



Reportable Event Guide for IRB Members

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

Audience: IRB Members

Summary: This resource guide will focus on the review of a reportable event 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.

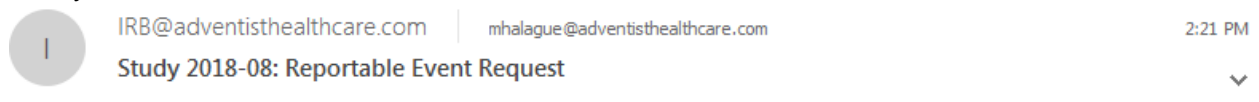
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Email Notifications:

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.



IRB Study Number: 2018-08

Study Title: CREST-H

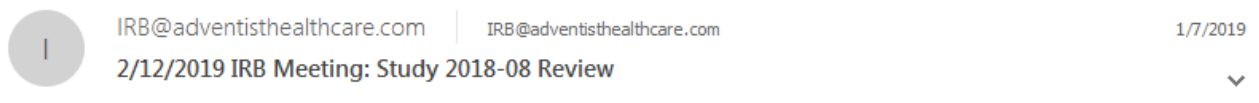
Dear Maria Halaguena,

A reportable event 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=31931de0-4102-4bd5-b021-fc2ed91bcaa5&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,

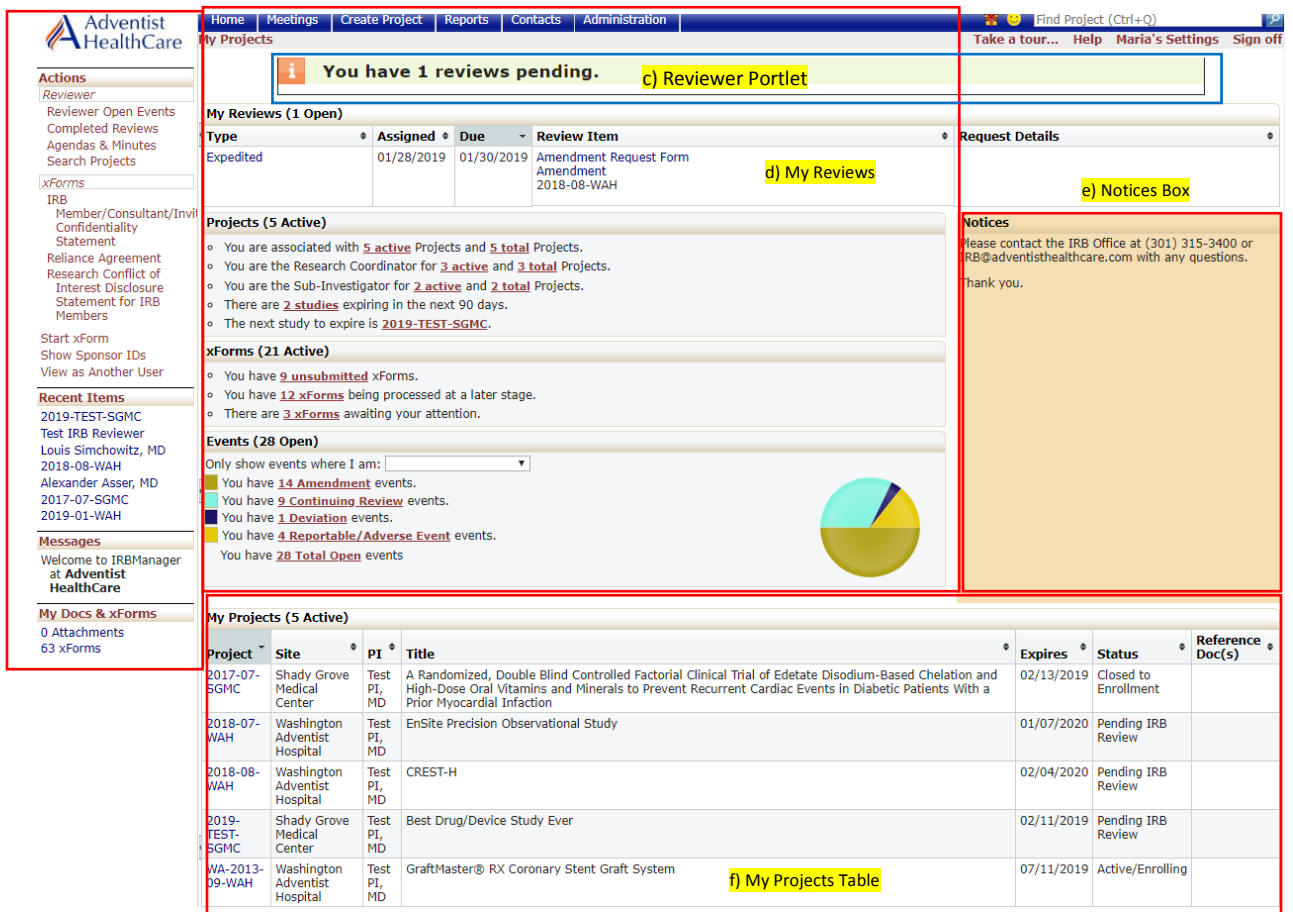
Will you please present the 2018-08-CREST-H to the IRB on Tuesday, 2/12/2019? Use this link to access the form <https://adventisthealthcare.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=77d6a7ce-8a52-406b-a747-e4d707977b14&ReasonGuid=d39e427b-f4eb-488d-9384-7abf8e7e0a98>.

