

For Conditional Offices: How to Review a Submission

These instructions are for a reviewer in a conditional office, who has been assigned a protocol to review. This process begins after the Intake user for the conditional office has assigned the micro task to a reviewer.

1. On your To Do List, you see a task like this:

To Do List

From

Create PPHS Protocol (TEMP-16-00120)
Correct Errors - Initial Application

Review and Route PPHS Protocol Submission (FACTS:MICRO) - IDS Demo 2016-02-24 A (IRB-16-00115) - William Rice
Process IRB Protocol Review

2. Click into the task.
3. After clicking into the task, you see the subtitle **Analyst Review** and the submission is displayed:

[Instructions](#)
[Investigator Submission Notes](#)

Analyst Review

Comments from Kelly Ware
This was previously reviewed via email. They are now submitting in the system.

General Comments

Action

Protocol Number: **IRB-16-00115**
Principal Investigator: William Rice

Summary | Research Personnel | Sites | Subjects | Procedures | Consent | Data | E

Title - Setup - Background

Protocol Title:

Principal Investigator:

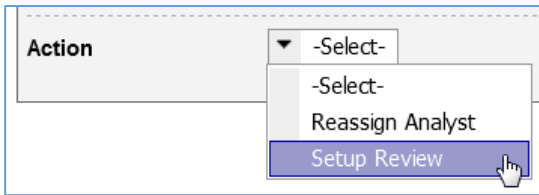
Primary Department:

Application Initiated By:

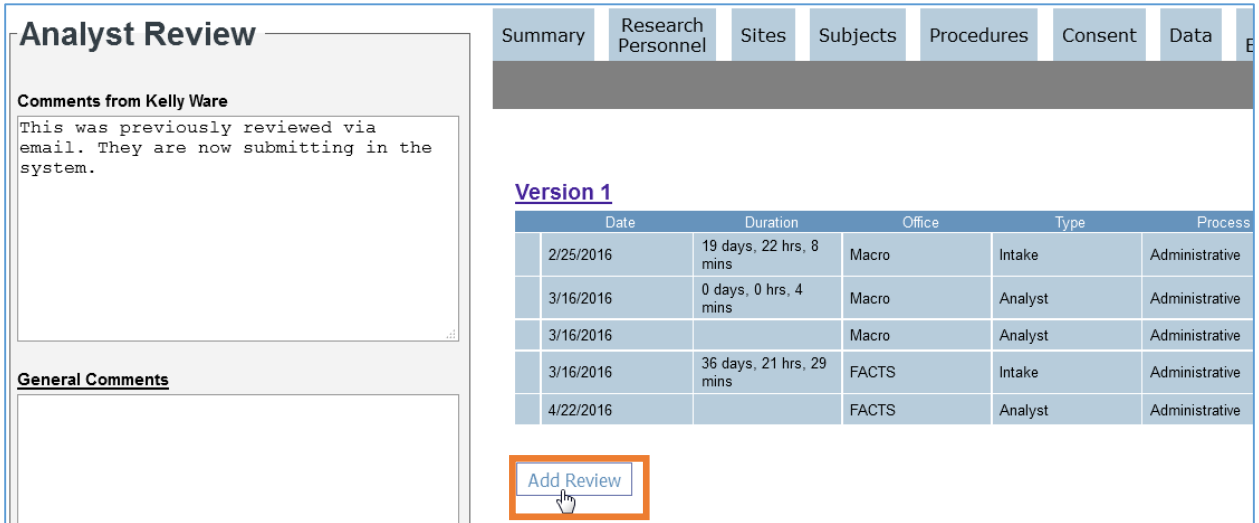
Lay Summary:

