



Amendment Resource Guide for IRB Members

Purpose: To provide guidance on how to review an amendment application

Audience: IRB Members

Summary: This resource guide will focus on the review of an amendment application. 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 as well as the amendment type. The reviewer link will directly take you to the reviewer form.



IRB@adventisthealthcare.com | IRB@adventisthealthcare.com

Mon 12:15 PM

Study T2019-003: Amendment Review Request

IRB Study Number: T2019-003

Study Title: Efficacy of Cardiac Rehabilitation On the Reduction of Hospital Readmission Rate Post STEMI, NSTEMI, and Unstable Angina


Dear Test IRB Manager, MD,

An amendment 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=da0a97a4-ea94-4cde-9781-32289f0a6607&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 take you directly to the reviewer form.



IRB@adventisthealthcare.com | IRB

8:47 AM

4/25/2019 IRB Meeting: Study T2017-07 Review

 If there are problems with how this message is displayed, click here to view it in a web browser.

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

IRB Study Number: T2017-07

Study Name: A Randomized, Double Blind Controlled Factorial Clinical Trial of Edetate Disodium-Based Chelation and High-Dose Oral Vitamins and Minerals to Prevent Recurrent Cardiac Events in Diabetic Patients With a Prior Myocardial Infarction

Dear Test IRB Manager, MD,

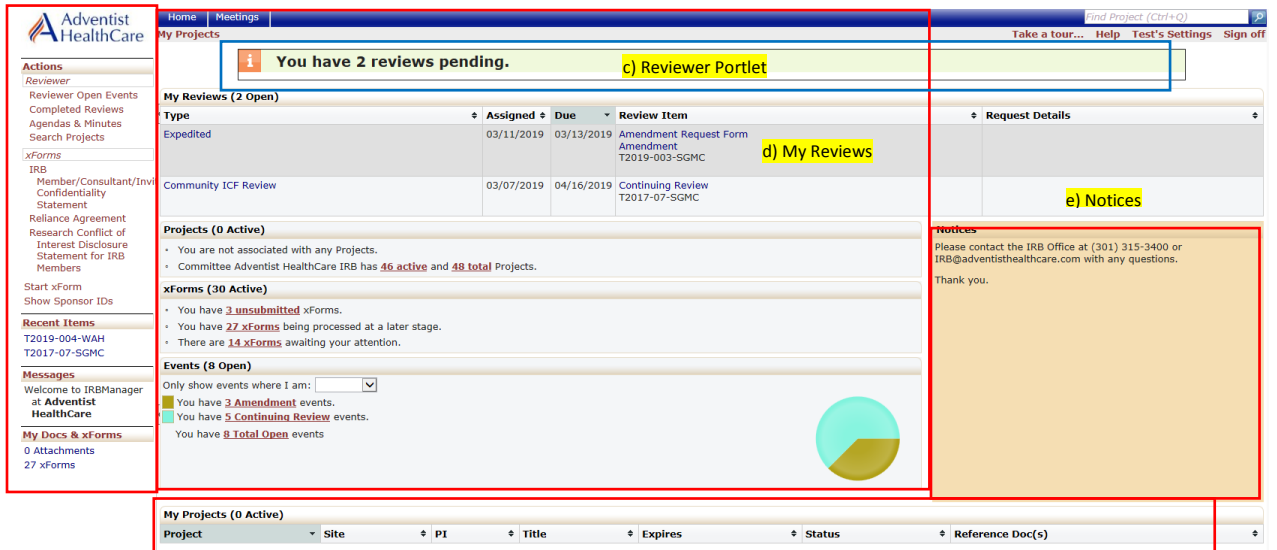
Will you please present the above referenced study to the IRB on Tuesday, 4/25/2019? Use this link to access the form <https://adventisthealthcare.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=6e12fd38-6f07-4fdc-bf2c-de141febe8c3&ReasonGuid=d39e427b-f4eb-488d-9384-7abf8e7e0a98>.

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.

