Adventist HealthCare

Site Closure Resource Guide for Research Personnel and Principal Investigators

Purpose: To provide guidance from data entry to IRB submission and determination letter dissemination.

Audience: Research Personnel and Principal Investigators

Summary: This resource guide will focus on the site closure from data entry to IRB submission and determination letter dissemination. The information provided in this resource guide contains helpful information for both research personnel and principal investigators. Please consult the Table of Contents below to find the information you need.

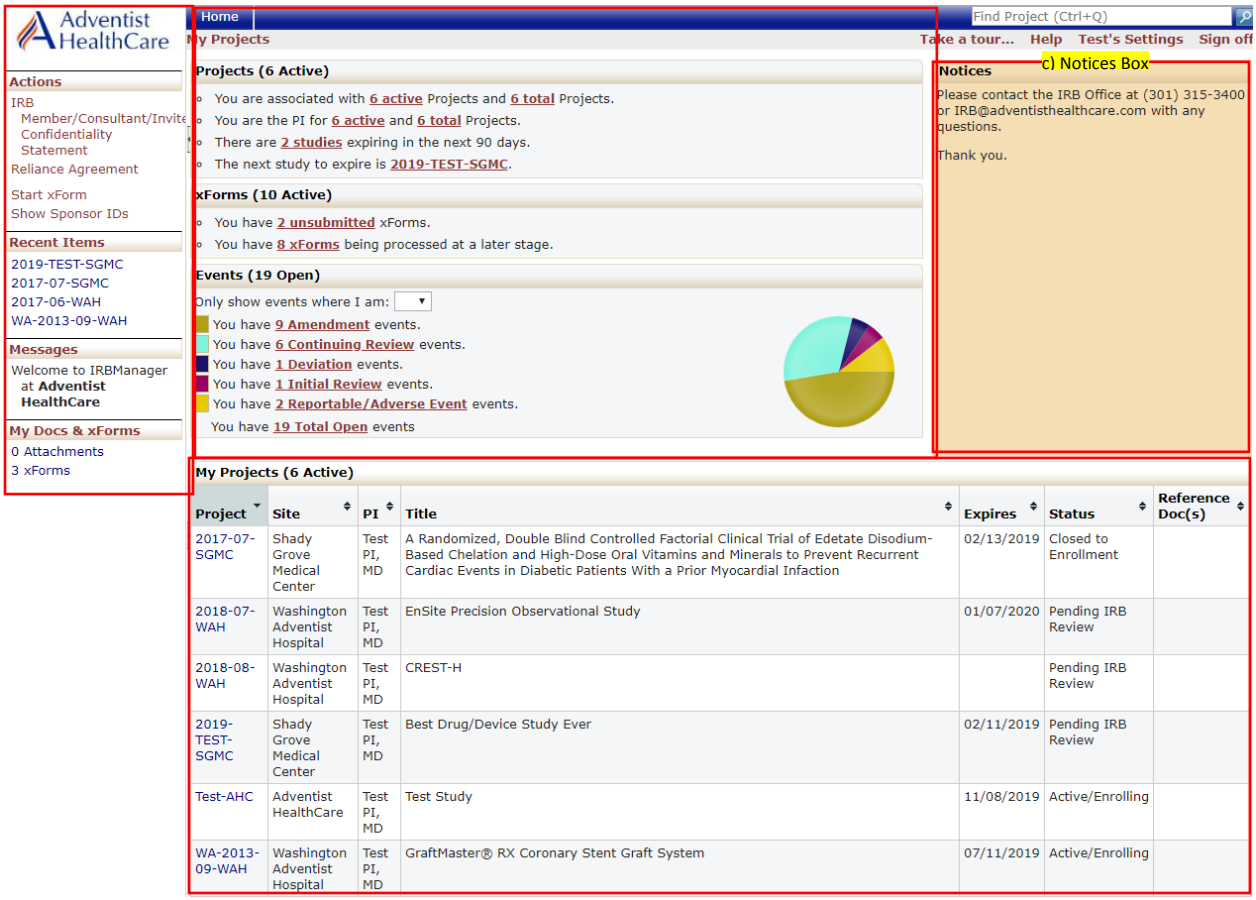
Table of Contents:

Dashboard Information:

1. When you log into IRBManager, your dashboard will appear. The information on your dashboard can be subdivided into four categories:
    a) Actions Sidebar: Here, you can start x-forms[1] 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[2], x-forms, and study events[3].
    c) Notices Box: Important IRB information can be found here.
    d) 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



