



Continuing Review Resource Guide for IRB Members

Purpose: To provide guidance on how to review a continuing review submission.

Audience: IRB Members

Summary: This resource guide will focus on the review of a continuing review application. The 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.

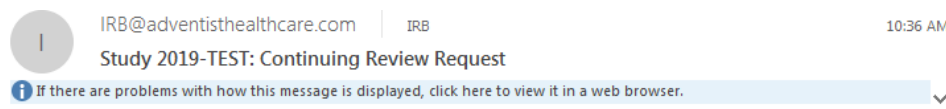
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Email Notifications:

Expedited Review

1. After the IRB 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.



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: 2019-TEST

Study Title: Best Drug/Device Study Ever

Dear Test IRB Manager, MD,

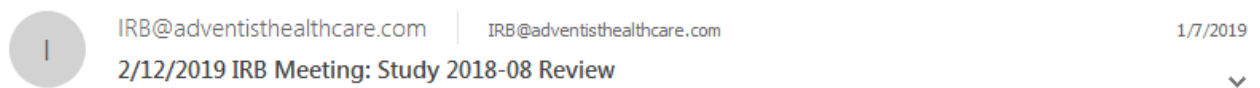
A continuing review for the above referenced study is ready for expedited review. Direct link to the documentation can be accessed here:

<https://adventisthealthcare.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=359f7c92-9e2a-4acf-9b9e-c7698b747b22&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.



Dear Test IRB Manager, MD,

Will you please present the 2018-08-CREST-H to the IRB on Tuesday, 2/12/2019? Use this link to access the form

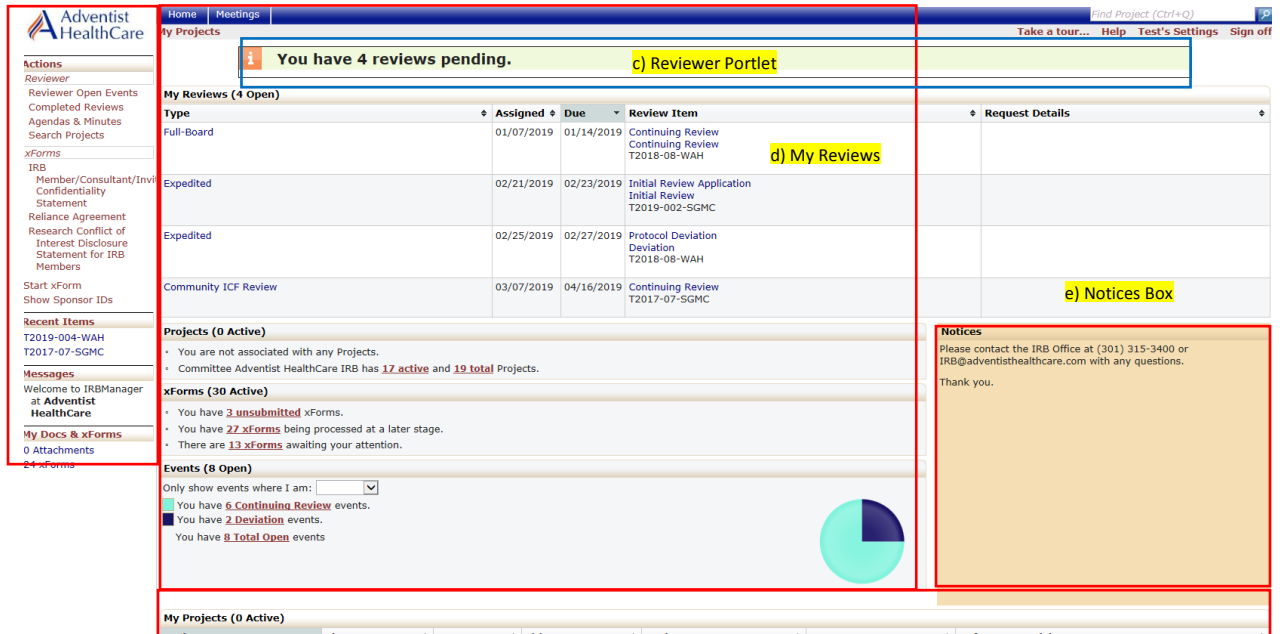
<https://adventisthealthcare.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=77d6a7ce-8a52-406b-a747-e4d707977b14&ReasonGuid=d39e427b-f4eb-488d-9384-7abf8e7e0a98>.