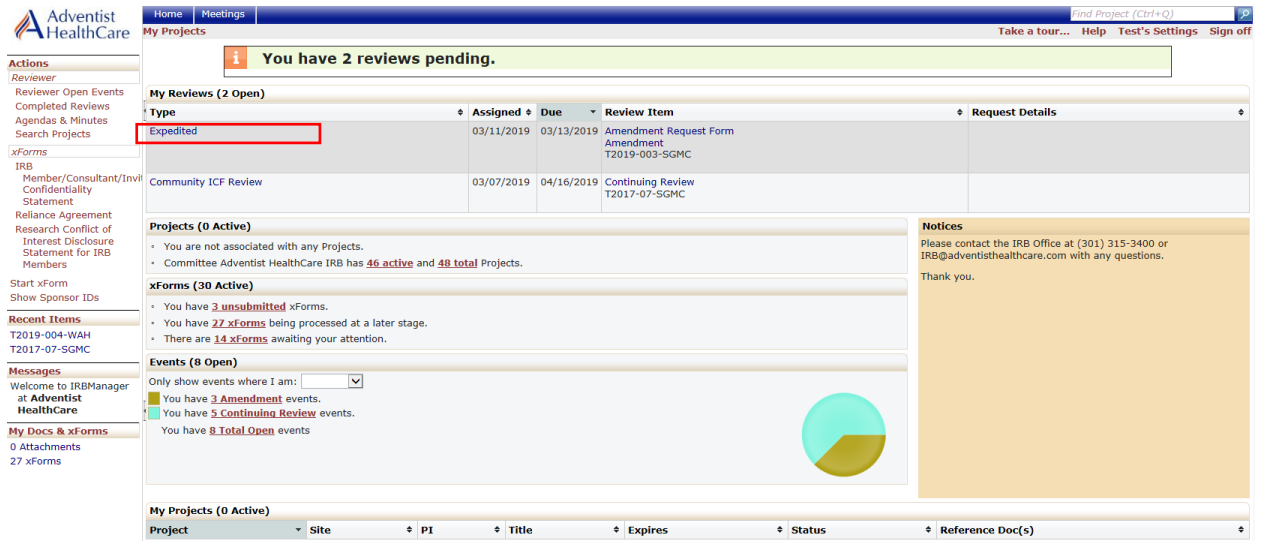
a) Actions Sidebar
b) My Projects Box



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.



My Reviews (2 Open)

Type	Assigned	Due	Review Item	Request Details
Expedited	03/11/2019	03/13/2019	Amendment Request Form Amendment T2019-003-SGMC	
Community ICF Review	03/07/2019	04/16/2019	Continuing Review T2017-07-SGMC	