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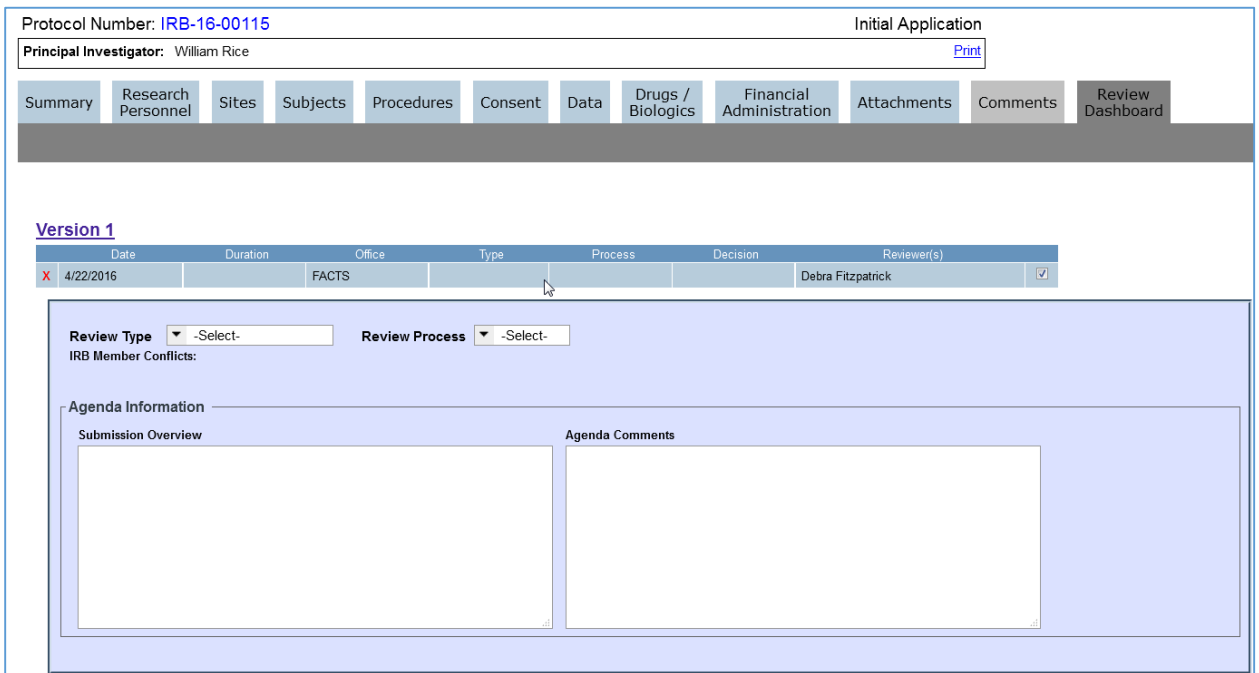
- If the Analyst who sent this left any comments for you, they will be shown in the **Comments from...** field.
- From the **Action** drop-down menu, select **Setup Review**.



- The **Review Dashboard** tab comes to the forefront. Click the **Add Review** button.



- A row for the review is added.



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8. For **Review Type**, select **Administrative Review**. The **Review Process** will automatically set to **Administrative**.

Version 1

Date	Duration	Office	Type
X 4/22/2016		FACTS	

Review Type **Review Process**

IRB Member Con -Select-

Agenda Inform -Select-

Submission Ov -Select-

Administrative Review

Member Review

Meeting Review

9. Navigate from tab to tab, and leave field-level comments as needed:

Summary	Research Personnel	Sites	Subjects	Procedures	Consent	Data	Drugs / Biologics	Financial Administration	Attachments	Comments
<p>This information will help the Financial Administration of Clinical Trials Services (FACTS) office determine whether a Medicare Coverage Analysis (MCA) is needed for the research study. If you have any questions while completing this form, please contact the FACTS office at (212) 731-7067 or FACTS@mssm.edu.</p> <p>Clinical Research Study Category Industry Sponsor Initiated <input type="checkbox"/> Add Comment</p> <p>Payment Options: * Option 1: No protocol-required services will be billed to patients or third-party payers. Does Not Need MCA * Option 2: Protocol-required services (i.e., routine care services) will be billed to patients or third-party payers. Must Have MCA * Option 3: Study is initiated and federally funded by a Government Sponsored Cooperative Group who will only pay for services that are solely conducted for research purposes and other protocol-required services (i.e., routine care services) will be billed to patients or third-party payers. Billing Grid Only Required, NO MCA * Option 4: Study involves only data collection and has no protocol-required clinical services. Does Not Need MCA * Option 5: Study is not described in any of the above options. Please describe the study and specify whether External Sponsor (i.e., industry, government, or philanthropic source) and/or patient/third party payer will pay for protocol required services. MCA MAY Be Required</p> <p>Payment Option Option 2 <input checked="" type="checkbox"/> Add Comment</p> <div style="border: 2px solid orange; padding: 5px; margin-top: 10px;"> <p><input checked="" type="checkbox"/> Add Comment</p> <p>This requires an MCA which must be uploaded under the Attachments tab.</p> </div>										

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10. You can examine attachments by downloading and opening them.

The screenshot shows the 'Attachments' tab in a web application. A table lists documents with columns for Type, Name, Attachment, Uploaded Date, and Comments. A dialog box titled 'Opening 1.docx' is overlaid on the table, showing file details and options to open or save the file.

