



Amendment 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 amendment application data entry to IRB submission and outcome 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
- Study Profile Information
- Start an Amendment Application
 - Amendment Application Data Entry
 - Protocol Change
 - Informed Consent Change
 - Principal Investigator Change
 - Adding New Study Staff
 - Remove Study Staff Member
 - Recruitment Materials
 - Data Collection Tools
- PI Sign-Off and Admin Pre-Review
- IRB Review
 - Expedited Review
 - Referral to Full-Board
 - Full-Board
- Principal Investigator Guidance
- Terminology for IRBManager

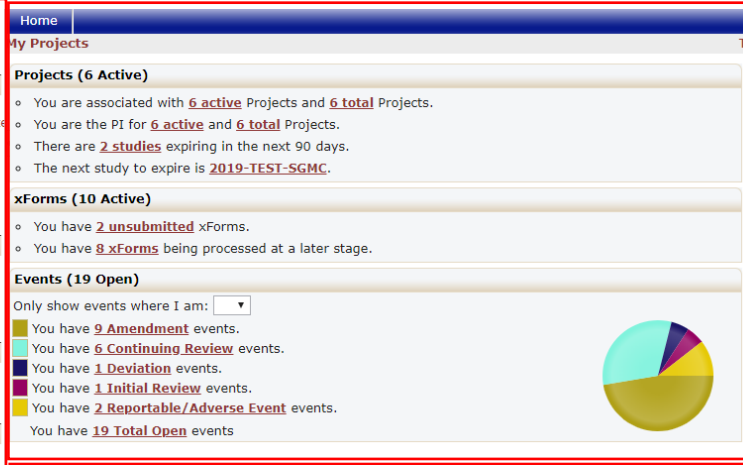
Dashboard Information:

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-forms¹ 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 projects², x-forms, and study events³.
 - 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.

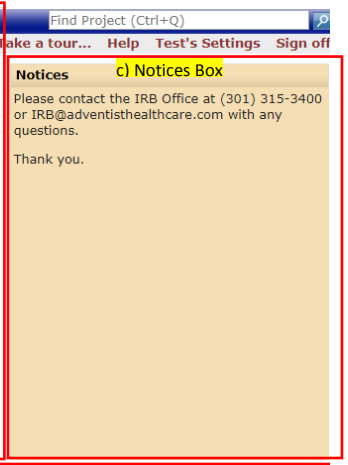
a) Actions Sidebar



b) My Projects Box



c) Notices Box




d) My Projects Table

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 Infarction	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	

Study Profile Information:

- Once you are on the study profile, you may begin submitting x-Forms. To submit an x-Form, go to the actions side bar and click 'Start xForm.' Afterwards, a list of available x-Forms will populate. Choose the Amendment Application.



The screenshot displays the 'Project 2019-TEST-SGMC (IRB)' profile. The left sidebar contains navigation options: 'Actions' (Send EMail, **Start xForm**, xForms (0)), 'Recent Items' (2019-TEST-SGMC, 2017-07-SGMC, 2017-06-WAH, WA-2013-09-WAH), 'Messages' (Welcome to IRBManager at Adventist HealthCare), and 'My Docs & xForms' (0 Attachments, 2 xForms). The main content area shows project details:

- Project:** 2019-TEST
- Committee:** Adventist HealthCare IRB
- Category:** Critical Care
- Department:** Critical Care
- Agent Types:** Device • Drug
- Title:** Best Drug/Device Study Ever
- Expedited Category:** 6, 1B
- Sponsor(s):** Duke Clinical Research Institute (Primary)
- Sponsor ID:**
- Grants:** TEST
- CRO:**
- Year:** 2018

Project-Site information:

- Site(s):** SGMC - Shady Grove Medical Center and others
- Status:** Pending IRB Review
- Approval:** February 13, 2018 for 11 months
- Initial Approval:** February 13, 2018
- ICF Version Date:** 10/25/2018
- PI:** Test PI, MD
- Additional:** N
- Expiration:** February 11, 2019
- Other Expirations:**
- Number of Subjects/Charts:** 15

Project-Site Contacts (2)

Name	Role
Elizabeth Carroll, MPH	Sub-Investigator
Maria Halaguena	Research Coordinator