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



Actions

Reviewer

- Reviewer Open Events
- Completed Reviews
- Agendas & Minutes
- Search Projects

xForms

- IRB
- Member/Consultant/Inv
- Confidentiality
- Statement
- Reliance Agreement
- Research Conflict of
- Interest Disclosure
- Statement for IRB
- Members

Start xForm

Show Sponsor IDs

View as Another User

Recent Items

- 2019-TEST-SGMC
- Test IRB Reviewer
- Louis Simchowicz, MD
- 2018-08-WAH
- Alexander Asser, MD
- 2017-07-SGMC
- 2019-01-WAH

Messages

Welcome to IRBManager at Adventist HealthCare

My Docs & xForms

- 0 Attachments
- 63 xForms

You have 1 reviews pending.

My Reviews (1 Open)

Type	Assigned	Due	Review Item
Expedited	01/28/2019	01/30/2019	Amendment Request Form Amendment 2018-08-WAH

Projects (5 Active)

- You are associated with **5 active** Projects and **5 total** Projects.
- You are the Research Coordinator for **3 active** and **3 total** Projects.
- You are the Sub-Investigator for **2 active** and **2 total** Projects.
- There are **2 studies** expiring in the next 90 days.
- The next study to expire is **2019-TEST-SGMC**.

xForms (21 Active)

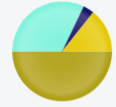
- You have **9 unsubmitted** xForms.
- You have **12 xForms** being processed at a later stage.
- There are **3 xForms** awaiting your attention.

Events (28 Open)

Only show events where I am: ▼

- You have **14 Amendment** events.
- You have **9 Continuing Review** events.
- You have **1 Deviation** events.
- You have **4 Reportable/Adverse Event** events.

You have **28 Total Open** events



My Projects (5 Active)

Project	Site	PI	Title	Expires	Status	Reference Doc(s)
2017-07-SGMC	Shady Grove Medical Center	Test PI, MD	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	02/13/2019	Closed to Enrollment	
2018-07-WAH	Washington Adventist Hospital	Test PI, MD	EnSite Precision Observational Study	01/07/2020	Pending IRB Review	
2018-08-WAH	Washington Adventist Hospital	Test PI, MD	CREST-H	02/04/2020	Pending IRB Review	
2019-TEST-SGMC	Shady Grove Medical Center	Test PI, MD	Best Drug/Device Study Ever	02/11/2019	Pending IRB Review	
WA-2013-09-WAH	Washington Adventist Hospital	Test PI, MD	GraftMaster® RX Coronary Stent Graft System	07/11/2019	Active/Enrolling	

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.