Thank you.

Dashboard Information:

3. 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 Box: 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.

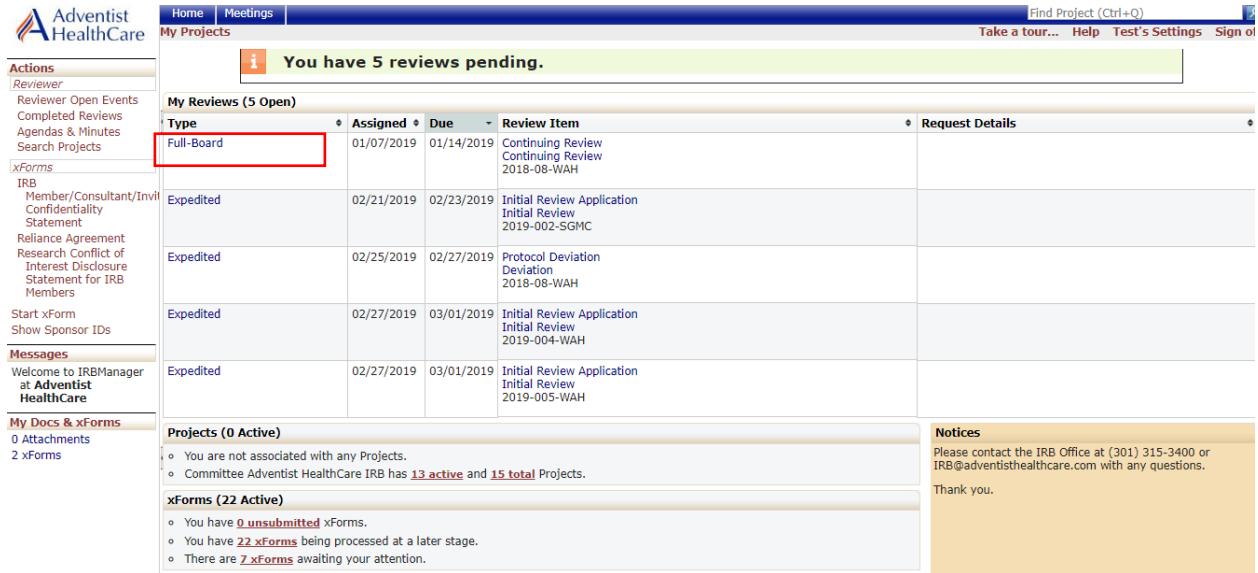
a) Actions Sidebar
b) My Projects Box



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 (5 Open)

Type	Assigned	Due	Review Item	Request Details
Full-Board	01/07/2019	01/14/2019	Continuing Review Continuing Review 2018-08-WAH	
Expedited	02/21/2019	02/23/2019	Initial Review Application Initial Review 2019-002-SGMC	
Expedited	02/25/2019	02/27/2019	Protocol Deviation Deviation 2018-08-WAH	
Expedited	02/27/2019	03/01/2019	Initial Review Application Initial Review 2019-004-WAH	
Expedited	02/27/2019	03/01/2019	Initial Review Application Initial Review 2019-005-WAH	

Projects (0 Active)

- You are not associated with any Projects.
- Committee Adventist HealthCare IRB has **13 active** and **15 total** Projects.

xForms (22 Active)