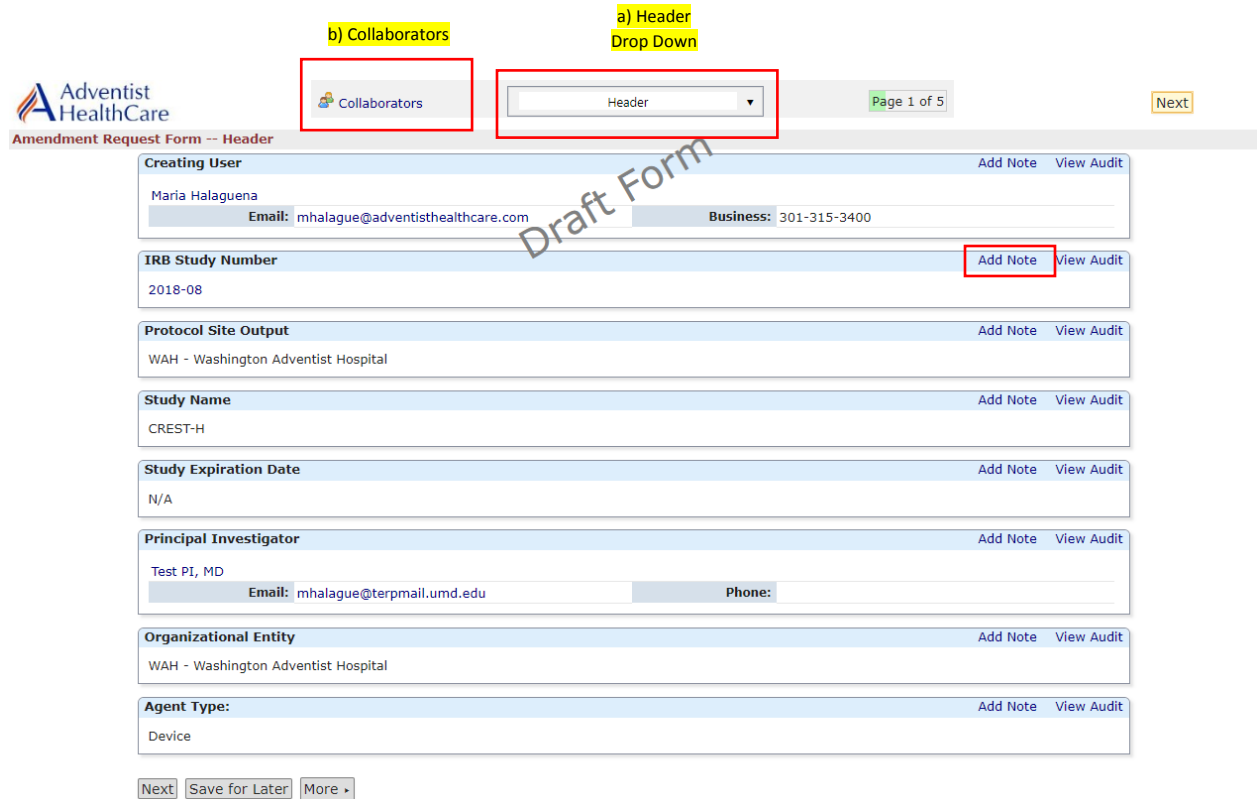
Events (3)

Event	Att	FE	Instance/UDF	Start	Complete	Last Mtg
Amendment	1			01/16/2019		
Amendment	5			01/14/2019		
Continuing Review	6			01/11/2019		

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Start an Amendment Application

- Once you select the amendment application, the Study Header page will populate. The Study Header page contains information on the IRB study number, protocol site⁴, study expiration date, Principal Investigator, and agent type⁵. The creating user⁶ will be the person who started the x-Form.



b) Collaborators

a) Header Drop Down

Adventist HealthCare
Amendment Request Form -- Header

Collaborators

Header

Page 1 of 5

Next

Creating User Add Note View Audit
 Maria Halaguena
 Email: mhalague@adventisthealthcare.com Business: 301-315-3400

IRB Study Number Add Note View Audit
 2018-08

Protocol Site Output Add Note View Audit
 WAH - Washington Adventist Hospital

Study Name Add Note View Audit
 CREST-H

Study Expiration Date Add Note View Audit
 N/A

Principal Investigator Add Note View Audit
 Test PI, MD
 Email: mhalague@terpmail.umd.edu Phone:

Organizational Entity Add Note View Audit
 WAH - Washington Adventist Hospital

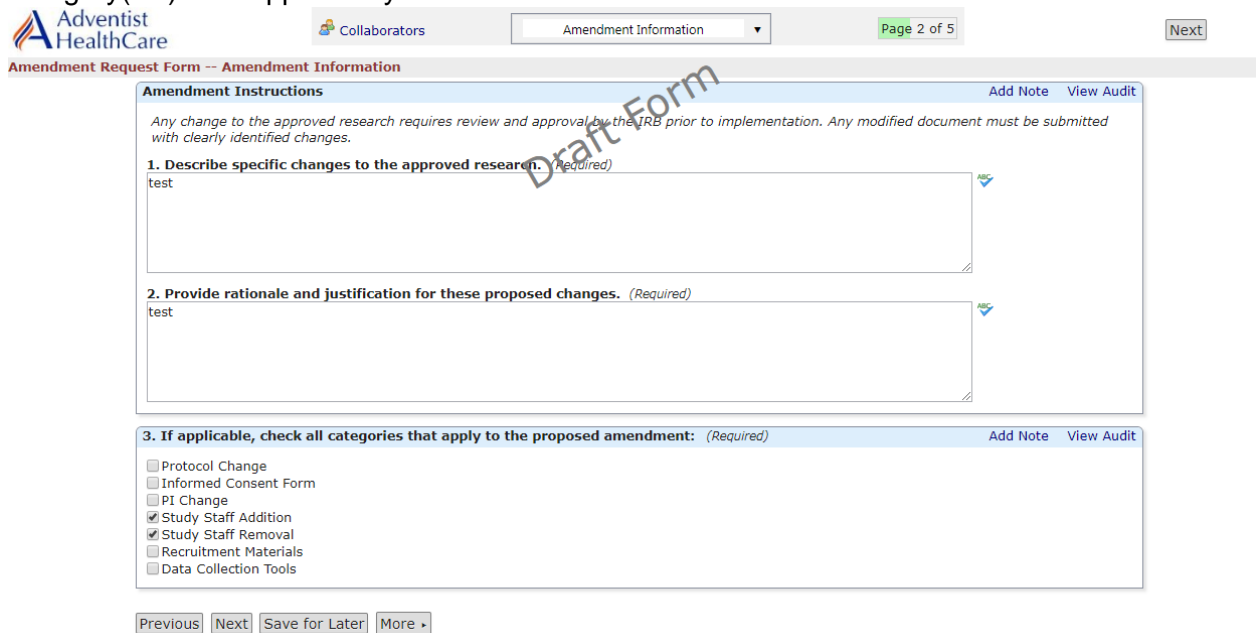
Agent Type: Add Note View Audit
 Device

Next Save for Later More >

- The header drop down allows you to skip from one page to the next.
- The collaborators icon allows you to add others to view, edit, manage, and/or submit the form.
- You may also add notes to communicate with other collaborators or create notes for yourself.
- 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.'

Amendment Application Data Entry

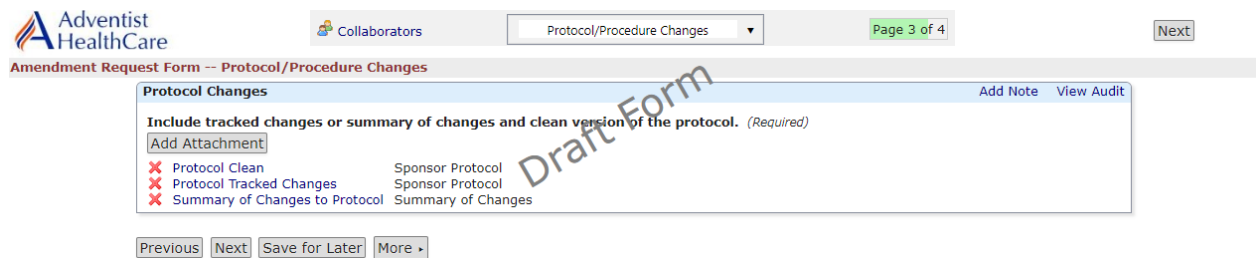
- The next page will take you to the Amendment Information page in which you will describe the specific changes to your research study and provide a rationale and justification for the proposed changes. In this page, you will also select which category(ies) best applies to your amendment.



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.