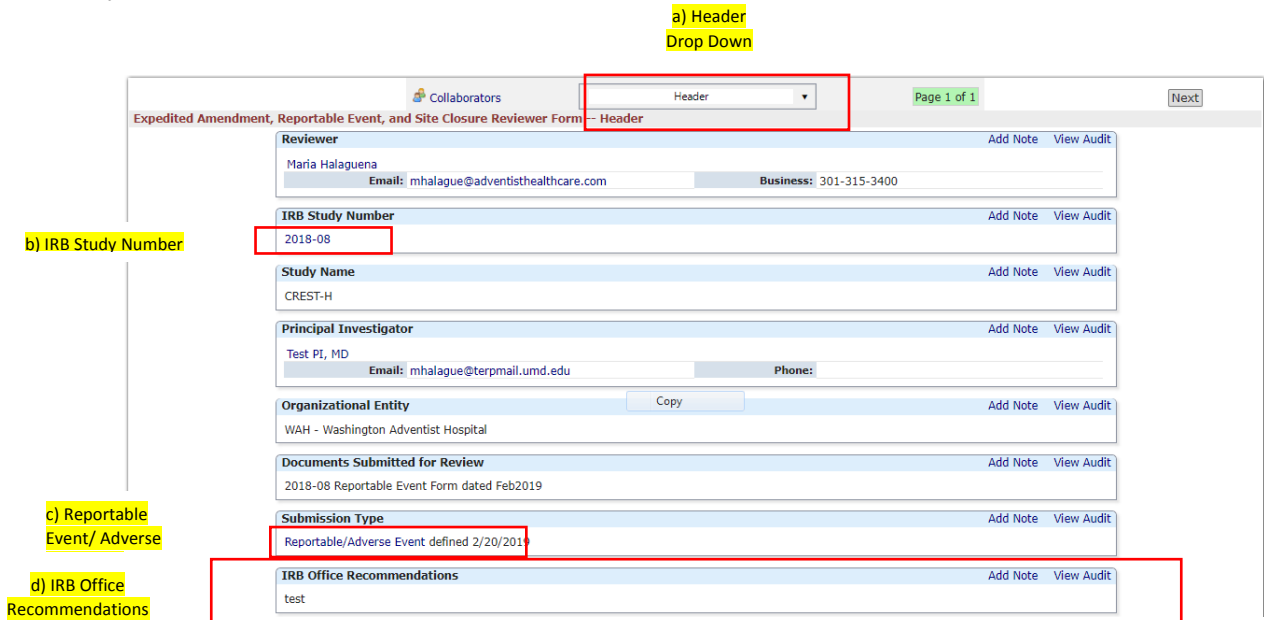
The screenshot shows the IRB Manager dashboard. At the top, a navigation bar includes Home, Meetings, Create Project, Reports, Contacts, and Administration. A search bar is on the right. A green banner at the top of the main content area states "You have 1 reviews pending." Below this is the "My Reviews (1 Open)" table, where one review is listed with a red box around the "Expedited" type. To the right of the reviews is a "Notices" section with contact information for the IRB Office. Below the reviews are sections for "Projects (5 Active)", "xForms (21 Active)", and "Events (28 Open)", each with a summary of counts and a pie chart. At the bottom is the "My Projects (5 Active)" table, listing project details like Project ID, Site, PI, Title, Expires, Status, and Reference Doc(s).

Expedited Review

- For **expedited review** items, you will use the 'Expedited Reviewer Form for Approved Studies'. 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 Reportable Event Form submitted by the researcher, click the blue form link and you will be directed to the form.

Review Assignment	
Review Type:	Expedited
Reviewer:	Maria Halaguena
Review Item:	Reportable Event
Assigned:	02/20/2019 by Maria Halaguena
Due:	02/22/2019

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



a) Header Drop Down

b) IRB Study Number

c) Reportable Event/ Adverse

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 reportable event/adverse event link will direct you to the study event where you can see more information such as the reportable event/adverse event.
- d) Recommendations from the IRB Office are available for your convenience and designed to help facilitate reviews.

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

Copy

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 mhalague@adventisthealthcare.com

Next Save for Later More -

e) Indicate the review type (expedited or refer to full-board) for the reportable event submission.

- f) Make recommendations on the approval status of the submission.
- g) If you have any additional comments, include them in the text box. These comments will go to the IRB Office and then ultimately to the researcher.
- h) Once you have completed the review, you will electronically sign-off on the document by inputting your IRBManager password.

Full-Board Review

7. For **full-board review** items, you will use the 'Full-Board Reviewer Form for Approved Studies'. The Full-Board Reviewer Form will also feature the Review Assignment Header and Study Header page.

