

Study Approvals and Submitting Contingencies

Important Information

- When the IRB meets to review applications, its decisions are recorded in eResearch and study teams are notified via email of the decision. The study team can view the status of the application at any time in eResearch.
- In some cases, submissions may be approved with contingencies. Study teams are required to submit additional information to satisfy the contingencies prior to full approval. Research cannot begin until final approval has been obtained.

eResearch Study Workspace

1. The study team is informed of pending contingencies via email notification. A link is provided to view this letter directly in eResearch. Any contingencies can be viewed in the **Outstanding Issues** section of the **Correspondence** tab
2. Click **Edit Study** to make the requested changes to the study application and save the changes or click on the blue text under Outstanding Issues to go directly to that section of the study.
 - Click **Exit** in the Study Application to return to the **Study Workspace**.
3. Click **PI&S Submit Contingencies** from the End of the Application or Study Workspace to indicate that you have completed the request.

Submit Contingencies Window

Submit Contingencies

Release 1. Training Study - for training only (HUM00005453)

Outstanding Identified Issues:

Section	Identified Issue
02 Sponsor Information	Update sponsor information.

4 * Indicate the changes you have made in response to the identified issues. Any changes to supporting documents will require that you attach the new document in the proper section of the application. Clicking on the section will open the application section that needs to be modified.

Made all requested changes in both application and supporting documents

Made some of the requested changes (comment required)

Did not make any changes (comment required)

[Clear](#)

Comments:

5

6

4. Indicate the changes made in response to the **identified issues**.

5. Add **Comments**, if necessary.

Note: If all requested changes were not made, a comment is required.

6. Click .

eResearch Home Workspace

eResearchM Ingrid Investigator | My Home | Logoff

All Submissions IBC

Home Workspace for Ingrid Investigator

7

My Roles
Study Team Member

Create

My Inbox **In Progress** Approved Exempt and Not Regulated Approaching Expiration Archived

This tab displays all the applications you are associated with that have not yet been approved. Click the name of submission for more information.

Filter by

Name	PI	Study Title	State	Type	Last State Change	ID
Sample Study VI	Investigator		Core Committee Staff Contingency Review	Application	7/30/2007 3:17 PM	HUM0001435
Sample Study IV	Investigator		Core Committee Staff Review	Application	7/30/2007 2:59 PM	HUM0001435
HUM00014348_Adverse Event - Mon Jul 30 12:36:15 EDT 2007	Investigator	Sample Study III	Changes Required By Core Staff	Adverse Event	7/30/2007 2:01 PM	Adv00002341
HUM00014348_Amendment - Wed Jul 25 08:42:51 EDT 2007	Investigator	Sample Study III	Pre Submission	Amendment	7/25/2007 8:46 AM	Ame00004811
Sample Study VII	Investigator		Pre Submission	Application	7/24/2007 1:41 PM	HUM0001435
Sample Study II	Investigator		Pre Submission	Application	7/19/2007 2:27 PM	HUM0001434
Sample Study	Investigator		Pre Submission	Application	7/19/2007 2:27 PM	HUM0001434

7. The submission will appear in your **In Progress** tab of your Home Workspace.