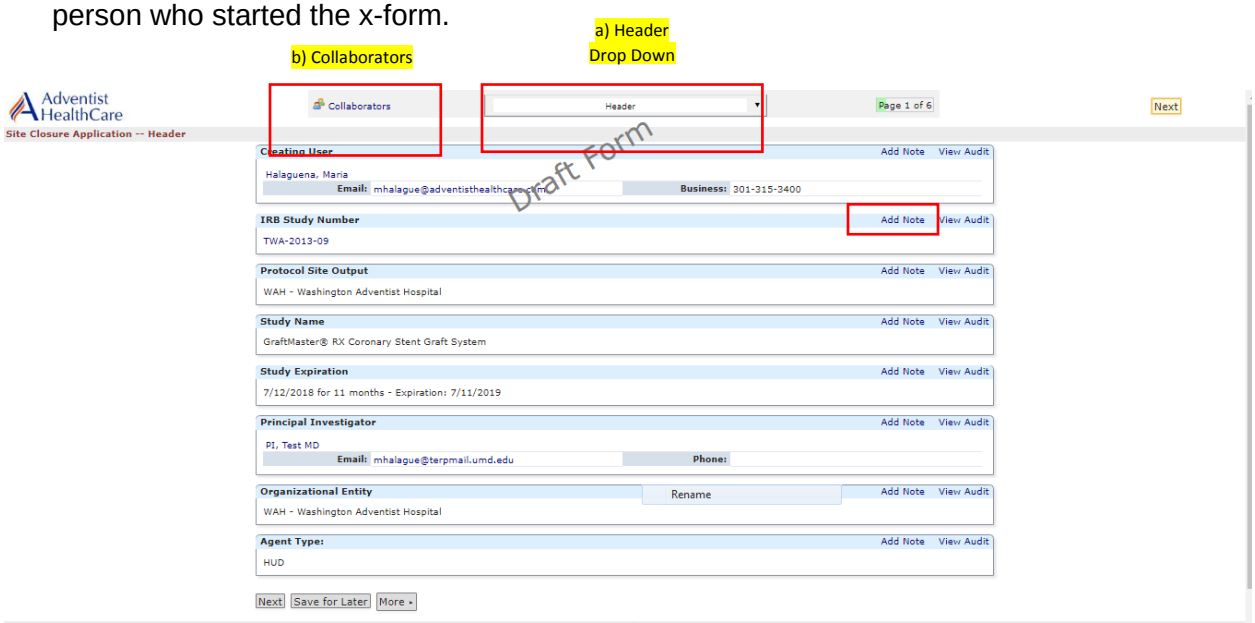
d) My Projects Table

Study Profile Information:

2. Once you are on the study profile, you may begin submitting x-forms. To submit a x-form, go to the actions side bar and click 'Start xForm.' Afterwards, a list of available x-forms will populate. Choose the Site Closure Application.

Start a Site Closure Form:

3. Once you select the site closure form, the Study Header page will populate. The Study Header page contains information on the IRB study number, protocol site[4], study expiration date, principal investigator, and agent type[5]. The creating user[6] will be the person who started the x-form.



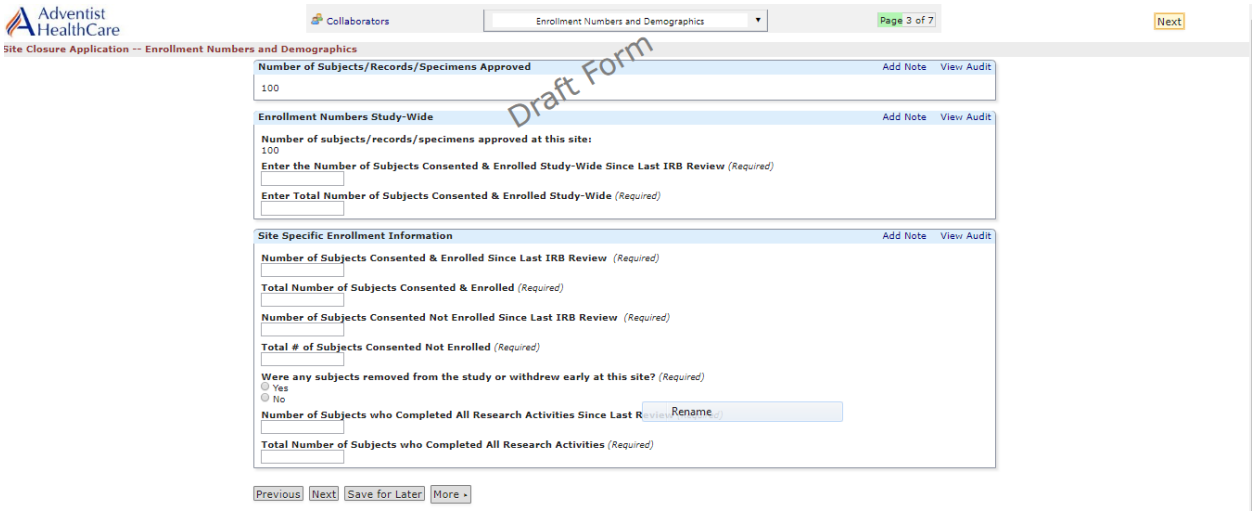
   a) The header drop down allows you to skip from one page to the next.
   b) The collaborators icon allows you to add others to view, edit, manage, and/or submit the form.
   c) You may also add notes to communicate with other collaborators or create notes for yourself.
   d) Click 'Next' to move to the next page of the form. If you wish to save and return to the form later, click 'Save for Later.'

