Adventist HealthCare

Protocol Deviation Resource Guide for Research Personnel and Principal Investigators

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

Audience: Research Personnel and Principal Investigators

Summary: This resource guide will focus on the protocol deviation 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:

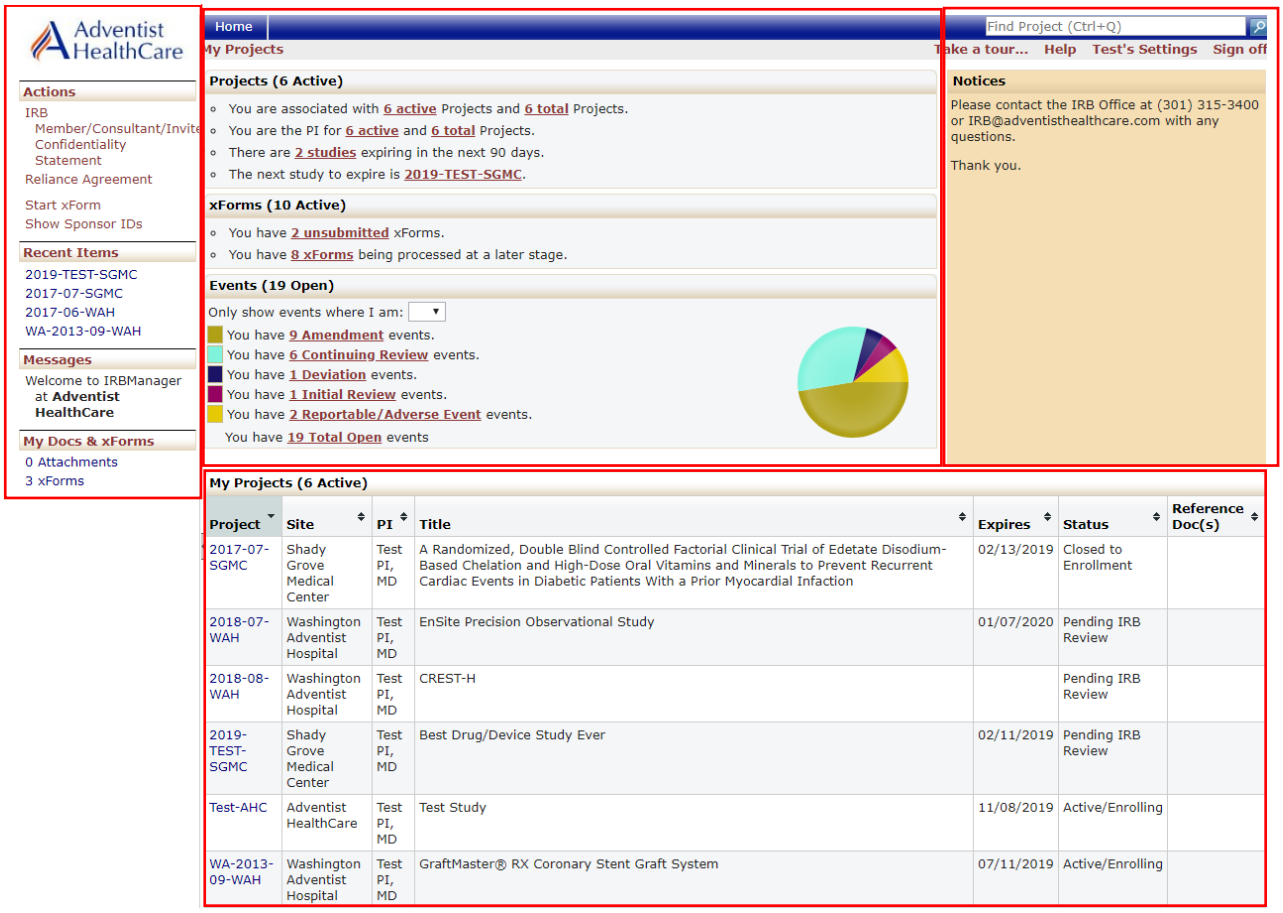
Dashboard Information:

