

## **Site Closure Guide for IRB Members**

**Purpose:** To provide guidance on how to review a site closure

**Audience:** IRB Members

**Summary:** This resource guide will focus on the review of a site closure 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.

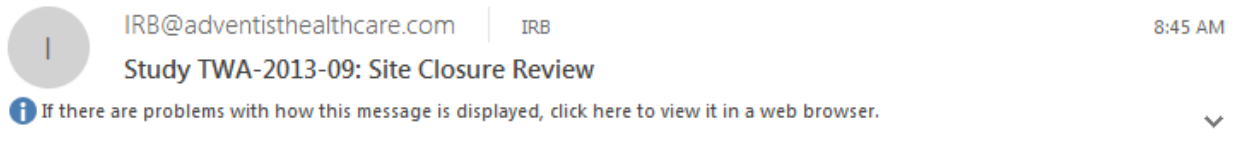
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## Email Notifications:

### 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.



**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: TWA-2013-09

Study Title: GraftMaster® RX Coronary Stent Graft System

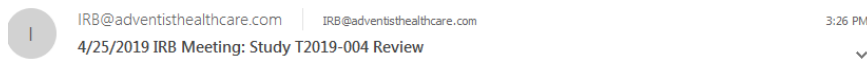
Dear Test IRB Manager, MD,

A site closure 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=cad84ea3-4967-40c7-a376-023725d1df89&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,

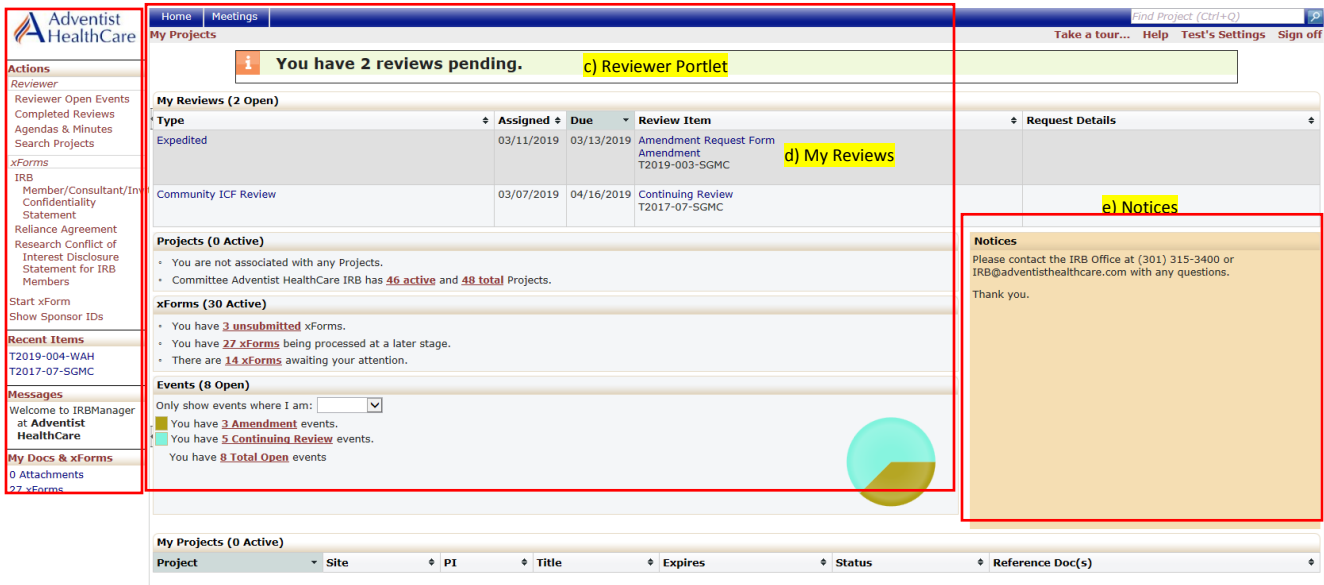
Will you please present the above referenced study to the IRB on Tuesday, 4/25/2019? Use this link to access the form <https://adventisthealthcare.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=6d317461-baab-4a19-9099-bb1b757b3af4&ReasonGuid=d39e427b-f4eb-488d-9384-7abf8e7e0a98>.

