



Protocol Deviation Guide for IRB Members

Purpose: To provide guidance on how to review a protocol deviation.

Audience: IRB Members

Summary: This resource guide will focus on the review of a protocol deviation form. This guide will cover the expedited and full-board review process as well as the different outcomes that can result from them. Please consult the Table of Contents below to find the information you need.

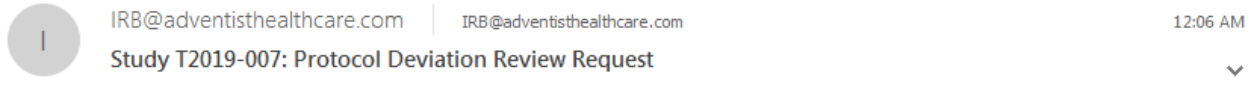
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Email Notifications:

Expedited Review

1. After the Office has finished administrative pre-review of a study submission, the study is ready to be reviewed. If the IRB Office has designated the study for **expedited review**, the reviewer will receive the following email, as shown below. The email contains important study information such as the study number and study title. The reviewer link will directly take you to the reviewer form.



IRB Study Number: T2019-007

Study Title: INITIAL REVIEW APPLICATION # 4

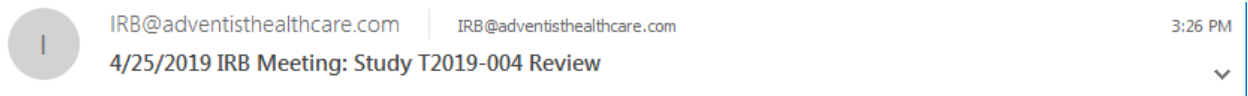
Dear Test IRB Manager, MD,

A protocol deviation for the above referenced study is ready for expedited review. Direct link to the documentation can be accessed here: <https://adventisthealthcare.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=607ed126-d11d-46c0-b5b4-bfca9c878903&ReasonGuid=720c2479-da0b-4b8a-bfd7-3582236aac67>.

Thank you.

Full-Board Review

2. If the IRB Office has designated the study for **full-board review**, the reviewer will receive the following email, as shown below. The reviewer link will directly take you to the reviewer form.



IRB Study Number: T2019-004

Study Name: Strategies Healthcare Managers Use to Reduce Hospital Acquired Infections

Dear Test IRB Manager, MD,

Will you please present the above referenced study to the IRB on Tuesday, 4/25/2019? Use this link to access the form <https://adventisthealthcare.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=6d317461-baab-4a19-9099-bb1b757b3af4&ReasonGuid=d39e427b-f4eb-488d-9384-7abf8e7e0a98>.

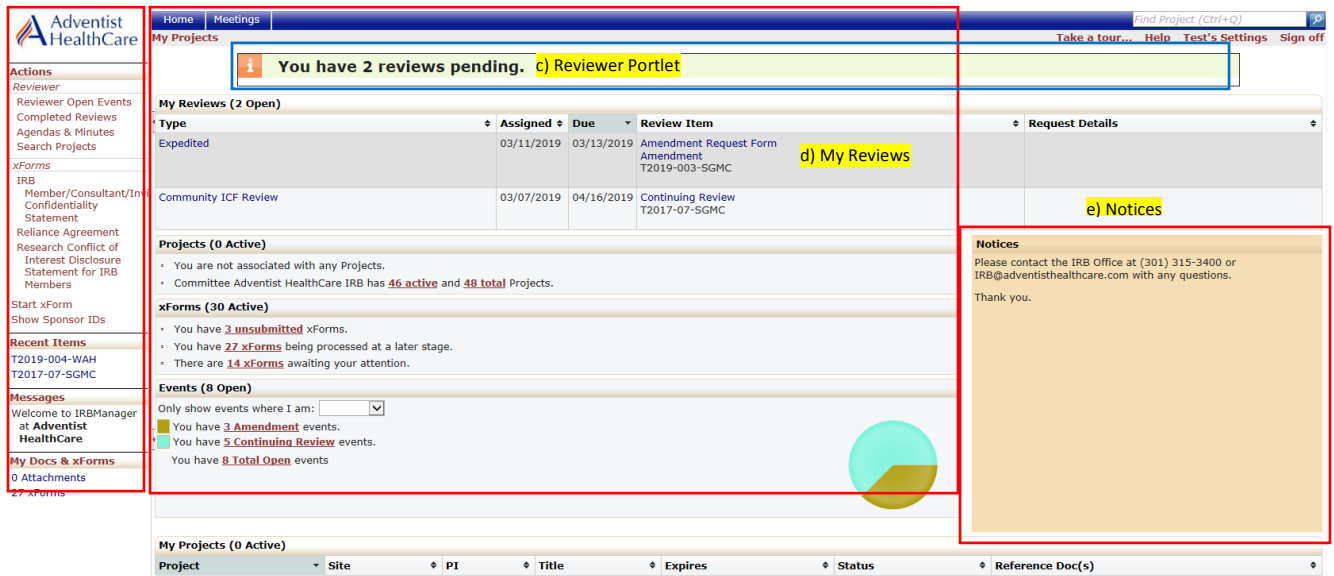
Thank you.