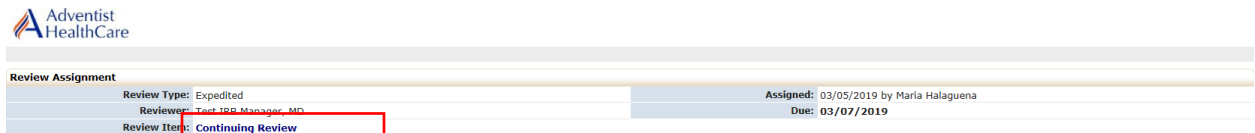
- You have **0 unsubmitted** xForms.
- You have **22 xForms** being processed at a later stage.
- There are **7 xForms** awaiting your attention.

Notices

Please contact the IRB Office at (301) 315-3400 or IRB@adventisthealthcare.com with any questions.
Thank you.

Expedited Review and Full-Board Review

- You will use the 'Initial or Continuing Reviewer Form' for both expedited and full-board 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 continuing review application submitted by the researcher, click the blue form link and you will be directed to the form.

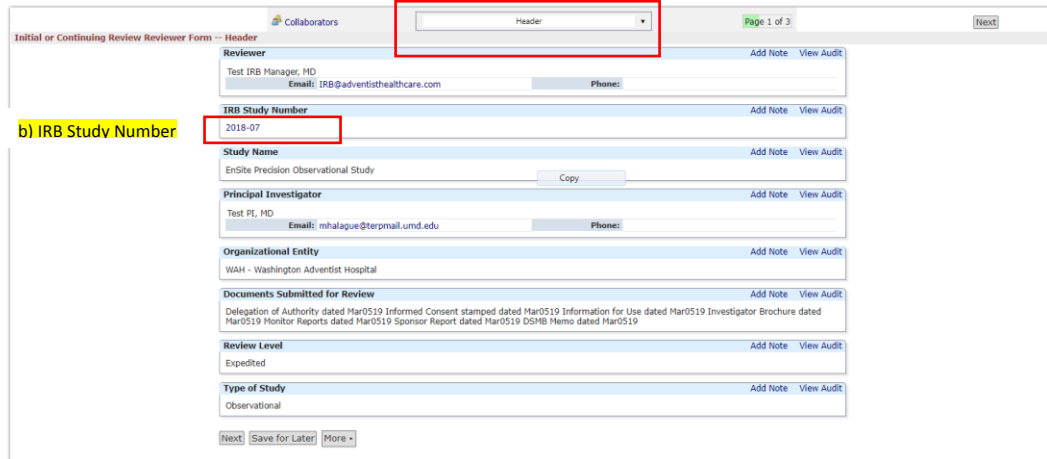


Review Assignment

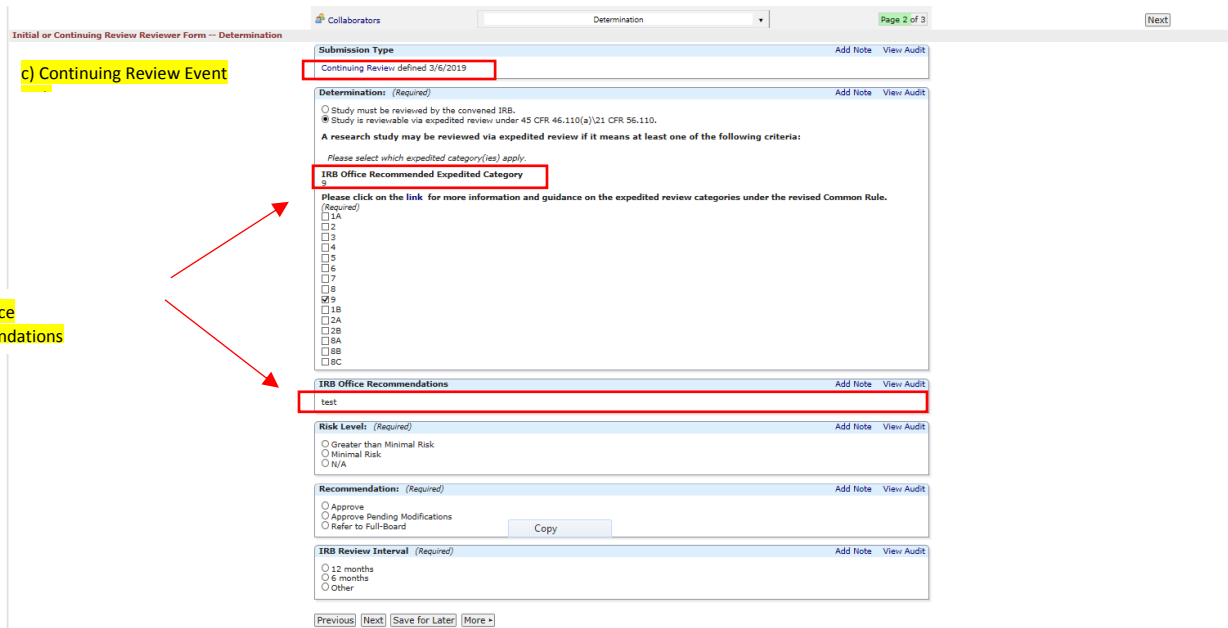
Review Type: Expedited	Assigned: 03/05/2019 by Maria Halaguena
Reviewer: Test IRB Manager, MD	Due: 03/07/2019
Review Item: Continuing Review	

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

a) Header
Drop Down



- 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 continuing review event link will direct you to the study event where you can see more information such as the continuing review application.
- d) Indicate the determination (expedited or refer to full-board).
- e) IRB Office Recommendations are available for your convenience and designed to help facilitate reviews. A link to the expedited categories under the revised Common Rule is also available for further guidance.