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

c) Notices Box



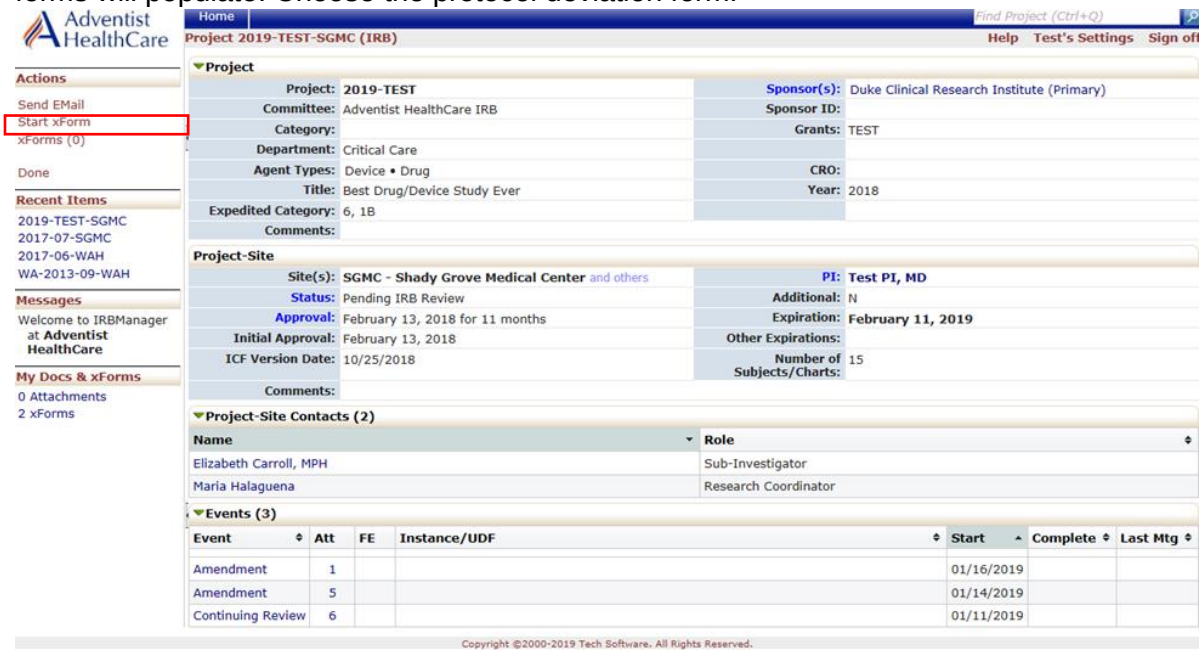
My Projects (6 Active)

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 Prior Myocardial Infaction	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		Pending IRB Review	
2019-TEST-SGMC	Shady Grove Medical Center	Test PI, MD	Best Drug/Device Study Ever	02/11/2019	Pending IRB Review	
Test-AHC	Adventist HealthCare	Test PI, MD	Test Study	11/08/2019	Active/Enrolling	
WA-2013-09-WAH	Washington Adventist Hospital	Test PI, MD	GraftMaster® RX Coronary Stent Graft System	07/11/2019	Active/Enrolling	

d) My Projects Table

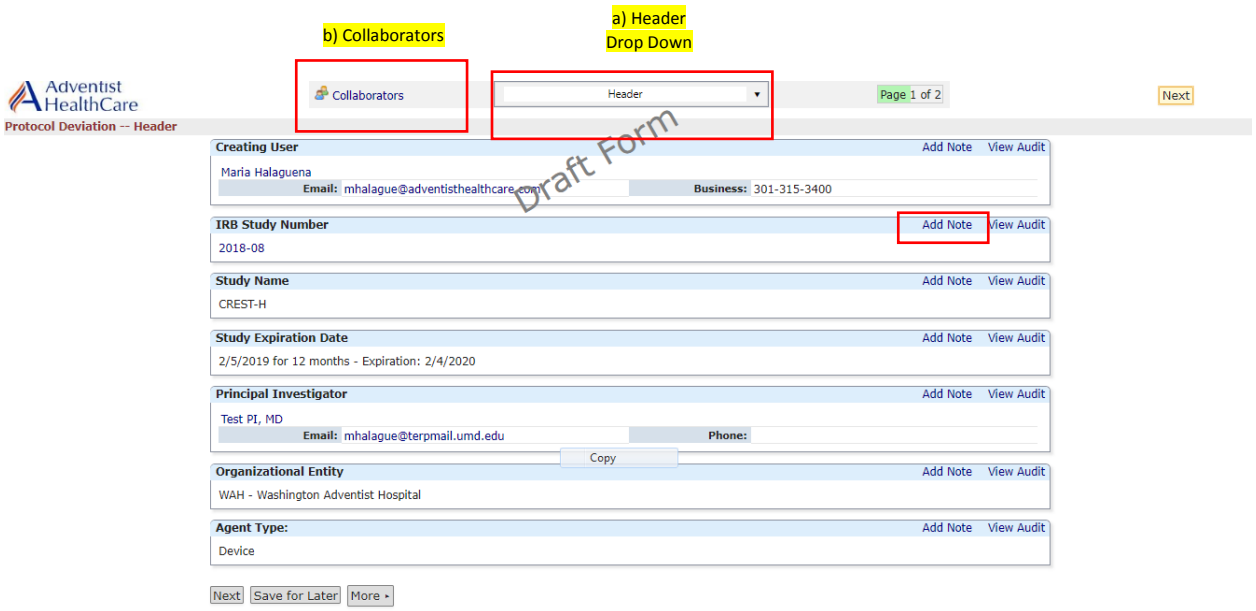
Study Profile Information:

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 protocol deviation form.



Start a Protocol Deviation Form:

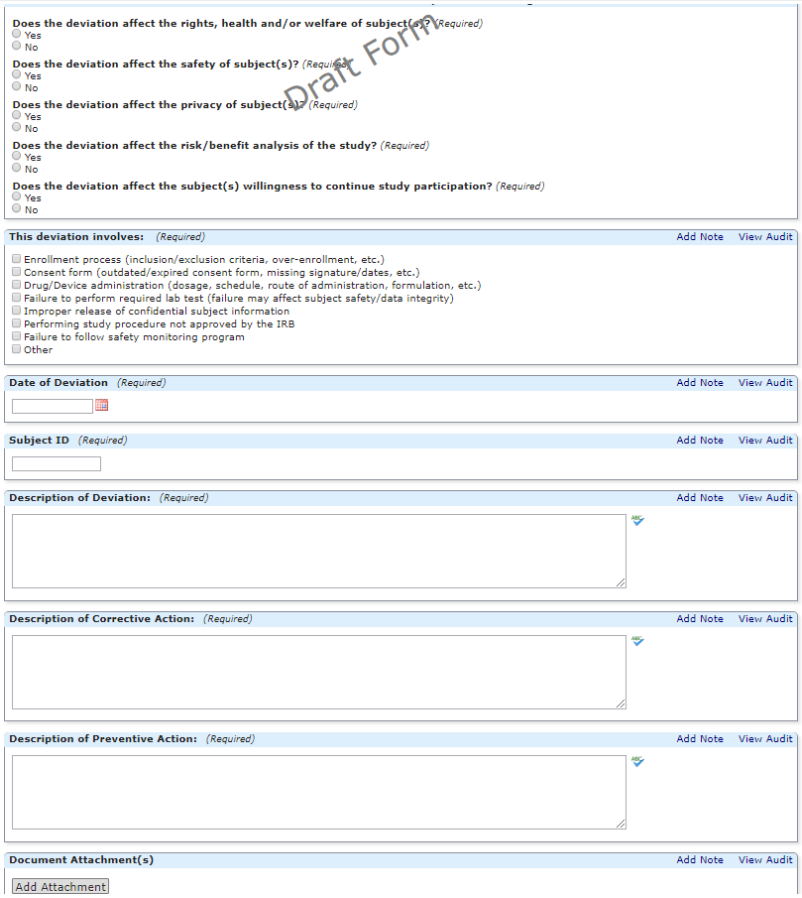
3. Once you select the protocol deviation form, the Study Header page will populate. The Study Header page contains information on the IRB study number, protocol site[4], study expiration date, principal investigator, and agent type[5]. The creating user[6] will be the person who started the x-form.



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.'