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)

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

- 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
8. 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.

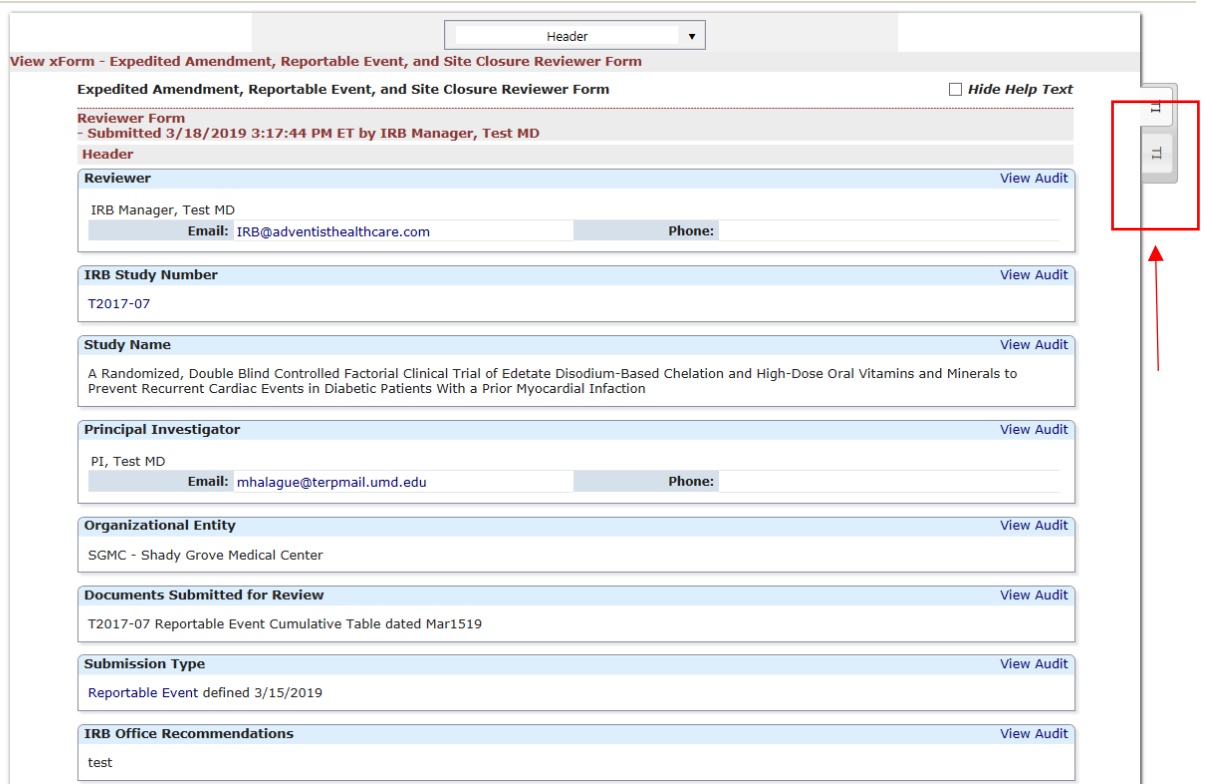
Review Outcomes:

Full Approval:

9. 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

10. If a 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.
11. 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.



Header

View xForm - Expedited Amendment, Reportable Event, and Site Closure Reviewer Form Hide Help Text

Expedited Amendment, Reportable Event, and Site Closure Reviewer Form

Reviewer Form
- Submitted 3/18/2019 3:17:44 PM ET by IRB Manager, Test MD

Header

Reviewer View Audit

IRB Manager, Test MD

Email: IRB@adventisthealthcare.com Phone:

IRB Study Number View Audit

T2017-07

Study Name View Audit

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

Principal Investigator View Audit

PI, Test MD

Email: mhalague@terpmail.umd.edu Phone:

Organizational Entity View Audit

SGMC - Shady Grove Medical Center

Documents Submitted for Review View Audit

T2017-07 Reportable Event Cumulative Table dated Mar1519

Submission Type View Audit

Reportable Event defined 3/15/2019

IRB Office Recommendations 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 reportable event application, 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.