- f) Provide a risk determination level for the study.


- g) Make recommendations on the approval status of the submission. If the study has been designated for full-board review by the IRB Office, the recommendation you make on the reviewer form is **not the final decision**.
- h) Provide an IRB review interval.
- i) The next page will ask you questions about the study's informed consent procedures, risks, benefits, and protections. In this section, you can also make required or recommended recommendations. Your recommendations will go to the IRB Office and then ultimately to the research team.

Please note: You will be asked to provide an explanation on certain questions based on your answer. Furthermore, questions marked as required cannot be left unanswered. You will not be allowed to submit the form until you answer the required questions.

- j) After completing the reviewer form, you will sign-off by inputting your IRBManager password.
- k) The completed reviewer forms 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 Meetings: Community Member ICF Review Form

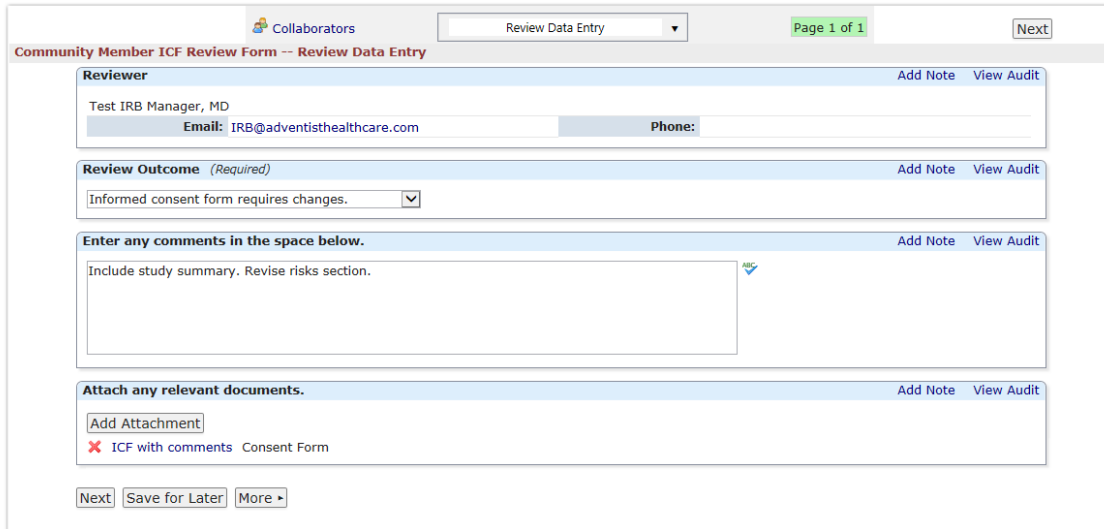
7. The 'Community Member ICF Review Form' is where you can review and make edits to the informed consent form in preparation for the IRB meeting. To access the form, you will go to the meetings tab and click on the pages icon of the meeting date.