Protocol Deviation Form Data Entry:

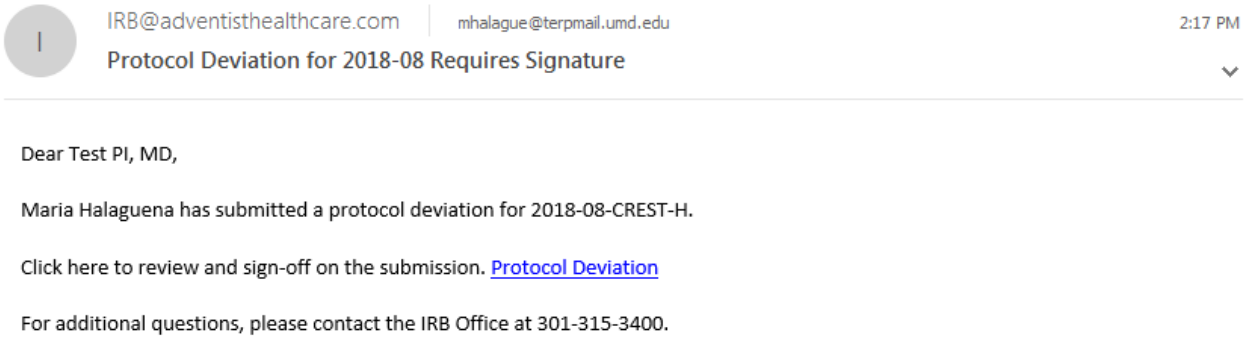
4. The next page will take you to the Protocol Deviation Information page in which you will provide more information on the deviation and how it has impacted subjects' rights and welfare. You will also provide a description of a corrective and preventative action plan. If there are additional documents that need to be reviewed, you may attach them below.



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.

PI Sign-Off and Admin Pre-Review:

5. 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.
6. The PI will receive the following email, as shown below, which will include information on the link to the Protocol Deviation form.



IRB@adventisthealthcare.com | mhalague@terpmail.umd.edu 2:17 PM

Protocol Deviation for 2018-08 Requires Signature

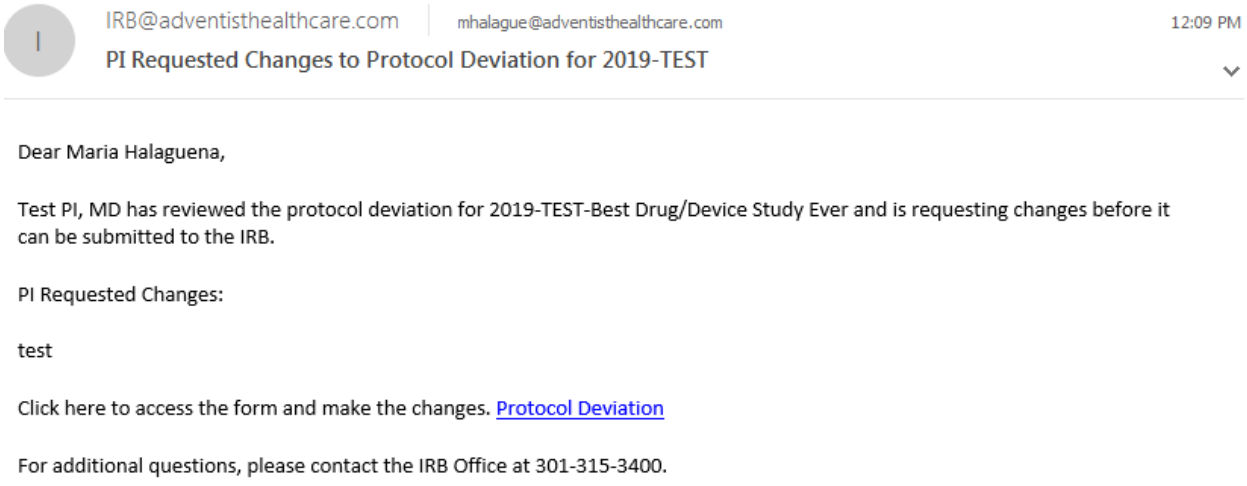
Dear Test PI, MD,

Maria Halaguena has submitted a protocol deviation for 2018-08-CREST-H.

Click here to review and sign-off on the submission. Protocol Deviation

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

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



IRB@adventisthealthcare.com | mhalague@adventisthealthcare.com 12:09 PM

PI Requested Changes to Protocol Deviation for 2019-TEST

Dear Maria Halaguena,

Test PI, MD has reviewed the protocol deviation for 2019-TEST-Best Drug/Device Study Ever and is requesting changes before it can be submitted to the IRB.