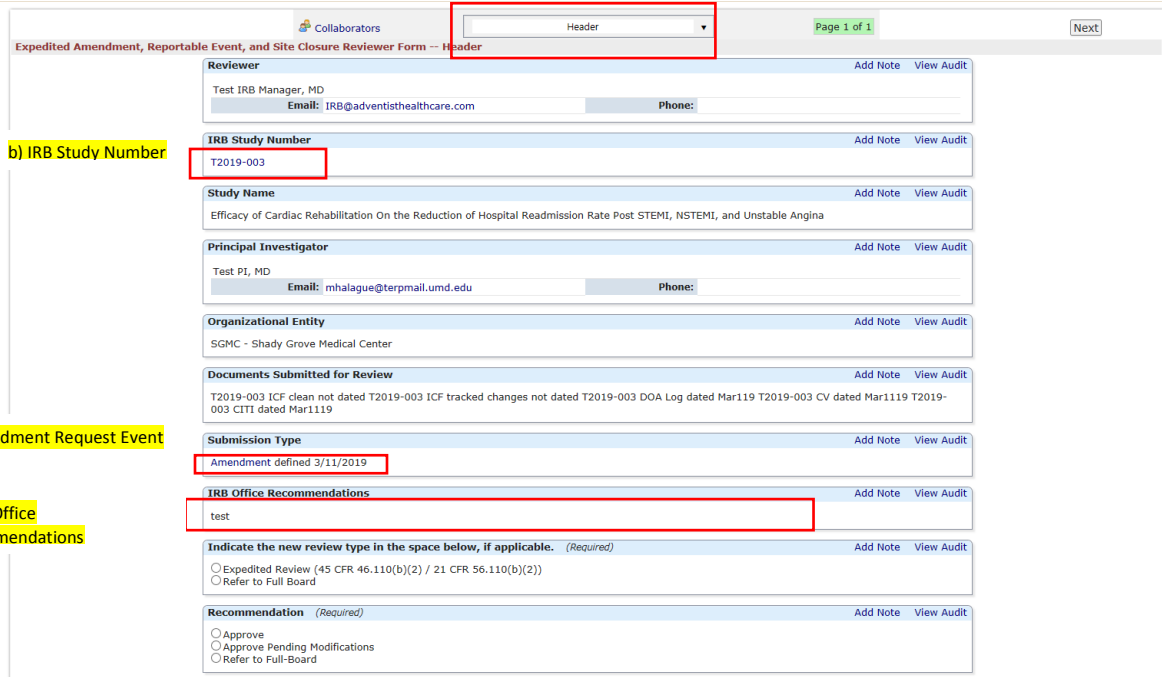
Expedited Review

- 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 Amendment Application submitted by the researcher, click the blue form link and you will be directed to the form.

Review Assignment	
Review Type:	Expedited
Reviewer:	Test IRB Manager, MD
Review Item:	Amendment Request Form
Assigned:	03/11/2019 by Maria Halaguena
Due:	03/13/2019

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

a) Header Drop
Down



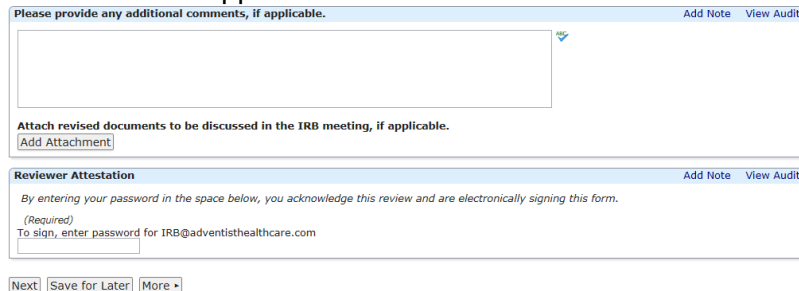
The screenshot shows a web-based form for IRB review. At the top, there is a 'Collaborators' section with a 'Header' dropdown menu highlighted by a red box. Below this, the form is divided into several sections, each with an 'Add Note' and 'View Audit' link. The sections include: 'Reviewer' (Test IRB Manager, MD), 'IRB Study Number' (T2019-003, highlighted by a red box), 'Study Name' (Efficacy of Cardiac Rehabilitation...), 'Principal Investigator' (Test PI, MD), 'Organizational Entity' (SGMC - Shady Grove Medical Center), 'Documents Submitted for Review' (T2019-003 ICF clean not dated T2019-003 ICF tracked changes not dated T2019-003 DOA Log dated Mar119 T2019-003 CV dated Mar1119 T2019-003 CITI dated Mar1119), 'Submission Type' (Amendment defined 3/11/2019, highlighted by a red box), 'IRB Office Recommendations' (test, highlighted by a red box), and 'Recommendation' (Approve, Approve Pending Modifications, Refer to Full-Board). A 'Next' button is visible in the top right corner.

b) IRB Study Number

c) Amendment Request Event
Link

d) IRB Office
Recommendations

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



This screenshot shows the bottom portion of the IRB review form. It features a large text box for 'Please provide any additional comments, if applicable.' with an 'Add Attachment' link below it. Below the text box is the 'Reviewer Attestation' section, which includes a required password field and a 'Next' button. The 'Next' button is highlighted with a red box. There are also 'Save for Later' and 'More -' buttons at the bottom.

- 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 full-board meetings, 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 bar by clicking on 'completed reviews.' A list of your completed forms will populate. Choose the reviewer form you need.

Full-Board Review

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

Recommendation Full-Board (Required) [Add Note](#) [View Audit](#)

Approve
 Conditionally Approved
 Defer
 Disapprove

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

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

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

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

[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

- 6.
- a) Make recommendations on the approval status of the submission. Please be aware that your recommendation is **not** the final board determination.
 - b) If you have any additional comments for the researchers, input them in the text boxes below. These will go to the IRB Office for processing and ultimately to the researchers.
 - c) If you have any revised documents that you would like to discuss in the full-board meeting, attach them.
 - d) After completing the reviewer form, you will sign-off by inputting your IRBManager password.
 - e) The completed reviewer form can be accessed in the actions side by by clicking on 'completed reviews.' A list of your completed forms will populate. Choose the reviewer form you need.