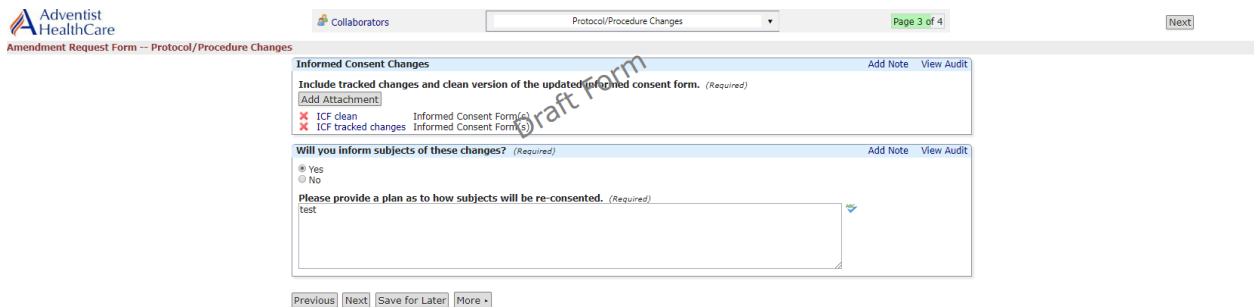
Protocol Change

- If you are submitting an amendment for a **protocol change**, select 'Protocol Change' on Question #3. The next page will prompt you to attach the tracked changes or summary of changes and clean version of the protocol. Lastly, answer the risk-benefit assessment question.



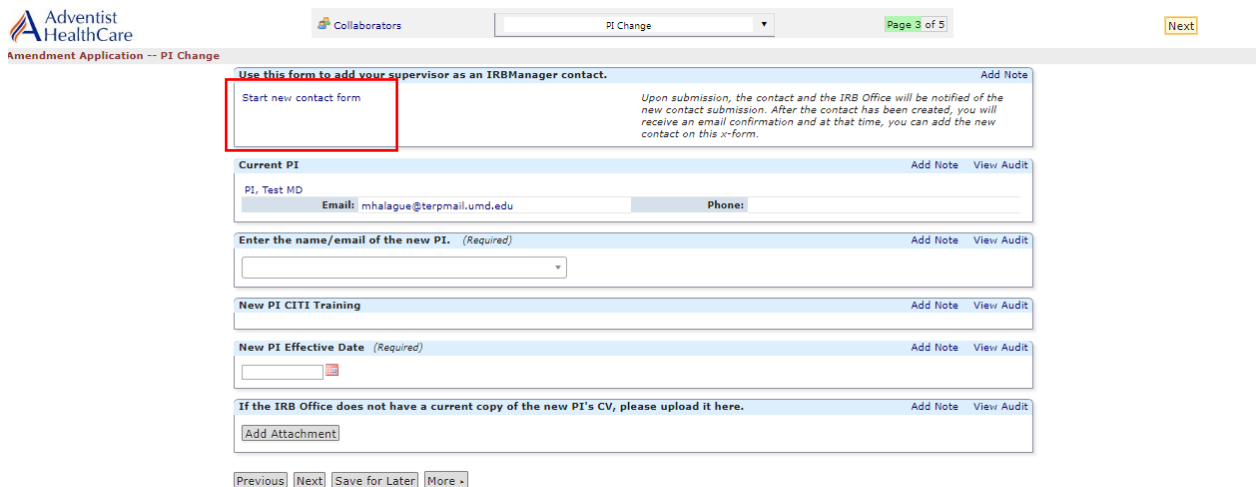
Informed Consent Change

- If you are submitting an amendment for an **informed consent change**, select 'Informed Consent Form' on Question #3. The next page will prompt you to attach the tracked changes and clean version of the updated informed consent form. Indicate whether subjects will be informed of the informed consent changes. Lastly, answer the risk-benefit assessment question.



Principal Investigator Change

- If there is a change in the **Principal Investigator (PI)**, select 'PI Change' on Question #3. The next page will prompt you to answer questions about the new Principal Investigator.