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-forms<sup>1</sup> 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 projects<sup>2</sup>, x-forms, and study events<sup>3</sup>.
  - 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 as follows:

- a) Actions Sidebar:** Located on the left, it contains navigation links for Actions, 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 27 xForms.
- b) My Projects Box:** A central area containing summary statistics for Projects (0 Active), xForms (30 Active), and Events (8 Open).
- c) Reviewer Portlet:** A notification box at the top center stating "You have 2 reviews pending."
- d) My Reviews:** A table listing review items with columns for Type, Assigned, Due, and Review Item.
- e) Notices:** A box on the right containing a message from the IRB Office.
- f) My Projects Table:** A table at the bottom listing active research studies with columns for Project, Site, PI, Title, Expires, Status, and Reference Doc(s).

Type	Assigned	Due	Review Item
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

Project	Site	PI	Title	Expires	Status	Reference Doc(s)
My Projects (0 Active)						

### 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, there is a navigation bar with 'Home' and 'Meetings' tabs. Below the navigation bar, a message states 'You have 2 reviews pending.' The main content area is titled 'My Reviews (2 Open)' and contains a table with the following data:

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	

Below the table, there are sections for 'Projects (0 Active)', 'xForms (30 Active)', and 'Events (8 Open)'. A pie chart is visible in the 'Events' section. On the right side, there is a 'Notices' section with contact information for the IRB Office.

### Expedited Review

- You will use the 'Expedited Amendment, Reportable Event, and Site Closure Reviewer Form' 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.

The screenshot shows the 'Review Assignment' header with the following information:

Review Type:	Expedited	Assigned:	03/20/2019 by Halaguena, Maria
Reviewer:	IRB Manager, Test MD	Due:	03/22/2019
Review Item:	Site Closure Application		

- 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**

<b>Reviewer</b>	Add Note View Audit
IRB Manager, Test MD	
Email: IRB@adventisthealthcare.com	Phone: _____
<b>IRB Study Number</b>	Add Note View Audit
TWA-2013-09	
<b>Study Name</b>	Add Note View Audit
GraftMaster® RX Coronary Stent Graft System	
<b>Principal Investigator</b>	Add Note View Audit
PI, Test MD	
Email: mhalague@terpmail.umd.edu	Phone: _____
<b>Organizational Entity</b>	Add Note View Audit
WAH - Washington Adventist Hospital	
<b>Documents Submitted for Review</b>	Add Note View Audit
TWA-2013-09 Site Closure Form dated Mar3019	
<b>Submission Type</b>	Add Note View Audit
Site Closure defined 3/20/2019	
<b>IRB Office Recommendations</b>	Add Note View Audit
test	

b) IRB Study Number

c) Site Closure 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 site closure review link will direct you the study even where you can see more information such as the site closure form.
- d) IRB Office Recommendations are available for your convenience and designed to help facilitate reviews.

<b>Indicate the new review type in the space below, if applicable.</b> <small>(Required)</small>	Add Note View Audit
<input type="radio"/> Expedited Review (45 CFR 46.110(b)(2) / 21 CFR 56.110(b)(2)) <input type="radio"/> Refer to Full Board	
<b>Recommendation</b> <small>(Required)</small>	Add Note View Audit
<input type="radio"/> Approve <input type="radio"/> Approve Pending Modifications <input type="radio"/> Refer to Full-Board	
<b>Please provide any additional comments, if applicable.</b>	Add Note View Audit
<div style="border: 1px solid #ccc; width: 100%; height: 100%;"></div>	
<b>Attach revised documents to be discussed in the IRB meeting, if applicable.</b>	
<input type="button" value="Add Attachment"/>	
<b>Reviewer Attestation</b>	Add Note View Audit
<p><i>By entering your password in the space below, you acknowledge this review and are electronically signing this form.</i></p> <p><small>(Required)</small></p> <p>To sign, enter password for IRB@adventisthealthcare.com</p> <div style="border: 1px solid #ccc; width: 100%; height: 20px;"></div>	
<input type="button" value="Next"/> <input type="button" value="Save for Later"/> <input type="button" value="More"/>	

Copy

- e) Indicate the review type (expedited or refer to full-board).
- f) Make recommendations on the approval status of the submission.
- 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 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 bay by clicking on 'completed reviews.' A list of your completed forms will populate. Choose the reviewer form you need.