Full-Board Meetings: Community Member ICF Review Form

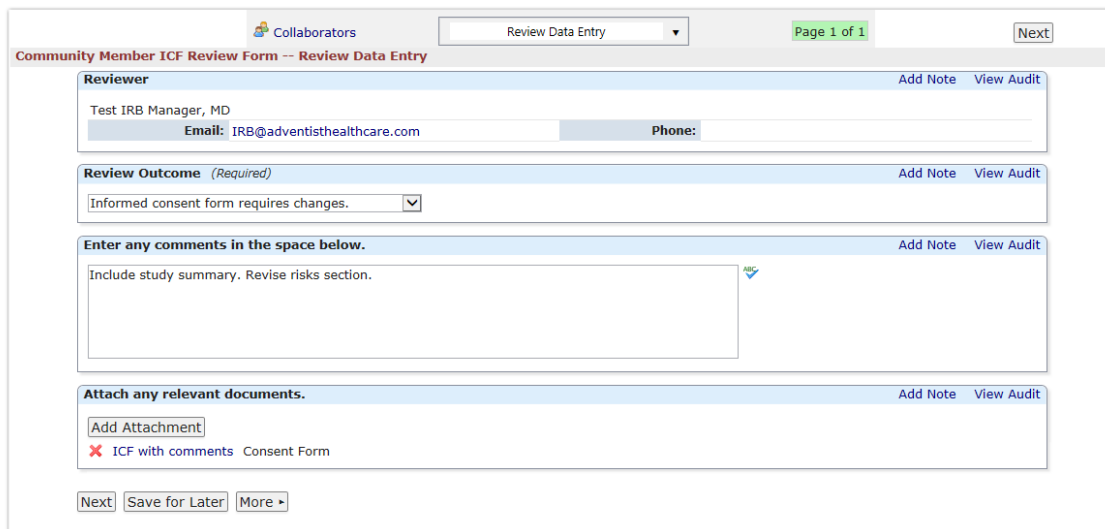
- The 'Community Member ICF Review Form' is where you can review and make edits to the informed consent form in preparation for the IRB meeting. To access the form, you will go to the meetings tab and click on the pages icon of the meeting date.

	12/02/2019	Adventist HealthCare IRB	Shady Grove Medical Center	01/25/2019	Not Finalized	Not yet created
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- You will see the meeting's agenda and all the review items. To review a study's informed consent form, click on the review link next to the event link. The review link will take you the 'Community Member ICF Review Form' where you can input all your comments and attach any relevant study documents.

Project	Title	PI	Instance	Reviewer
T2017-07-SGMC (Event) (Review)	A Randomized, Double Blind Controlled Factorial Clinical Trial of Edetate Disodium-Based Chelation a (hover for more...)	Test PI, MD		Test IRB Manager, MD

9.



Collaborators | Review Data Entry | Page 1 of 1 | Next

Community Member ICF Review Form -- Review Data Entry

Reviewer [Add Note](#) [View Audit](#)
 Test IRB Manager, MD
 Email: IRB@adventisthealthcare.com | Phone:

Review Outcome (Required) [Add Note](#) [View Audit](#)
 Informed consent form requires changes.

Enter any comments in the space below. [Add Note](#) [View Audit](#)
 Include study summary. Revise risks section.

Attach any relevant documents. [Add Note](#) [View Audit](#)
 Add Attachment
 ICF with comments Consent Form

Next | Save for Later | More >

- Decide on a review outcome (i.e. requires changes or no changes necessary).
- If you have any comments, enter them in the text box.
- Attach any relevant documents.