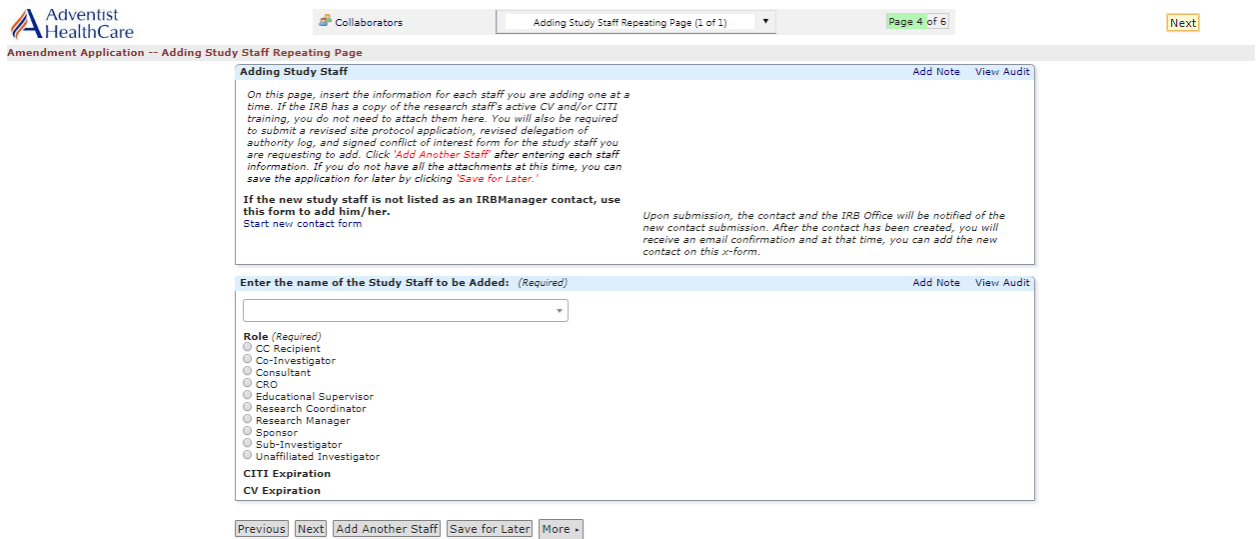


- Enter the name or email of the new PI in the box. If the new PI has not previously conducted research with AHC and/or does not have an IRBManager account, please submit a New Contact Form to the IRB Office before submitting the Amendment Application.

- b) If the new PI is missing CITI training or has expired training, it will be noted in red text and you are required to attach a CITI completion certificate to submit to the IRB Office.
- c) The new PI effective date is when the PI will assume the PI role and responsibilities.
- d) Please attach the new PI's CV if the IRB Office does not have a copy.
- e) Other required documents such as the Conflict of Interest Form, PI Certification Form, and Unaffiliated Investigator Certification Form will be a separate submission from the amendment application.
- f) Lastly, answer the risk-benefit question.

Adding New Study Staff

8. If you are submitting an amendment to **add a new study staff**, select 'Study Staff Addition' on question #3. The next following pages page will prompt you to answer questions about the new study staff member and attach the required documents.



Amendment Application -- Adding Study Staff Repeating Page

Collaborators Adding Study Staff Repeating Page (1 of 1) Page 4 of 6 Next

Adding Study Staff Add Note View Audit

On this page, insert the information for each staff you are adding one at a time. If the IRB has a copy of the research staff's active CV and/or CITI training, you do not need to attach them here. You will also be required to submit a revised site protocol application, revised delegation of authority log, and signed conflict of interest form for the study staff you are requesting to add. Click 'Add Another Staff' after entering each staff information. If you do not have all the attachments at this time, you can save the application for later by clicking 'Save for Later.'

If the new study staff is not listed as an IRBManager contact, use this form to add him/her.
Start new contact form

Upon submission, the contact and the IRB Office will be notified of the new contact submission. After the contact has been created, you will receive an email confirmation and at that time, you can add the new contact on this x-form.

Enter the name of the Study Staff to be Added: (Required) Add Note View Audit

Role (Required)

- CC Recipient
- Co-Investigator
- Consultant
- CRO
- Educational Supervisor
- Research Coordinator
- Research Manager
- Sponsor
- Sub-Investigator
- Unaffiliated Investigator

CITI Expiration
CV Expiration

- a) Enter the name of the study staff member in the box. If the new study staff member has not previously conducted research with AHC and/or does not have an IRBManager account, please submit a New Contact Form to the IRB Office before submitting the Amendment Application.
- b) Indicate the role of the new study staff member on the study.
- c) If the new study staff member is missing CITI training or has expired training, it will be noted in red text and you are required to attach a completion certificate to submit to the IRB Office.
- d) Please attach the new study staff member's CV.
- e) If you wish to add another new study staff member, click 'Add Another Staff.' This will take you to a separate page in which you will enter the name of the study staff member and his/her role.

- f) The next page will prompt you to attach the revised site protocol application and delegation of authority log with the new study staff added. Other required documents, such as the Conflict of Interest Form, Sub-Investigator Certification Form and Unaffiliated Investigator Certification Form, will be a separate submission from the Amendment Application.
- g) Lastly, answer the risk-benefit assessment question.