Site Closure Data Entry:

4. The next page will prompt you to enter the date of study closure and whether the study involved the use or access of PHI.

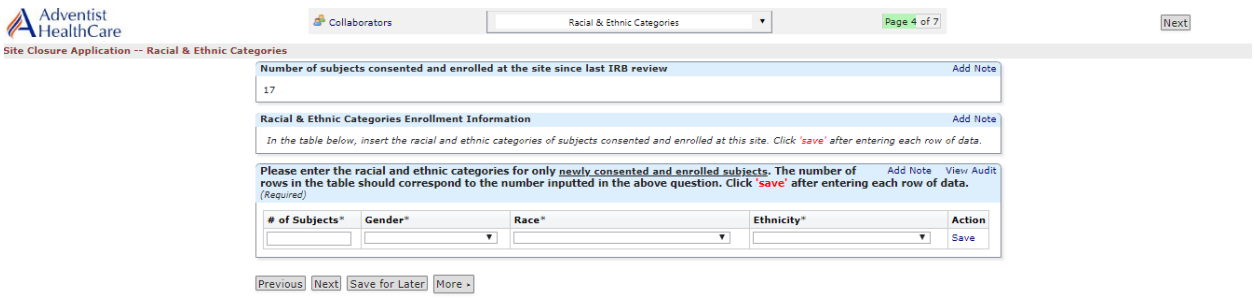
   Please note: Questions on the x-forms are specifically conditioned based on your responses. In other words, certain questions will appear based on your answer(s) to a previous question(s). Furthermore, questions marked as required cannot be left unanswered. You will not be allowed to submit the form until you answer the required questions.

5. The following page will ask you for the study enrollment information at the site and study-wide since last IRB review.



a) The approved number of subjects/records/specimens is available for your reference.
b) Enter the number of subjects consented and enrolled for the site and study-wide since last IRB review.
c) Enter the site-specific enrollment information.

6. Enter the race/ethnicity information for **only subjects that were consented and enrolled at the site since last IRB review.**



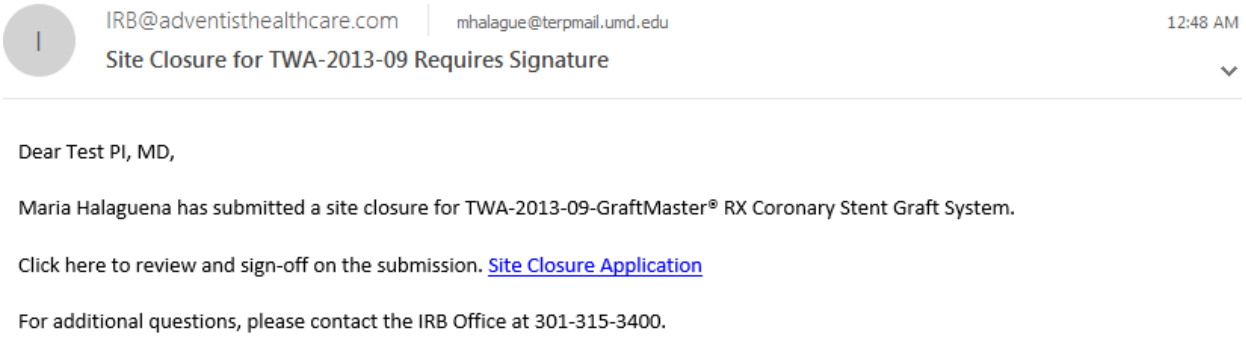
a) The number for subjects consented and enrolled at the site since the last IRB review is available for your convenience.
b) Enter the subject's ID, gender, race, and ethnicity. If there were no subjects consented and enrolled since the last IRB review, enter '0' for the subject ID, and 'N/A' for the drop downs.
c) You must save the information entered before adding another row of information.

7. For the following pages, you will answer questions about the study's safety and adverse events, protected health information/data management/record retention, and data management/research records.

PI Sign-Off and Admin Pre-Review:

8. After you have entered all the required information, you may now submit the form or save for later. Once the form is submitted, it will go directly to the PI for sign-off.

9. The PI will receive the following email, as shown below, which will include information on the Site Closure and a link to the Site Closure Form.