	12/02/2019	Adventist HealthCare IRB	Shady Grove Medical Center	01/25/2019	Not Finalized	Not yet created
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8. 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 ▾

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

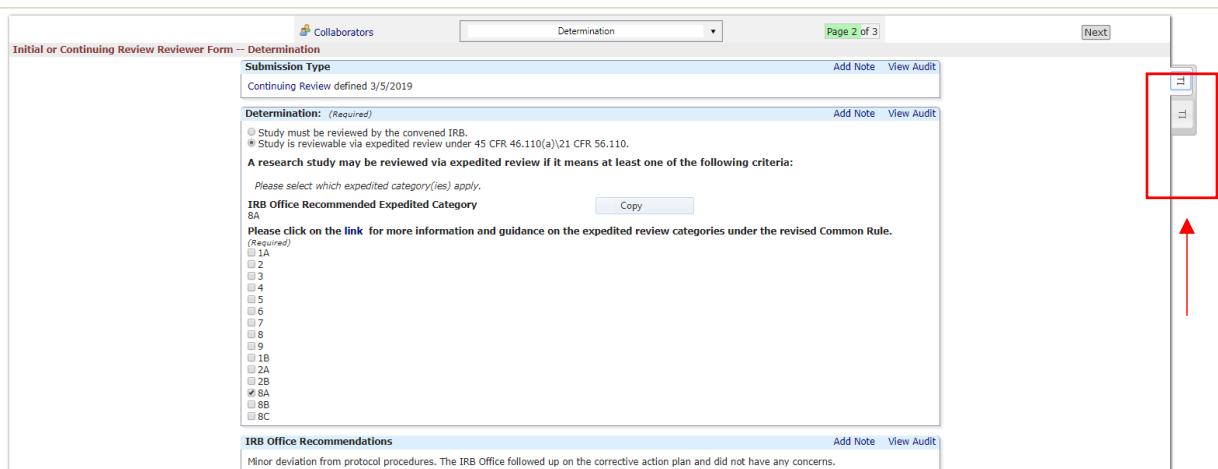
Review Outcomes:

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 a 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.
12. 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.



Collaborators | Determination | Page 2 of 3 | Next

Initial or Continuing Review Reviewer Form - Determination

Submission Type [Add Note](#) [View Audit](#)
Continuing Review defined 3/5/2019

Determination: (Required) [Add Note](#) [View Audit](#)
 Study must be reviewed by the convened IRB.
 Study is reviewable via expedited review under 45 CFR 46.110(a)(2) 21 CFR 56.110.
A research study may be reviewed via expedited review if it means at least one of the following criteria:
 Please select which expedited category(ies) apply.
IRB Office Recommended Expedited Category [Copy](#)
 8A
 Please click on the link for more information and guidance on the expedited review categories under the revised Common Rule.
 (Required)
 1A
 2
 3
 4
 5
 6
 7
 8
 9
 1B
 2A
 2B
 8A
 8B
 8C

IRB Office Recommendations [Add Note](#) [View Audit](#)
Minor deviation from protocol procedures. The IRB Office followed up on the corrective action plan and did not have any concerns.

- 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 continuing 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 review, and reportable event