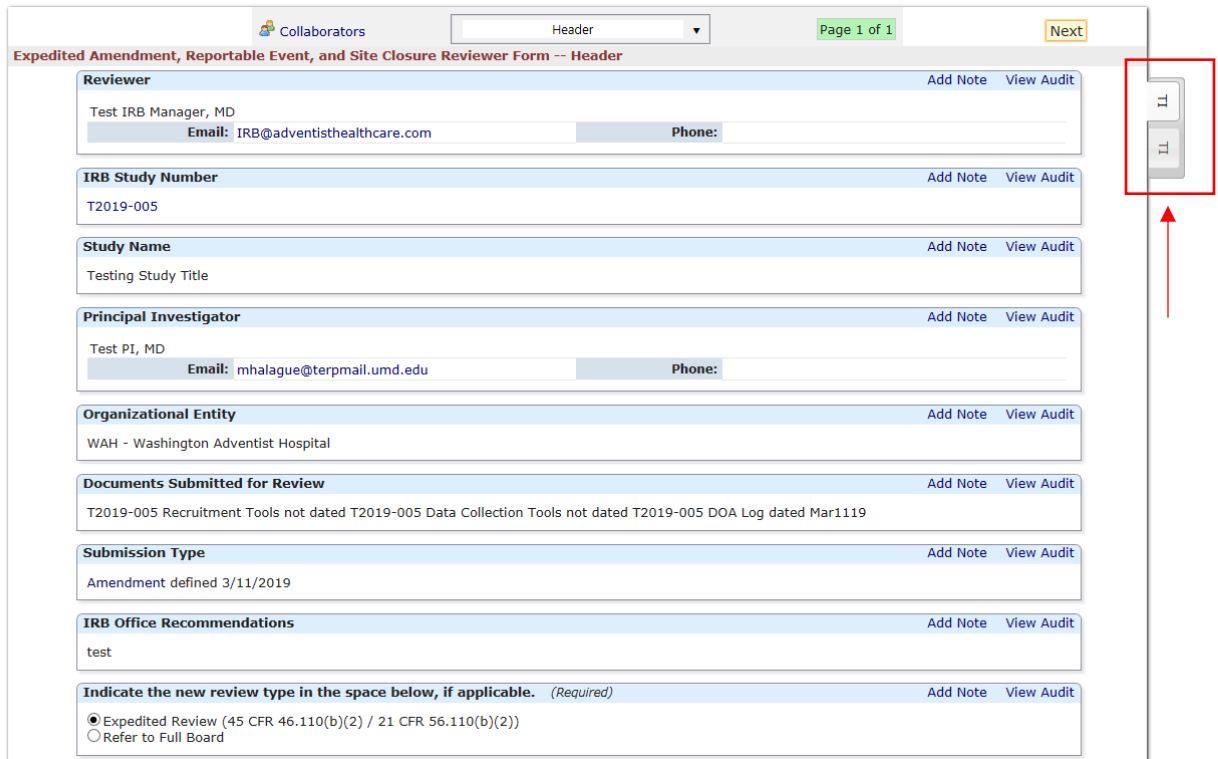
Review Outcomes:

Full-Approval

10. 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

- 11. If the study 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.
- 12. After the 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.



Collaborators Header Page 1 of 1 Next

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

Reviewer Add Note View Audit
 Test IRB Manager, MD
 Email: IRB@adventisthealthcare.com Phone:

IRB Study Number Add Note View Audit
 T2019-005

Study Name Add Note View Audit
 Testing Study Title

Principal Investigator Add Note View Audit
 Test PI, MD
 Email: mhalague@terpmail.umd.edu Phone:

Organizational Entity Add Note View Audit
 WAH - Washington Adventist Hospital

Documents Submitted for Review Add Note View Audit
 T2019-005 Recruitment Tools not dated T2019-005 Data Collection Tools not dated T2019-005 DOA Log dated Mar1119

Submission Type Add Note View Audit
 Amendment defined 3/11/2019

IRB Office Recommendations Add Note View Audit
 test

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

- 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 initial review application, complete the reviewer form and sign-off.

Terminology for IRBManager:

- ¹X-forms: online version of the currently existing submission documents with slight modifications.
- ²Projects: research studies
- ³Study Events/Events: actions or reviews for research studies. Examples include amendments, continuing reviews, and reportable events.
- ⁴Protocol site output: where the study will primarily take place. There may be more than one site listed.
- ⁵Agent type: description of the nature of the study or the investigational aspect of the study (e.g., observational, specimen review, drug, device, etc.).
- ⁶Creating user: the study staff member who started the x-form data entry.