IRB@adventisthealthcare.com | mhalague@terpmail.umd.edu 12:48 AM

Site Closure for TWA-2013-09 Requires Signature

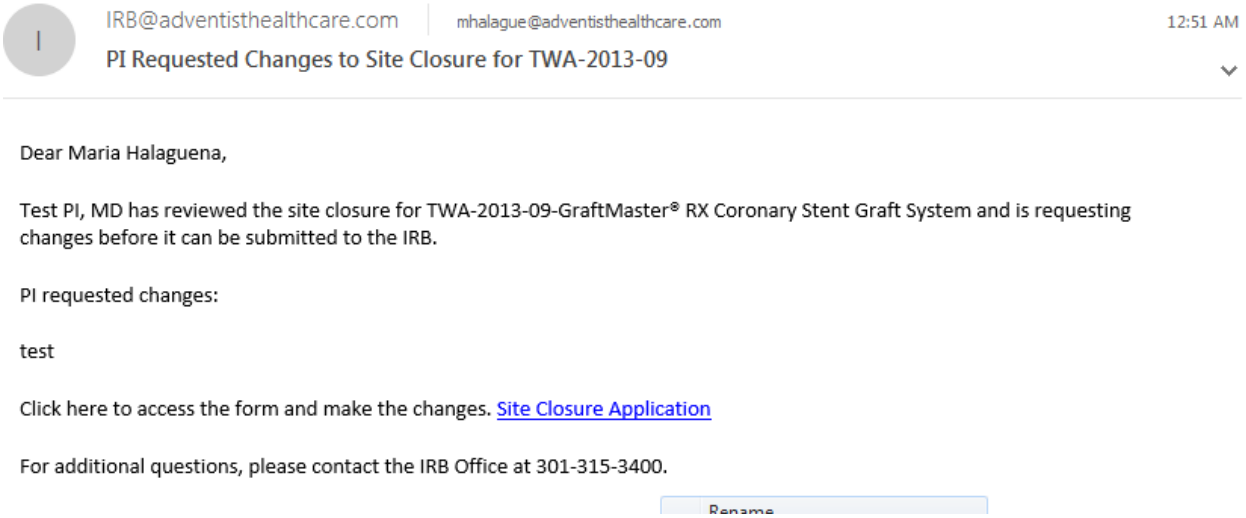
Dear Test PI, MD,

Maria Halaguena has submitted a site closure for TWA-2013-09-GraftMaster® RX Coronary Stent Graft System.

Click here to review and sign-off on the submission. Site Closure Application

For additional questions, please contact the IRB Office at 301-315-3400.

10. If the PI has suggested comments/modifications to the site closure form prior to IRB submission, you will receive the following email, as shown below. The site closure form will go back to data entry and you may edit the form accordingly.



IRB@adventisthealthcare.com | mhalague@adventisthealthcare.com 12:51 AM

PI Requested Changes to Site Closure for TWA-2013-09

Dear Maria Halaguena,

Test PI, MD has reviewed the site closure for TWA-2013-09-GraftMaster® RX Coronary Stent Graft System and is requesting changes before it can be submitted to the IRB.

PI requested changes:

test

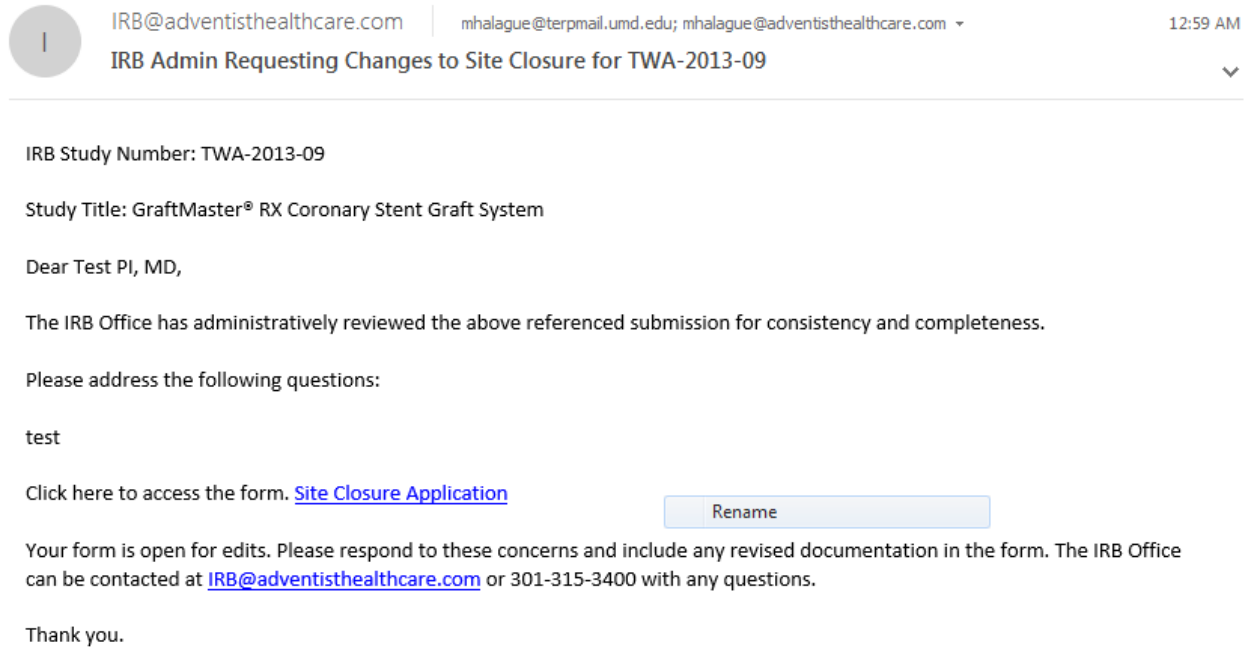
Click here to access the form and make the changes. Site Closure Application

For additional questions, please contact the IRB Office at 301-315-3400.