Type	Name	Attachment	Uploaded Date	Comments
Consent Documents	Consent Form.docx	Consent Form.docx	02/24/2016	View
Data Collection Sheet	Data Co			View
Sponsor Protocol Imprinted with IND Number	Protoco			View
Written Communication from the Sponsor Documenting the IND Number	letter.pdf			View
Written Communication from the FDA Documenting the IND Number	New Drug Applications (NDAs) _ Approval Letter.pdf	New Drug Applications (NDAs) _ Approval Letter.pdf	02/24/2016	View

11. You can leave comments for an attachment. You can also upload a suggested document, for example, a marked-up version of the document that the researcher submitted.

The screenshot shows the 'Attachments' tab with a comment box open for the 'Consent Form.docx' document. The comment box contains text about compensation and track changes. The 'Add Comment' option is checked in the comment options menu.

Type	Name	Attachment	Uploaded Date	Comments
Consent Documents	Consent Form.docx	Consent Form.docx	02/24/2016	View

New Doc Required
 Upload Suggestion
 Add Comment

Consent form needs to state specific amount of compensation that participants will be give. Please upload a revised version, and also a version with track changes turned on so we can see this change.

12. When you finish leaving comments, check the **Comments** tab to ensure that it contains all of the comments that you intended:

The screenshot shows the 'Comments' tab with a 'Summary of Comments' table. The table lists comments with columns for Location, Field, Current Value, and Comments.

Location	Field	Current Value	Comments
Financial Administration	Payment Option	2	This requires an MCA which must be uploaded under the Attachments tab.
Attachments	Document type / Name	Consent Documents / Consent Form.docx	Consent form needs to state specific amount of compensation that participants will be give. Please upload a revised version, and also a version with track changes turned on so we can see this change.

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13. In the **Review Comments** field in the left margin, enter generalized comments for the investigator.

Analyst Review

Comments from Kelly Ware

This was previously reviewed via email. They are now submitting in the system.

General Comments

Contact the Office of Research Services if you need assistance with the MCA.

Action ▼ Setup Review

Submit

Summary

Summary

Location

[Financial A](#)

[Attachment](#)

14. Return to the **Review Dashboard** tab. You might need to re-open the row containing your review:

Summary	Research Personnel	Sites	Subjects	Procedures	Consent	Data	Drugs / Biologics	Financial Administration*	Attachments*	Comments	Review Dashboard
Version 1											
Date	Duration	Office	Type	Process	Decision	Reviewer(s)					
2/25/2016	19 days, 22 hrs, 8 mins	Macro	Intake	Administrative	Assigned Analyst	David Dalton					
3/16/2016	0 days, 0 hrs, 4 mins	Macro	Analyst	Administrative	Assigned Offices	Selina Deluca					
3/16/2016		Macro	Analyst	Administrative		Selina Deluca					
3/16/2016	36 days, 21 hrs, 29 mins	FACTS	Intake	Administrative	Assigned Administrator	Kelly Ware					
4/22/2016	0 days, 0 hrs, 3 mins	FACTS	Analyst	Administrative	Setup Review	Debra Fitzpatrick					
X 4/22/2016		FACTS	Administrative Review	Administrative		Debra Fitzpatrick					

For Conditional Offices: How to Review a Submission

15. Select a **Motion**:

The screenshot shows a web application interface for reviewing a submission. At the top, there is a navigation bar with tabs: Summary, Research Personnel, Sites, Subjects, Procedures, Consent, Data, Drugs / Biologics, Financial Administration*, Attachments*, Comments, and Review Dashboard. Below this is a section titled "Version 1" containing a table with columns: Date, Duration, Office, Type, Process, Decision, and Reviewer(s). The table has one row with the following data: X, 4/22/2016, FACTS, Administrative Review, Administrative, Debra Fitzpatrick, and a checkmark. Below the table are several form fields: "Review Type" (Administrative Review), "Review Process" (Administrative), "IRB Member Conflicts:", "Reviewer(s)", "Add Reviewer", and "Add Consultants". There are two large text areas for "Regulatory determinations and supporting findings supporting those determinations" and "Rationale for a significant device determination". Below these is a section for "Controverted issues and their resolution (0) set/view" with a "Motion:" dropdown menu. The dropdown menu is open, showing options: -Select-, Not Human Subjects, Not Research, Revisions Required (highlighted), and Approved. At the bottom, there is an "Agenda Information" section with "Submission Overview" and "Agenda Comments".

16. The **Set Result** button appears. Click to set the result.

The screenshot shows the same web application interface as in the previous screenshot. The "Motion:" dropdown menu is now closed, and the "Review Date" field is visible, containing the date 04/22/2016. A red button labeled "Set Result" is now visible in the bottom right area of the form, with a mouse cursor hovering over it. The rest of the interface remains the same as in the previous screenshot.

17. Click the **Submit** button. The review is completed and the task is removed from your To Do List.