PI Requested Changes:

test

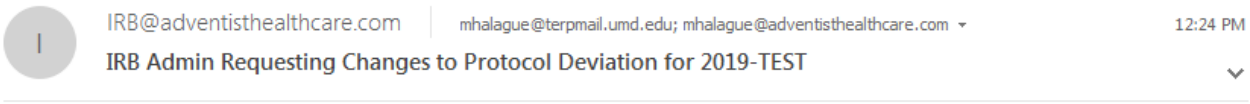
Click here to access the form and make the changes. Protocol Deviation

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

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

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

9. The IRB Office will review the Protocol Deviation form and if there are any changes requested, you will receive the following email.



IRB@adventisthealthcare.com mhalague@terpmail.umd.edu; mhalague@adventisthealthcare.com 12:24 PM

IRB Admin Requesting Changes to Protocol Deviation for 2019-TEST

IRB Study Number: 2019-TEST

Study Title: Best Drug/Device Study Ever

Dear Test PI, MD,

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

Please address the following questions:

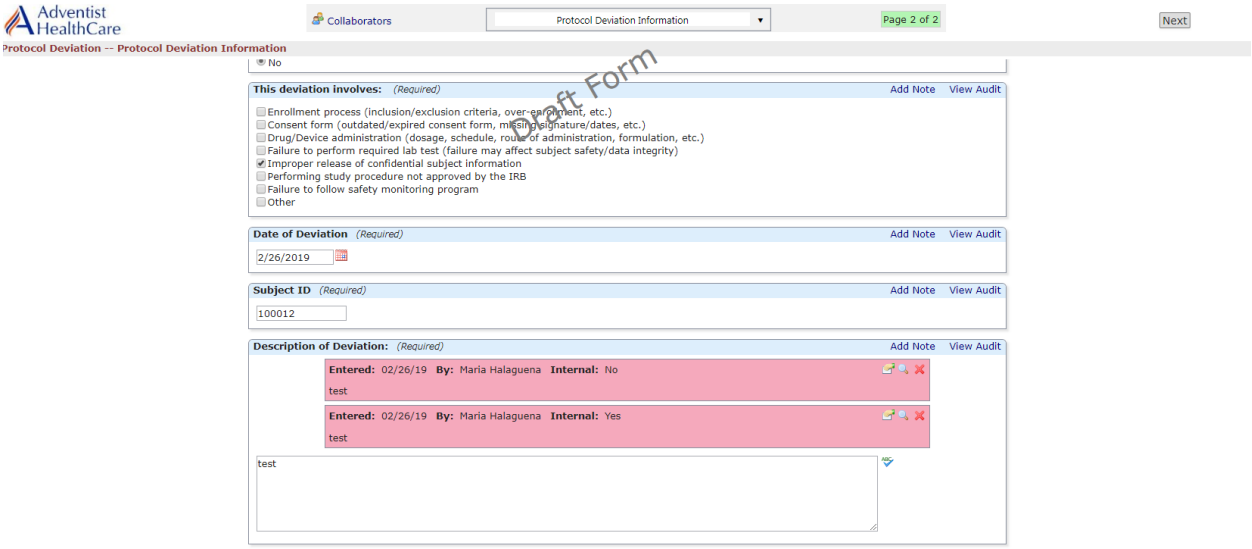
test

Click here to access the form. Protocol Deviation

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.

10. To make the changes requested by the IRB Office, click on the blue form link in the email 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 designating them as internal.



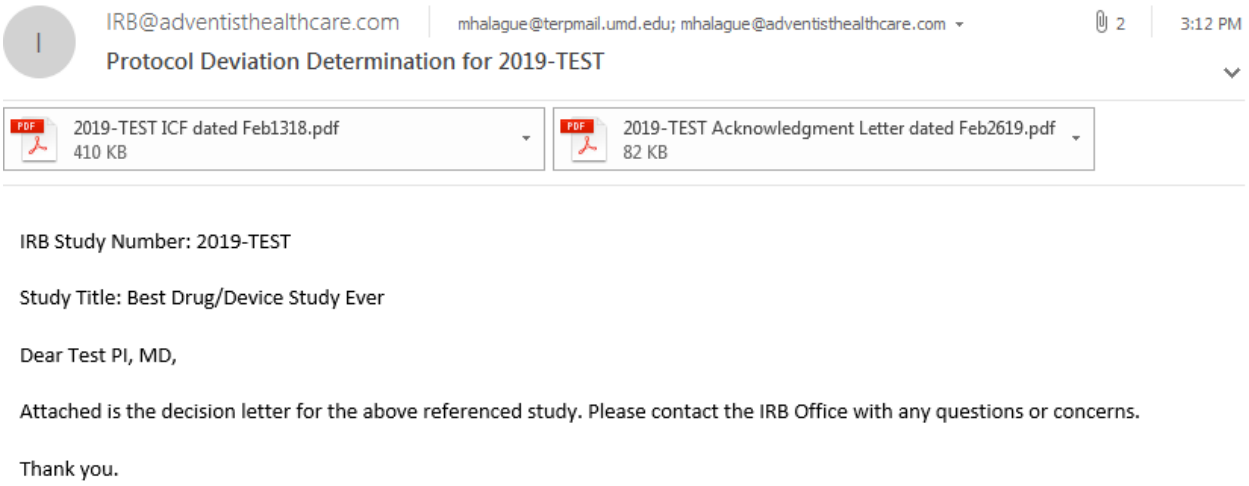
Please note: You cannot submit the form until the changes requested by the IRB Office have been made.