### Full-Board Review

5. 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](#) 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

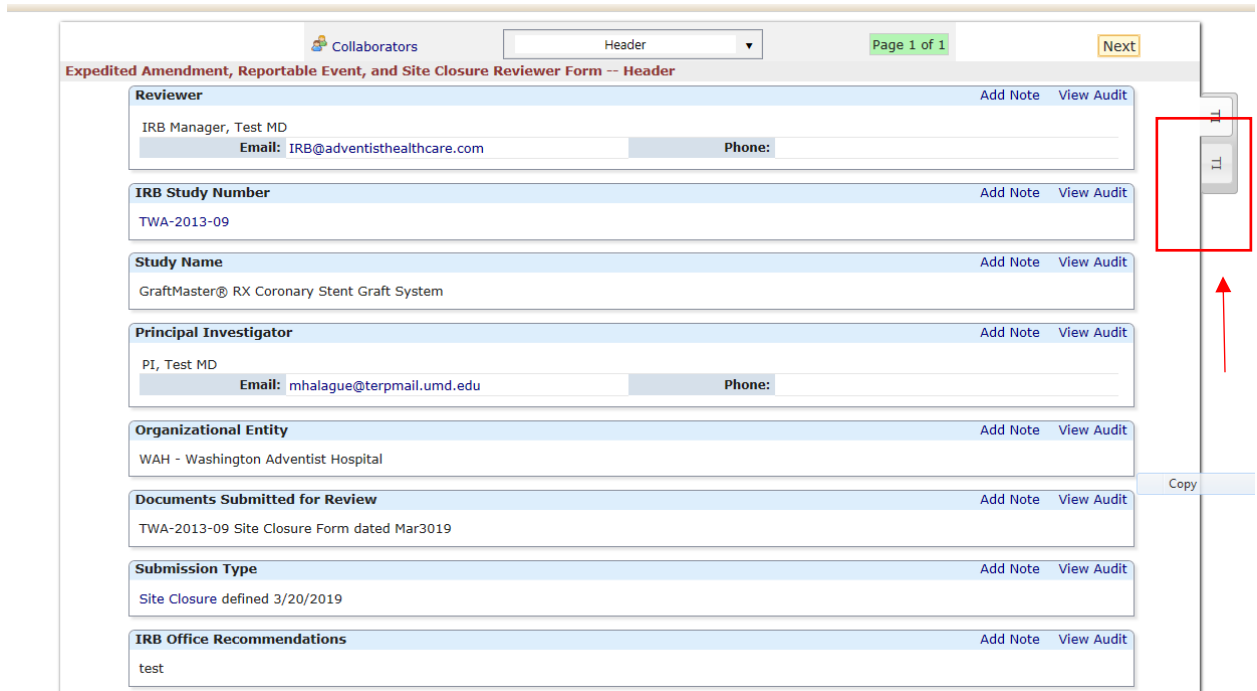
**Review Outcomes:**

**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**

<b>Reviewer</b>	Add Note View Audit
IRB Manager, Test MD	
Email: IRB@adventisthealthcare.com	Phone:
<b>IRB Study Number</b>	Add Note View Audit
TWA-2013-09	
<b>Study Name</b>	Add Note View Audit
GraftMaster® RX Coronary Stent Graft System	
<b>Principal Investigator</b>	Add Note View Audit
PI, Test MD	
Email: mhalague@terpmail.umd.edu	Phone:
<b>Organizational Entity</b>	Add Note View Audit
WAH - Washington Adventist Hospital	
<b>Documents Submitted for Review</b>	Add Note View Audit
TWA-2013-09 Site Closure Form dated Mar3019	
<b>Submission Type</b>	Add Note View Audit
Site Closure defined 3/20/2019	
<b>IRB Office Recommendations</b>	Add Note View Audit
test	

Copy

- 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:**

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