11. After you have finished making the revisions, the form will go back to the PI for sign off.

    Please note: Every time a change is made to the study documents, the PI must sign off afterwards.

12. The IRB Office will review the site closure form and if there are any changes requested, you will receive the following email.



IRB@adventisthealthcare.com mhalague@terpmail.umd.edu; mhalague@adventisthealthcare.com 12:59 AM

IRB Admin Requesting Changes to Site Closure for TWA-2013-09

IRB Study Number: TWA-2013-09

Study Title: GraftMaster® RX Coronary Stent Graft System

Dear Test PI, MD,

The IRB Office has administratively reviewed the above referenced submission for consistency and completeness.

Please address the following questions:

test

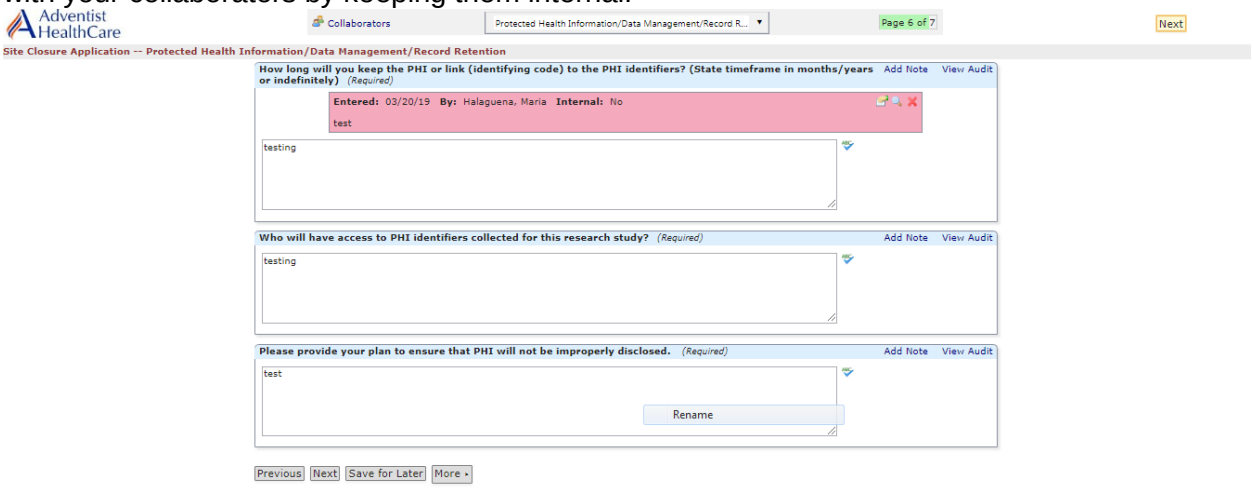
Click here to access the form. Site Closure Application

Rename

Your form is open for edits. Please respond to these concerns and include any revised documentation in the form. The IRB Office can be contacted at IRB@adventisthealthcare.com or 301-315-3400 with any questions.

Thank you.

13. To make the changes requested by the IRB Office, click on the blue form link and you will be directed to the x-form. The IRB Office will utilize the notes feature to communicate the required changes to the research study teams, which will make it easier to identify the required changes on the x-form. You may also use the notes feature to communicate with your collaborators by keeping them internal.



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Site Closure Application -- Protected Health Information/Data Management/Record Retention

How long will you keep the PHI or link (identifying code) to the PHI identifiers? (State timeframe in months/years or indefinitely) *(Required)* Add Note View Audit

Entered: 03/20/19 By: Halaguena, Maria Internal: No

test

testing

Who will have access to PHI identifiers collected for this research study? *(Required)* Add Note View Audit

testing

Please provide your plan to ensure that PHI will not be improperly disclosed. *(Required)* Add Note View Audit