11. After you have made the changes requested by the IRB Office, the form will go to the PI for sign off.
12. If no additional changes are requested by the PI and IRB Office, the protocol deviation form is ready to be reviewed by the IRB.

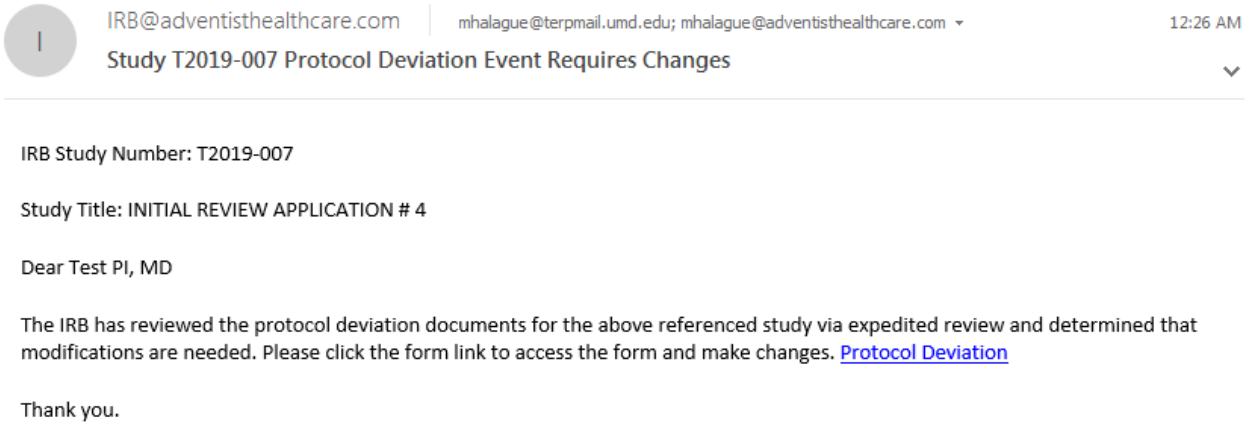
IRB Review:

Expedited Review

13. The type of review is contingent upon whether the risk-benefit ratio remains appropriate, and the rights, health, and welfare of subjects are safeguarded. If the protocol deviation is reviewed via expedited review, the study team should receive an outcome letter within 4-5 business days. The outcome letter and informed consent form (if applicable) will be sent to the PI and creating user via email, as shown below.



14. If modifications or revisions are needed to the protocol deviation, you will receive an email, as shown below, prompting you to make revisions to your form. To make the changes, click on the blue form link. After you have made your revisions, the form will go to the PI for sign-off and the IRB will conduct a second review.



IRB@adventisthealthcare.com mhalague@terpmail.umd.edu; mhalague@adventisthealthcare.com 12:26 AM