Dashboard Information:

1. When you log into IRBManager, your dashboard will appear. The information on your dashboard can be subdivided into six categories:
 - a) Actions Sidebar: Here, you can start x-Forms¹ or go to your recently reviewed items. You can also see the progress status of all your x-forms.
 - b) My Projects Boxes: Under 'My Projects,' you will see more information on your projects², x-forms, and study events³.
 - c) Reviewer Portlet: Notifications on pending reviews can be found here.
 - d) My Reviews: The table will contain all your review items as well as more information on the item such as the type of review, assigned date, and due date.
 - e) Notices Box: Important IRB information can be found here.
 - f) My Projects Table: The table is a listing of all your active research studies. By clicking on the blue study link, you will be directed to the study profile.

a) Actions Sidebar

b) My Projects Box



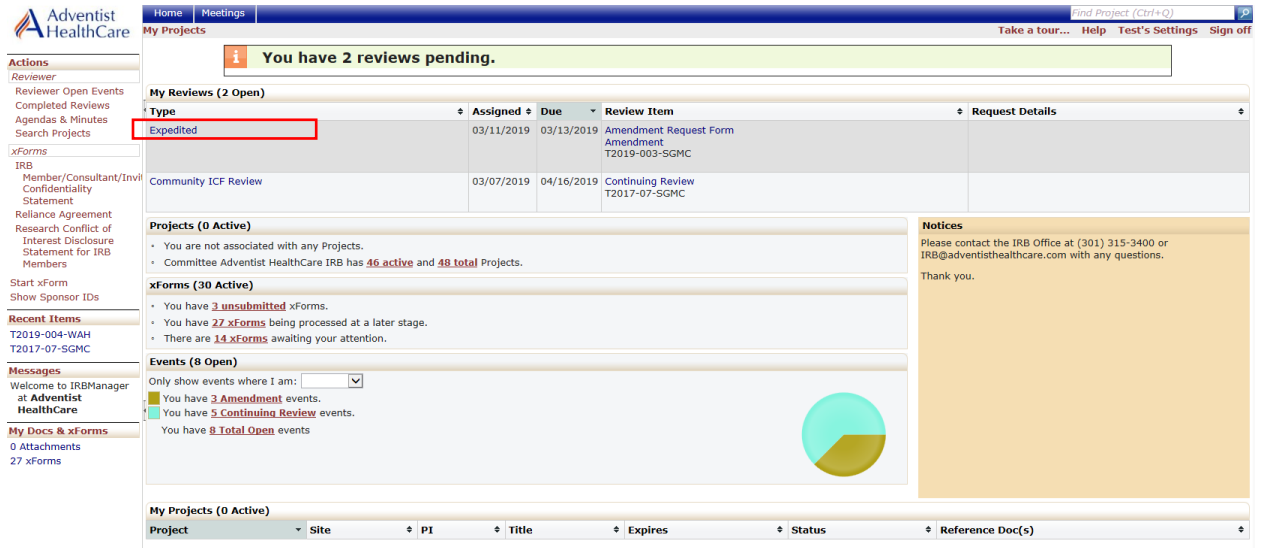
The screenshot shows the IRBManager dashboard interface. Key sections are highlighted with red boxes and labeled:

- a) Actions Sidebar:** Located on the left, it contains navigation links for Reviewer, Reviewer Open Events, Completed Reviews, Agendas & Minutes, Search Projects, xForms, IRB, Member/Consultant/In-Confidentiality Statement, Reliance Agreement, Research Conflict of Interest Disclosure Statement for IRB Members, Start xForm, Show Sponsor IDs, Recent Items, Messages, My Docs & xForms, and Attachments.
- b) My Projects Box:** A header area at the top right of the main content area.
- c) Reviewer Portlet:** A notification box stating "You have 2 reviews pending."
- d) My Reviews:** A table with columns: Type, Assigned, Due, and Review Item. It lists two review items: "Expedited" (Amendment Request Form Amendment) and "Community ICF Review" (Continuing Review).
- e) Notices:** A box on the right side containing a message from the IRB Office.
- f) My Projects Table:** A table at the bottom of the dashboard with columns: Project, Site, PI, Title, Expires, Status, and Reference Doc(s).

f) My Projects Table

Completing a Review:

- To complete a review, click on the review link on the 'My Reviews' table of your dashboard. The review link will direct you to the reviewer form.