test

Rename

Previous Next Save for Later More

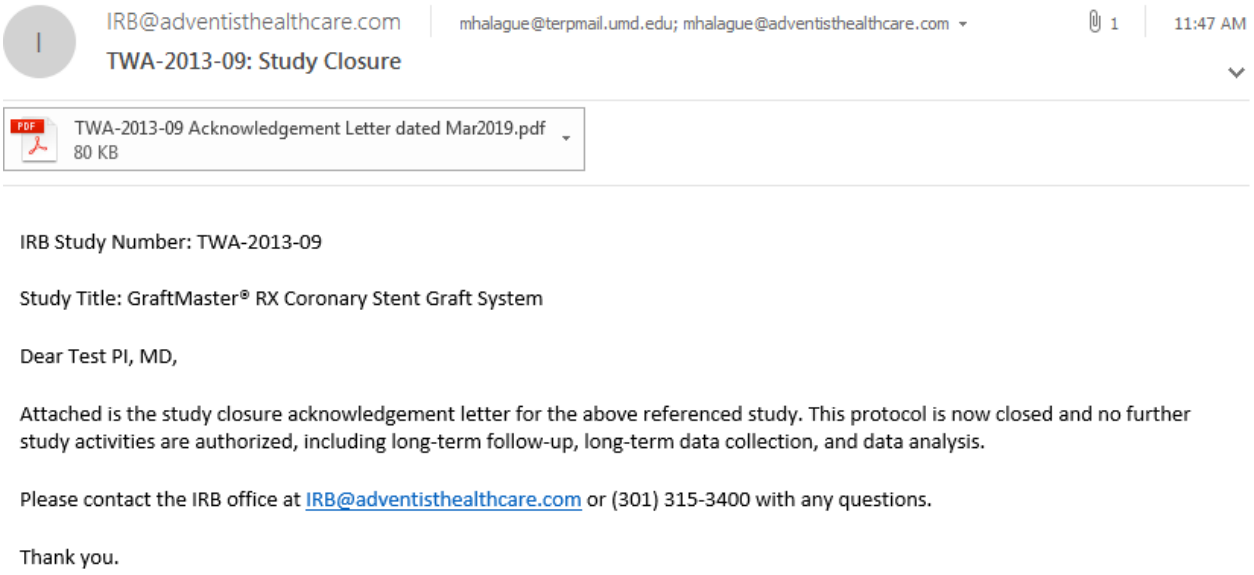
Please note: You cannot submit the form until the changes requested by the IRB Office have been made.

14. After you have made the changes requested by the IRB Office, the form will go to the PI for sign off.
15. If no additional changes are requested by the PI and IRB Office, the site closure form is ready to be reviewed by the IRB.

IRB Review:

Expedited Review

16. If the site closure is reviewed via expedited review, the study team should receive an acknowledgement letter within 4-5 business days. The acknowledgement letter will be sent to the PI and creating user via email, as shown below.



I IRB@adventisthealthcare.com mhalague@terpmail.umd.edu; mhalague@adventisthealthcare.com 1 11:47 AM

TWA-2013-09: Study Closure

TWA-2013-09 Acknowledgement Letter dated Mar2019.pdf
80 KB

IRB Study Number: TWA-2013-09

Study Title: GraftMaster® RX Coronary Stent Graft System

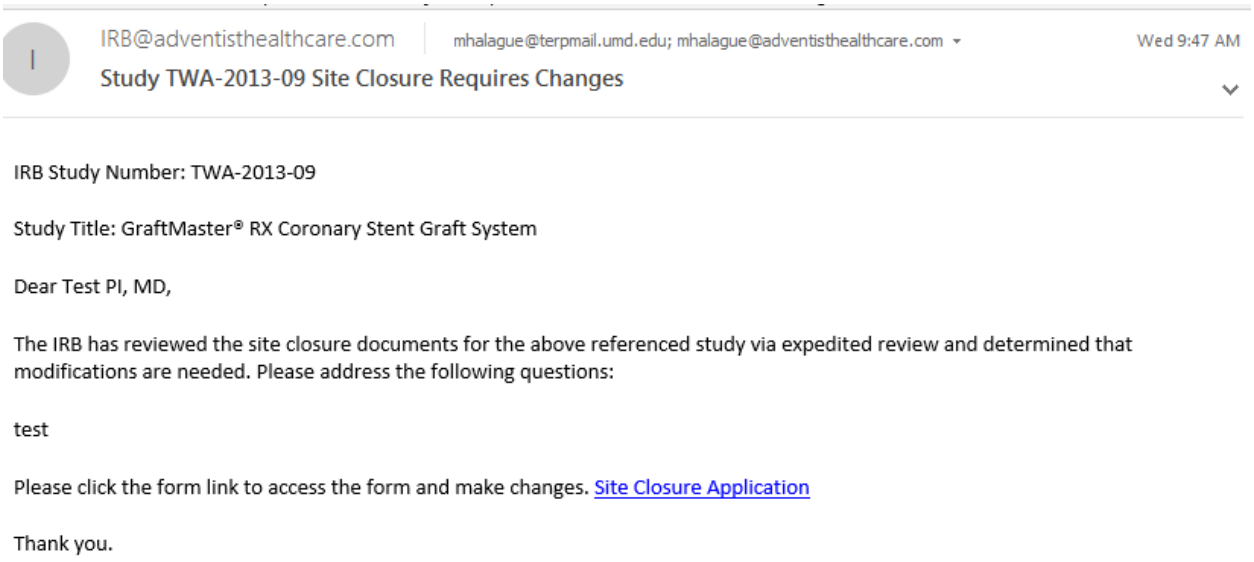
Dear Test PI, MD,

Attached is the study closure acknowledgement letter for the above referenced study. This protocol is now closed and no further study activities are authorized, including long-term follow-up, long-term data collection, and data analysis.

