

DEPARTMENT CHAIR GUIDANCE

Reviewing a Study for Administrative Approval in eIRB

There are three steps for department chairs in approving IRB submission of new studies (formerly “Administrative Certification”) in the eIRB system:

- Access the study
- Review the submitted study
- Submit the review

STEP 1: ACCESS THE STUDY

You will receive an email notification similar to the following format:

Notification of Ancillary Review

To: [Francis Firth](#)

Link: [STUDY000071](#)

P.I.: Anita Anderson

Title: CHROME

Description: An IRB submission has been assigned to you for ancillary review.

Click the link above to access and review the study.

Clicking on the blue link “[STUDY Number](#)” in the email takes you to the main study page. Log on with your standard KUMC username and password. Your view of the Study Summary Screen follows:

The screenshot shows the eIRB system interface for the study "STUDY0000071: CHROME". The page includes a navigation bar with "Home", "IRB", and "COI" links. The study title "STUDY0000071: CHROME" is prominently displayed. Key information includes the Principal investigator (Anita Anderson), Submission type (Initial Study), Primary contact (Anita Anderson), and IRB coordinator (Anita Anderson). The IRB office is identified as KUMC. A flowchart illustrates the review process: Pre-Submission leads to IRB Pre-Review, which can lead to IRB Review or Post Review. IRB Review and Post Review can lead to Clarifications Requested, which then leads to Modifications Required, and finally to Review Complete. The "My Current Actions" section includes buttons for "View Study", "Printer Version", "View Differences", "Add Private Comment", "Add Comment", and "Submit Ancillary Review". The "History" section shows a table of activities:

Activity	Author	Activity Date
Managed Ancillary Reviews	Blackwell, Karen Tiemann	7/31/2013 5:22 PM CDT
Submitted	Anderson, Anita	7/24/2013 8:47 AM CDT
Study Created	Anderson, Anita	7/24/2013 8:38 AM CDT

STEP 2: REVIEW THE SUBMITTED STUDY

You can see the documents uploaded for the study by clicking on the **Documents** tab. From this page, you can open any of the study documents: protocol, investigator's brochure, consent documents, etc.

The screenshot shows the IRB submission review interface for 'STUDY0000071: CHROME'. The page includes a navigation bar with 'Home', 'IRB', and 'COI' links. The main content area displays the study title and key information: Principal investigator: Anita Anderson, Submission type: Initial Study, Primary contact: Anita Anderson, and IRB coordinator: [blank]. A flowchart illustrates the review process: Pre-Submission → IRB Pre-Review (with a feedback loop for Clarifications Requested) → IRB Review (with a feedback loop for Clarifications Requested) → Post Review (with a feedback loop for Modifications Required) → Review Complete. On the left, 'My Current Actions' includes buttons for View Study, Printer Version, View Differences, Add Private Comment, Add Comment, and Submit Ancillary Review. Below the flowchart, a 'Documents' tab is active, showing a table of uploaded files:

Draft	Category	Final	Last Finalized
Expedited PProject Description	Supplemental Application Form		
Consent form 3-2-12	Consent Form		
IB 2-3-12	Drug Attachment		
Protocol 3-12-13	IRB Protocol		

You can also select the **Printer Version** on the left column, to see the details such as PI, funding source, study team, and internal reporting items. Hit "Close" to return to the Study Summary Screen.

The screenshot shows the 'Basic Information' section of the study details page. It includes a date and time stamp: 'Date: Tuesday, August 06, 2013 5:25:57 PM'. The 'Basic Information' section contains the following details:

- Title of study:** New study
- Short title:** CHROME
- Brief description:** demo
- Principal investigator:** Anita Anderson
- Does the investigator have a financial interest related to this research?** Yes No
- Which IRB should oversee this study?** KUMC
- Will an external IRB act as the IRB of record for this study?** Yes No
- Attach the protocol:** (include the investigator protocol and full sponsor protocol)

Document	Category	Date Modified
View Protocol 3-12-13(0.01)	IRB Protocol	7/24/2013

Below this, there are links for 'Use one of these templates:' including 'HRP-503 - ProtocolLinks'.

The 'Funding Sources' section is also visible, with the following details:

- Identify each organization supplying funding for the study:**

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
AstraZeneca			

The 'Study Team Members' section is partially visible at the bottom, with the following details:

- Identify each additional person involved in the design, conduct, or reporting of the research:**

Name	Roles	Financial Interest	Involved in Consent	E-mail	Phone
------	-------	--------------------	---------------------	--------	-------

STEP 3: SUBMIT YOUR REVIEW

After reviewing the documents, the Chair selects the “Submit Ancillary Review” in the left column of the main study page.