Expedited Review

- You will use the 'Expedited Reviewer Form for Approved Studies' for expedited review items. The Review Assignment Header contains more information on the review type, review item, assigned date, and due date. If you would like to see the protocol deviation form submitted by the researcher, click the blue form link and you will be directed to the form.

Review Assignment	
Review Type: Expedited	Assigned: 03/19/2019 by Halaguena, Maria
Reviewer: IRB Manager, Test MD	Due: 03/21/2019
Review Item: Protocol Deviation	

4. The Study Header page will also populate below, and it contains more information on the study and submission documents.

a) Header Drop
Down

Collaborators Header ▼ Page 1 of 1 Next

Expedited Amendment, Reportable Event, and Site Closure Reviewer Form -- Header

Reviewer	Add Note View Audit
IRB Manager, Test MD	
Email: IRB@adventisthealthcare.com	Phone:
IRB Study Number	Add Note View Audit
T2019-007	
Study Name	Add Note View Audit
INITIAL REVIEW APPLICATION # 4	
Principal Investigator	Add Note View Audit
PI, Test MD	
Email: mhalague@terpmail.umd.edu	Phone:
Organizational Entity	Add Note View Audit
CCPL - Capital Choice Pathology Lab	
Documents Submitted for Review	Add Note View Audit
T2019-007 Protocol Deviation Reporting Form dated Mar1919 T2019-007 Corrective Action Plan dated Mar1919	
Submission Type	Delete Add Note View Audit
Deviation defined 3/18/2019	
IRB Office Recommendations	Add Note View Audit
test	

b) IRB Study Number

c) Protocol Deviation Event Link

d) IRB Office Recommendations

- a) The header drop down allows you to skip from one page to the next.
- b) If you want more information on the study, click the blue IRB study number link.
- c) The protocol deviation review link will direct you the study even where you can see more information such as the protocol deviation form.
- d) IRB Office Recommendations are available for your convenience and designed to help facilitate reviews.
- e) Indicate the review type (expedited or refer to full-board).
- f) Make recommendations on the approval status of the submission.

Indicate the new review type in the space below, if applicable. *(Required)* [Add Note](#) [View Audit](#)

Expedited Review (45 CFR 46.110(b)(2) / 21 CFR 56.110(b)(2))
 Refer to Full Board

Recommendation *(Required)* [Add Note](#) [View Audit](#)

Approve
 Approve Pending Modifications
 Refer to Full-Board

Please provide any additional comments, if applicable. [Add Note](#) [View Audit](#)

Attach revised documents to be discussed in the IRB meeting, if applicable.

[Add Attachment](#)

Reviewer Attestation [Add Note](#) [View Audit](#)

By entering your password in the space below, you acknowledge this review and are electronically signing this form.

(Required)
To sign, enter password for IRB@adventisthealthcare.com

[Delete](#)

[Next](#) [Save for Later](#) [More >](#)

- g) If you have any additional comments for the researchers, input them in the text box. These comments will go to the IRB Office for processing and ultimately to the research team.
- h) If you have revised documents that you would like to discuss in the full-board meeting, attach them.
- i) After completing the reviewer form, you will sign-off by inputting your IRBManager password.
- j) The completed reviewer form can be accessed in the actions side bay by clicking on 'completed reviews.' A list of your completed forms will populate. Choose the reviewer form you need.

Full-Board Review

5. The 'Expedited Reviewer Form for Approved Studies' will also feature the Review Assignment Header and Study Header similar to the expedited reviewer form.