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

Thank you.

17. If the site closure receives a determination other than a full-approval, you will receive an email, as shown below, prompting you to make revisions to the form. To make the changes, click on the blue form link. After you have made revisions, the form will go to the PI for sign-off.



IRB@adventisthealthcare.com mhalague@terpmail.umd.edu; mhalague@adventisthealthcare.com Wed 9:47 AM

Study TWA-2013-09 Site Closure Requires Changes

IRB Study Number: TWA-2013-09

Study Title: GraftMaster® RX Coronary Stent Graft System

Dear Test PI, MD,

The IRB has reviewed the site closure documents for the above referenced study via expedited review and determined that modifications are needed. Please address the following questions:

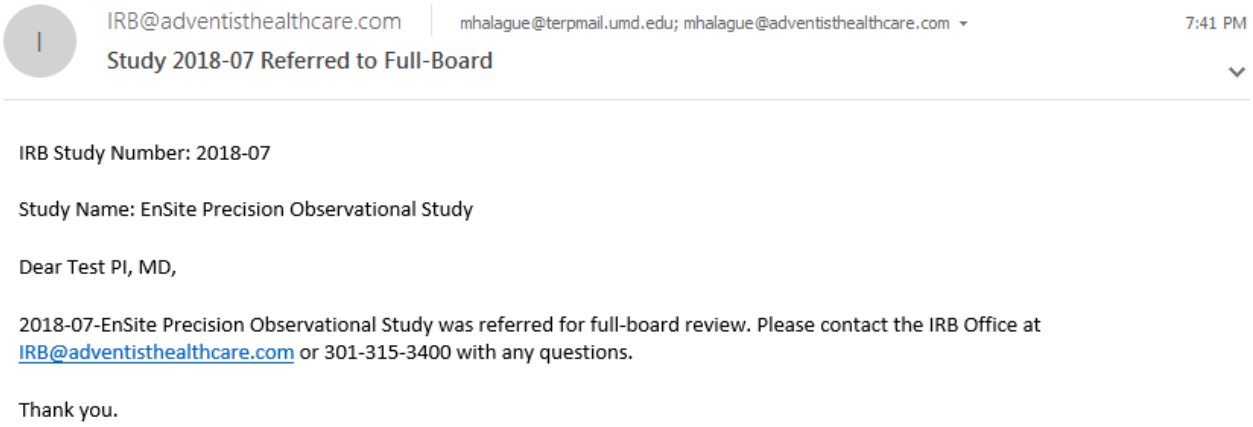
test

Please click the form link to access the form and make changes. Site Closure Application

Thank you.

Referral to Full-Board

18. If the site closure is referred to full-board review, you will receive the email, as shown below, informing you of the referral.



IRB@adventisthealthcare.com mhalague@terpmail.umd.edu; mhalague@adventisthealthcare.com 7:41 PM

Study 2018-07 Referred to Full-Board

IRB Study Number: 2018-07

Study Name: EnSite Precision Observational Study

Dear Test PI, MD,

2018-07-EnSite Precision Observational Study was referred for full-board review. Please contact the IRB Office at IRB@adventisthealthcare.com or 301-315-3400 with any questions.

Thank you.

Full-Board

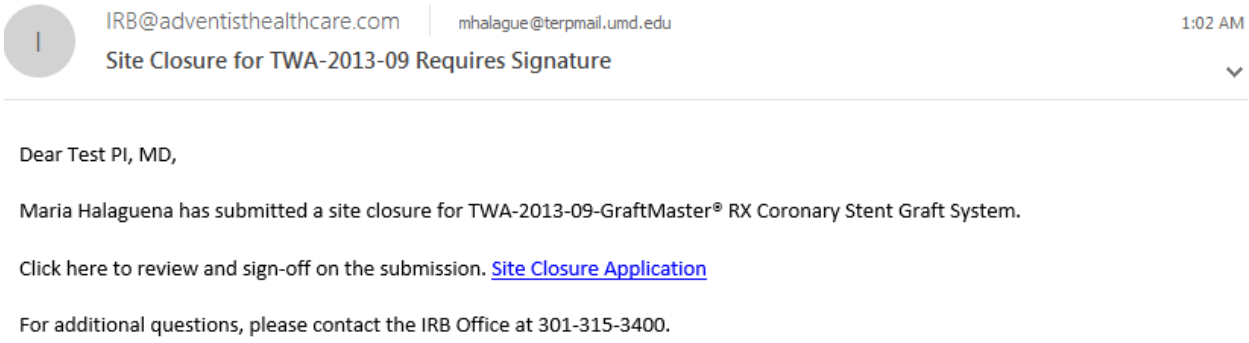
19. After the convened IRB meeting, the PI and creating user will receive an email containing the determination letter and informed consent form (if applicable) within two days of the IRB meeting.

