pfizer, Inc.
 Protocol Target Accrual: Accrual To Date: 4 Protocol Status: OPEN TO ACCRUAL
 RC Total Accrual Goal (Upper): IRB Expiration: 06/22/2019

Review Information

Review Date	<input type="text" value="Type here to search"/>	Submit Date	<input type="text"/>	Committee	<input type="text"/>	Review Reason	<input type="text"/>	Review Type	<input type="text"/>
Action	<input type="text"/>	Action Date	<input type="text"/>	Expiration Date	<input type="text"/>				

Summary

4000 character(s) remaining

Yes Votes	<input type="text"/>	No Votes	<input type="text"/>	Abstain Votes	<input type="text"/>	Institution	<input type="text"/>
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Details (0)
Reviewers (0)
Communications (0)
Notes

							Add	Select Previous Details/Docs
Type	Amendment No.	Received Date	Version Date	Description	Comments	Global?	Reconsent Required?	Delete?
No records found								

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7. Click **Submit**.
8. Go to the **Details** tab at the bottom of the screen.
9. Click **Add**.
 - a. Add the documents submitted to the IRB.
10. Click **Save**, then **Submit and Close**.
11. Go to **PC Console > Status**
 - a. If the protocol status has not yet been switched to **Closed to Accrual**, this must be performed first before the study can be fully closed out.
 - b. Click the **IRB Study Closure** button if the protocol is closing normally and has met its objectives.
 - c. Click the **Terminated** button if the protocol is being closed prematurely prior to reaching its objective (low accrual, insufficient resources, sponsor closure, end of funding, etc.)

- d. The study is now closed in OnCore.
12. Add the CRSO Closeout Task List to the study to track the activities required for closeout if not already added.
13. Navigate to the **PC Console > Status** tab on the left-hand side of the screen and click the >> on the right side of the tab which will bring you to the Task Lists screen.
14. Click **Copy Template** to add the CRSO Closeout Task List and click **Save**.

The screenshot displays the 'Select Task List Templates' window. It features a table of available templates with columns for 'Workflow Order', 'Type', 'Name', and 'Copy'. The 'CRSO Calendar Build' template (Workflow Order 1) is checked. Other templates include CDA, PRC, PIM, Regulatory, IRB, Clinical Trial Agreement, Budgets, Site Visits, Study Closeout - Financial, NIH and NCI Reporting, and Data Monitoring. The background shows the 'Status' tab of the protocol console with a sidebar menu on the left.

Document Archive Information

1. Go to **PC Console > Documents/Info**.
2. Click on the **Archive/Notes** tab.
3. Click **Update**.
4. Click **Add** under Archive Details and add the applicable document storage info.
5. Click **Save**.
6. Click **Close**.

The screenshot shows the 'Archive/Notes' tab in the system. The 'Archive Details' section has an 'Add' button and fields for Archive Date, Archive Type, Location, Box, and Contents. Below it, the 'Notes Details' section also has an 'Add' button and fields for Note Date and Note. The sidebar on the left shows the 'Documents/Info' tab selected.

Financial Closure

1. Click the **Annotations** tab.
2. Click the **Create Annotations Form** hyperlink.
3. Submit any final necessary invoices.
4. Refer to the Study Closeout Policy for managing any account related activity that must happen as part of account closure, including write-offs.
 - a. If you need a write-off, please contact your department FA (Financial Advisor).
The CRSO will complete any write-offs in OnCore.
5. Make sure all steps are completed in the Close Out task list.
6. Once the protocol has been fully financially closed, meaning after IRB is closed, final payment is received, WBS is closed and FFR is finalized (90 days after WBS closure) go to **PC Console > Annotations** Tab and enter a date for the Financial Closure of the protocol.