Recommendation Full-Board <i>(Required)</i> <input type="radio"/> Approve <input type="radio"/> Conditionally Approved <input type="radio"/> Defer <input type="radio"/> Disapprove	Add Note View Audit
Please provide any required modifications, if applicable. <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>	Add Note View Audit
Please provide any recommended modifications, if applicable. <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>	Add Note View Audit
Please provide any additional comments, if applicable. <div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>	Add Note View Audit
Attach revised documents to be discussed in the IRB meeting, if applicable. <i>(Required)</i> <input type="button" value="Add Attachment"/>	
Reviewer Attestation <i>By entering your password in the space below, you acknowledge this review and are electronically signing this form.</i> <i>(Required)</i> To sign, enter password for IRB@adventisthealthcare.com <input type="password"/>	Add Note View Audit

- a) Indicate your recommendation for the study. This will **not** be the final determination for the study.
- b) Provide any required or recommended modifications if applicable.
- c) Attach any relevant documents you would like to discuss in the full-board meeting.
- d) Once you have completed the review, you will electronically sign-off on the document by inputting your IRBManager password

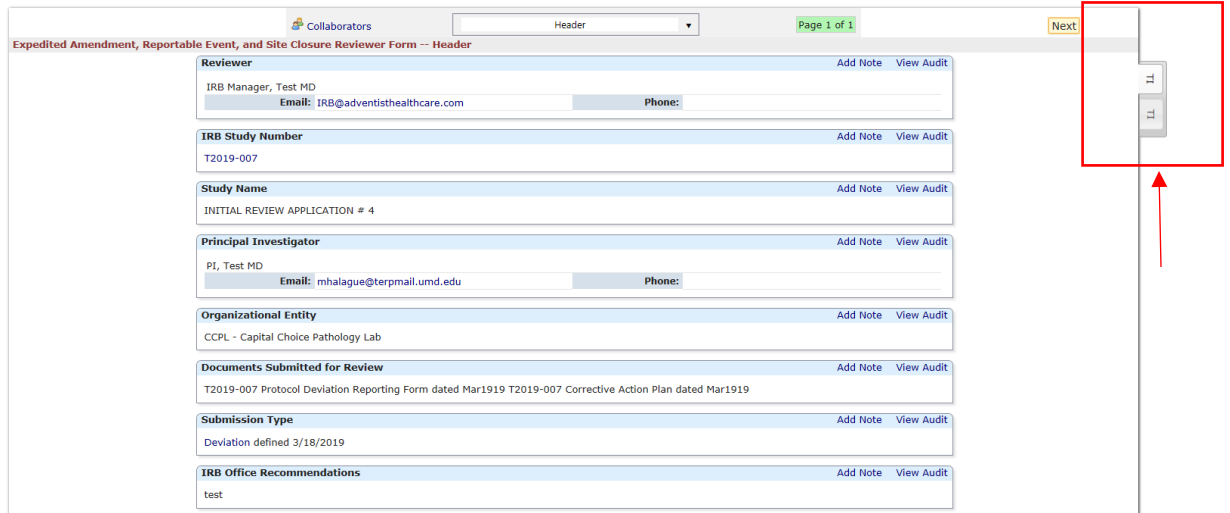
Review Outcomes:

Full-Approval

6. After the study has been granted full-approval, no further action is required and the reviewer form moves back to the IRB Office for processing.

Conditional Approval/Deferral/Disapproval

7. If the study is conditionally approved or does not receive full-approval, the comments and suggestions you indicated on the reviewer form will be sent to the IRB Office for processing and ultimately to the research team.
8. After study changes have been made, you will receive an email notification to conduct a second review of the study. Click on the blue form link and it will take you back to the reviewer form.



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Expedited Amendment, Reportable Event, and Site Closure Reviewer Form -- Header

Reviewer Add Note View Audit
IRB Manager, Test MD Email: IRB@adventisthealthcare.com Phone:
IRB Study Number Add Note View Audit
T2019-007
Study Name Add Note View Audit
INITIAL REVIEW APPLICATION # 4
Principal Investigator Add Note View Audit
PI, Test MD Email: mhalague@terpmail.umd.edu Phone:
Organizational Entity Add Note View Audit
CCPL - Capital Choice Pathology Lab
Documents Submitted for Review Add Note View Audit
T2019-007 Protocol Deviation Reporting Form dated Mar1919 T2019-007 Corrective Action Plan dated Mar1919
Submission Type Add Note View Audit
Deviation defined 3/18/2019
IRB Office Recommendations Add Note View Audit
test

- a) You will have access to the initial reviewer form you answered earlier. The tabs to the side of the reviewer form show you the current and previous reviewer form, respectively.
- b) After reviewing the changes to the protocol deviation form, complete the reviewer form and sign-off.

Terminology for IRBManager:

- ¹X-forms: online version of the currently existing submission documents with modifications.
- ²Projects: research studies
- ³Study Events/Events: actions or reviews for research studies. Examples include amendments, continuing review, and reportable events.