20. If the IRB has determined that modifications are needed to the site closure form, the IRB Office will send an email to the PI and creating user of the changes requested. The determination letter will be available in both a pdf and word copy for your convenience. The form will then go back to data entry and PI sign off.

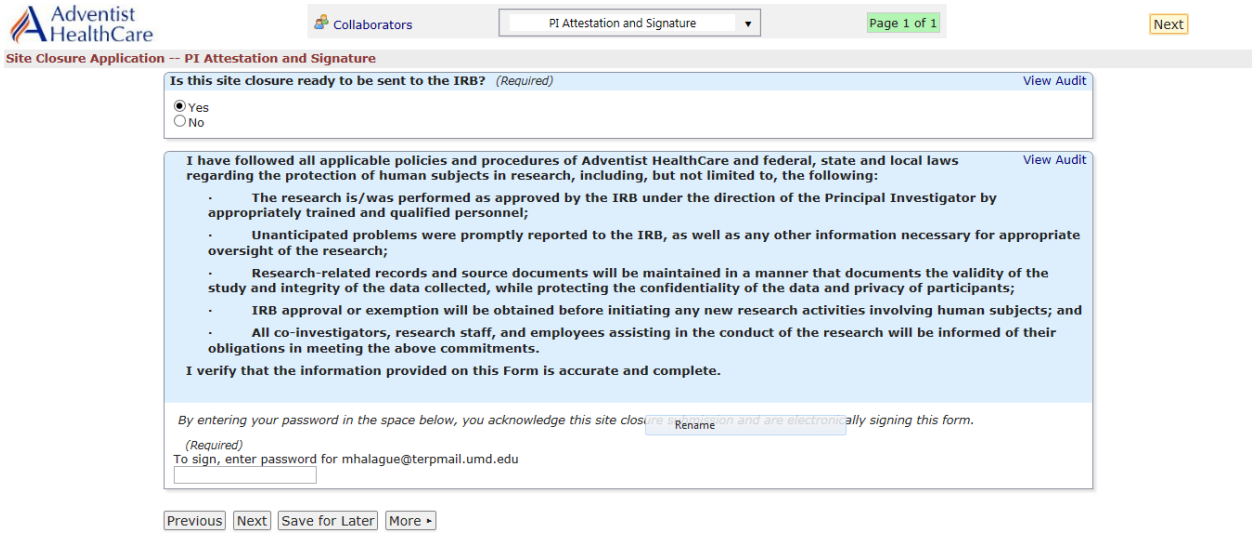
21. To view the determination letter and stamped informed consent form within IRBManager, go to the study profile and click on the 'Site Closure event'. On the 'actions side bar', go to 'attachments' and then 'generated docs'.

Principal Investigator Guidance

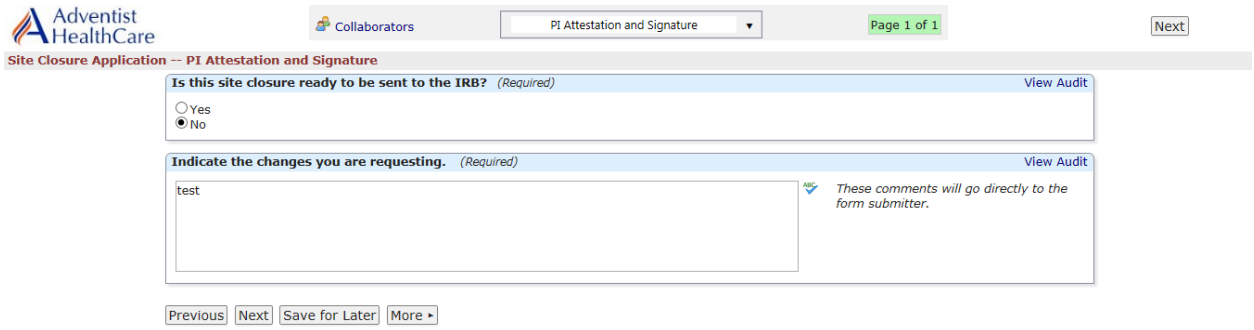
1. You will receive an email from IRB@adventisthealthcare.com informing you an x-form has been completed by a research staff member. The email will contain a link to the site closure form.



2. The blue form link will take you directly to the x-form for your signature. You can see the information entered by the creating user such as the specific changes to the research, rationale and justification for the proposed changes, attachments, etc.
3. If you agree with the information put forth in the submission and attest to the closure of the study, you will electronically sign-off on the document by inputting your IRBManager password.



4. If you would like to request changes to the submission, you can indicate the changes you are requesting in the text box. These comments will go directly to the creating user.



5. Please be aware that your signature is required every time a change is made to the study documents. Any changes made to the study documents will be highlighted in yellow.

Terminology for IRBManager:

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