Study T2019-007 Protocol Deviation Event Requires Changes

IRB Study Number: T2019-007

Study Title: INITIAL REVIEW APPLICATION # 4

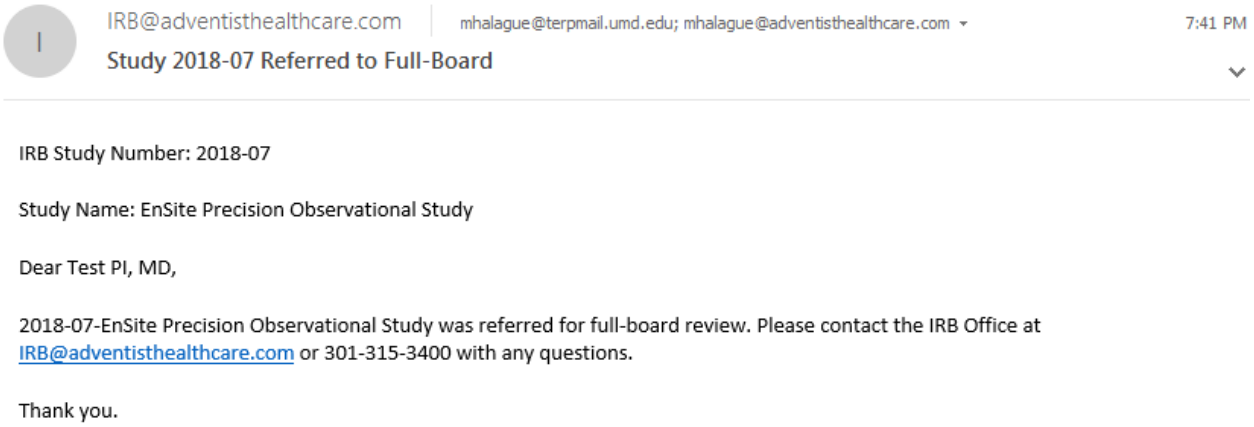
Dear Test PI, MD

The IRB has reviewed the protocol deviation documents for the above referenced study via expedited review and determined that modifications are needed. Please click the form link to access the form and make changes. Protocol Deviation

Thank you.

Referral to Full-Board

15. If the protocol deviation is referred for 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

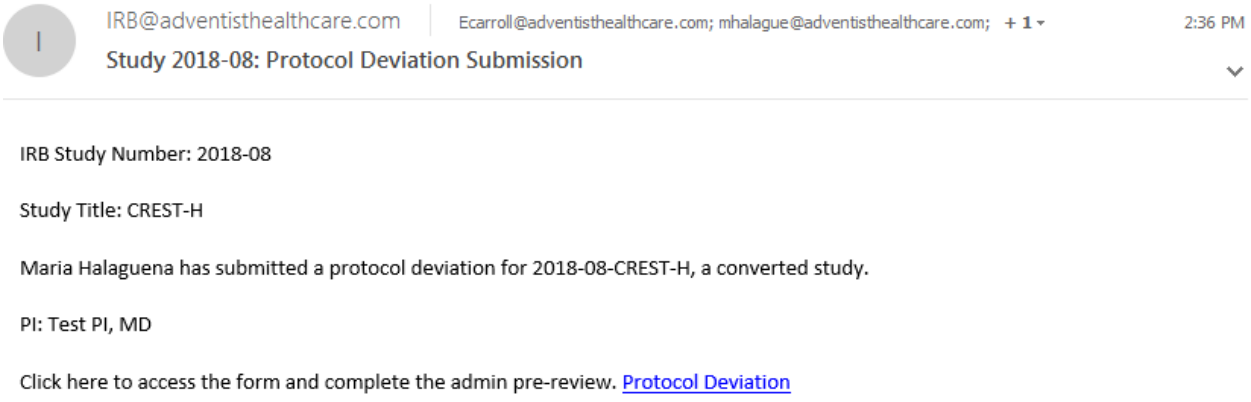
16. After the convened IRB meeting, the PI and creating user will receive an email containing the determination letter and informed consent form (if applicable) within two days of the IRB meeting.

17. If the IRB has determined that modifications are needed to the study, 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.

18. To view the determination letter and stamped informed consent form within IRBManager, go to the study profile and click on the 'reportable 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 include information on a link to the protocol deviation form.


IRB@adventisthealthcare.com Ecarroll@adventisthealthcare.com; mhalague@adventisthealthcare.com; + 1 2:36 PM

Study 2018-08: Protocol Deviation Submission

IRB Study Number: 2018-08

Study Title: CREST-H

Maria Halaguena has submitted a protocol deviation for 2018-08-CREST-H, a converted study.

PI: Test PI, MD

Click here to access the form and complete the admin pre-review. Protocol Deviation

2. The blue form link will take you directly to the x-form for your signature. You can see the protocol deviation information entered by the creating user.
3. If you agree with the changes put forth in the submission, 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 document 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