

## **Completing Department Review**

Some projects submitted to the IRB require department review. The IRB Contact will send information for department review through ESTR, to the named department reviewer.

Department reviewers are pre-set in ESTR by the IRB office. If you think you have received a notice for department review in error or if you encounter difficulty navigating the submission, please contact <a href="mailto:ESTRhelp@harvard.edu">ESTRhelp@harvard.edu</a>.

## **Steps to Complete Department Review**

- 1. Log in to irb.harvard.edu
- 2. Navigate to the item requiring review
  - Via email link: Go to the email indicating that review is required, and select the link for the study (underlined text).
     OR
  - b. Via Personal Workspace: After logging in with your HUID and PIN, you will be directed to your personal workspace.

My In	box								
Filter by 🖗 ID 🔻 Go Clear Advanced									
ID ID	Name	Date Created	Date Modified	State	PI First Name	PI Last Name	PI Department	Submission Type	Expiration Date
IRB14- 1738	Visible Agenda and Meeting Productivity	5/30/2014 2:13 PM	8/28/2014 12:01 AM	Department Review	Kara	Thrace	Nutrition	Initial Study	
8 items			4	page 4 of 8	$\triangleright$			:	1 / page

- 3. Access the study by selecting the Name of the study (or the study title).
- 4. View the information submitted as part of the study.

To view the details of a study:

- a. Go to the Study Workspace.
- b. Click View Study under My Current Actions.
  - i. Click through the pages of the Smartform.
  - ii. Click **Documents** tab to view any attached documents.

Alternatively, to view the details of a study in one web-page, with links to attachments:

- c. Go to the Study Workspace.
- d. Click Printer Version under My Current Actions.
  - i. Scroll through the Smartform responses.
    - ii. Click the linked documents to view any attached documents.
- 5. If needed, request revisions or clarifications from the study team. To request changes from the study workspace, once the issues/concerns have been identified:
  - a. Click Request Clarification by Department Reviewer under My Current Actions.



- b. In the **Request Clarification by Department Reviewer** window, note down the required changes. Add any supporting documents if necessary.
- c. Click OK.
  - i. A notice will be sent to the Investigator, indicating that changes are required.
  - Once the Investigator makes the changes, you will receive an email indicating that the changes are ready for your review.
  - iii. If the changes are not satisfactory, you can request additional changes.
- d. The submission will be available to the study team to make changes and respond to questions. Once the

response is complete, you will receive a notice to proceed with your review.

- 6. If you have requested changes and received a response, to view and verify requested changes:
  - a. Navigate to the submission workspace, you can view its history log to any changes made, as shown below.

History	Project Contacts	Documents	Snapshots	
Filter by 🤅	Activity	•		Go Clear A
Activity	1		Author	
➡ Chang	es Submitted	Stein (ir	bd), Ira	
Clarifications Requested by Department Revie			ewer Adminis	trator, System

- b. To view and verify requested changes:
  - i. Click on View Differences under My Current Actions.

My C	Current Actions	
	View Study	
C	Printer Version	
	View Differences	

- ii. On the View Changes to IRB Submission page
- iii. Use the dropdown to select the version that you want to compare to the current version.





iv. Any saved changes made will be shown. If more than one change has been made, use the arrows or dropdown selector next to the **Changed Steps** to navigate through the changes.

View Changes to IRB Submission: aTest					
Show Changes made between Current Version (0.4) and	0.3 10/18/2012 3:08 AM Submit to IRB				
Changed Steps: Study Scope	☑ Limit Steps to Current SmartForm Path				

- v. Click Close to exit the View Changes to IRB Submission page.
- 7. Issue Department Approval. To complete department review and issue departmental approval:
  - a. In **My Inbox**, Click on the study name to open it.
  - b. Click View Study under My Current Actions on the left.
  - c. To issue a decision, from the study workspace, click **Issue Departmental Approval**.
  - d. Provide any comments or attachments in the Issue
    Departmental Approval popup (as necessary) to make a determination.
  - e. Click OK.
    - The study will transition to the IRB office (Pre-Review).
    - The IRB office can begin review of the application.