Pre-Review **STUDY0000071: CHROME** **IRB office: KUMC**

Entered IRB: 7/24/2013
 Initial approval:
 Effective:
 Approval end:
 Modified: 7/31/2013 5:22 PM

Principal investigator: Anita Anderson
Submission type: Initial Study
Primary contact: Anita Anderson
IRB coordinator:

Workflow: Pre-Submission → IRB Pre-Review → IRB Review → Post Review → Review Complete
 (IRB Pre-Review, IRB Review, and Post Review each have a 'Clarifications Requested' or 'Modifications Required' loop back to the previous stage.)

My Current Actions

- View Study
- Printer Version
- View Differences
- Add Private Comment
- Add Comment
- Submit Ancillary Review

History | Project Contacts | Documents | Reviews | Snapshots

Filter by: Activity [Go] [Clear] [Advanced]

Activity	Author	Activity Date
Managed Ancillary Reviews	Blackwell, Karen Tiemann	7/31/2013 5:22 PM CDT
Submitted	Anderson, Anita	7/24/2013 8:47 AM CDT
Study Created	Anderson, Anita	7/24/2013 8:38 AM CDT

It will take you to the Ancillary Review page, shown below:

Submit Ancillary Review

- * Select the review you are submitting:**

Organization	Person	Review Type	Required
<input type="checkbox"/>	Francis Firth	Department	yes
- * Do you accept the proposed study?**
 Yes No [Clear](#)
- Comments:**
- Supporting documents:**

Name
There are no items to display

If scientific review is complete and the Chair is approving IRB submission:

The Chair completes the ancillary review and hits “OK.”

Submit Ancillary Review

1. * **Select the review you are submitting:**

Organization	Person	Review Type	Required
<input checked="" type="checkbox"/>	Francis Firth	Department	yes

2. * **Do you accept the proposed study?**
 Yes No [Clear](#)

3. **Comments:**
Department approval for IRB submission

4. **Supporting documents:**
[Add](#)
Name
There are no items to display

[OK](#) [Cancel](#)

If the Chair is submitting both the Scientific Merit Review and Departmental Approval:

The Chair saves the Scientific Review form to the desktop and completes it , found on the IRB website at:<http://www.kumc.edu/compliance/human-research-protection-program/institutional-review-board/forms.html> The form is uploaded in item 4. The Chair hits “OK” to submit.

Submit Ancillary Review

1. * **Select the review you are submitting:**

Organization	Person	Review Type	Required
<input checked="" type="checkbox"/>	Francis Firth	Department	yes

2. * **Do you accept the proposed study?**
 Yes No [Clear](#)

3. **Comments:**
Scientific Review attached; approved for submission

4. **Supporting documents:**
[Add](#)
Name
[Upload Revision](#) [Anderson Scientific Review](#)

[OK](#)

Note that the **History** tab of the main study page now shows that the Ancillary Review has been submitted by Dr. Firth.

STUDY0000071: CHROME

Principal investigator: Anita Anderson
 Submission type: Initial Study
 Primary contact: Anita Anderson
 IRB coordinator:

IRB office: KUMC

Entered IRB: 7/24/2013
 Initial approval:
 Effective:
 Approval end:
 Modified: 7/31/2013 5:32 PM

My Current Actions

- View Study
- Printer Version
- View Differences
- Add Private Comment
- Add Comment
- Submit Ancillary Review

History | Project Contacts | Documents | Reviews | Snapshots

Filter by: Activity

Activity	Author	Activity Date
<input checked="" type="checkbox"/> Submitted Ancillary Review	Firth, Francis	7/31/2013 5:32 PM CDT
<input type="checkbox"/> Managed Ancillary Reviews	Blackwell, Karen Tiemann	7/31/2013 5:22 PM CDT
<input type="checkbox"/> Submitted	Anderson, Anita	7/24/2013 8:47 AM CDT
<input type="checkbox"/> Study Created	Anderson, Anita	7/24/2013 8:38 AM CDT

The IRB staff and the study team can see that the Ancillary Review is complete.

STUDY0000071: CHROME

Principal investigator: Anita Anderson
 Submission type: Initial Study
 Primary contact: Anita Anderson
 IRB coordinator:

IRB office: KUMC

Entered IRB: 7/24/2013
 Initial approval:
 Effective:
 Approval end:
 Modified: 7/31/2013 5:32 PM

My Current Actions

- View Study
- Printer Version
- View Differences
- Withdraw
- Discard
- Assign Primary Contact
- Manage Guest List
- Copy Submission
- Add Comment

Reviews | History | Project Contacts | Documents | Snapshots

Ancillary Reviews

Review Type	Organization	Person	Reqd	Accepted	Comments	Docs
Department		Francis Firth	yes	yes	Department approval for IRB submission	