Remove Study Staff Member

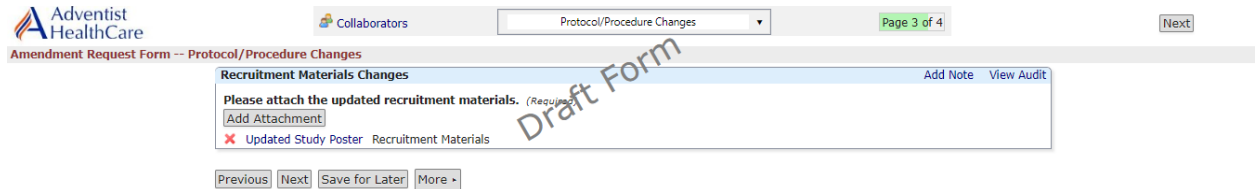
- 9. If you are submitting an amendment to **remove a study staff member**, select ‘Study Staff Removal’ on question #3. The following page will prompt you to answer questions about the removal of the study staff member and reason for removal.

Name	Role
Bree Hammock	Research Coordinator
Elizabeth Carroll	Sub-Investigator
Maria Halaguena	Research Coordinator
Test PI, MD	Principal Investigator
Testing New Study Staff, RN	Sub-Investigator

- a) The current study staff table will be available for your convenience. Under ‘Display Removal Study Staff Table,’ select the study staff member to be removed from the study by clicking ‘Add Contact.’
- b) Provide a reason for removal.
- c) If you are removing more than one study staff member, click ‘Save’ after entering each row of data.
- d) Attach the revised Delegation of Authority Log.
- e) Lastly, answer the risk-benefit question.

Recruitment Materials

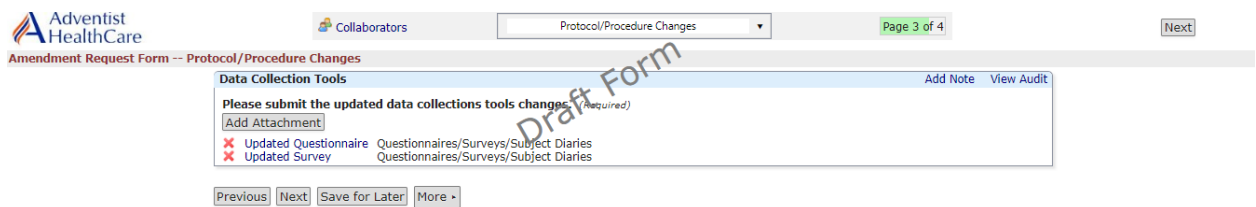
10. If you are submitting an amendment to submit updated **Recruitment Materials** from the sponsor, select 'Recruitment Materials' on Question #3. The next page will prompt you to attach the updated recruitment materials and answer the risk-benefit assessment question.



The screenshot shows the 'Recruitment Materials Changes' section of the 'Amendment Request Form -- Protocol/Procedure Changes'. The page is on 'Page 3 of 4'. The section title is 'Recruitment Materials Changes' with links for 'Add Note' and 'View Audit'. The instruction reads: 'Please attach the updated recruitment materials. (Required)'. Below this is an 'Add Attachment' button and a list of attachments: 'Updated Study Poster' (marked with a red X) and 'Recruitment Materials'. At the bottom of the section are buttons for 'Previous', 'Next', 'Save for Later', and 'More -'.

Data Collection Tools

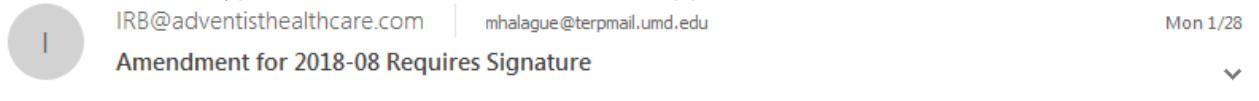
11. If you are submitting an amendment to submit **Data Collection Tools**, select 'Data Collection Tools' on Question #3. The next page will prompt you to attach the updated data collection tools and answer the risk-benefit question.



The screenshot shows the 'Data Collection Tools' section of the 'Amendment Request Form -- Protocol/Procedure Changes'. The page is on 'Page 3 of 4'. The section title is 'Data Collection Tools' with links for 'Add Note' and 'View Audit'. The instruction reads: 'Please submit the updated data collections tools changes. (Required)'. Below this is an 'Add Attachment' button and a list of attachments: 'Updated Questionnaire' (marked with a red X) and 'Updated Survey' (marked with a red X), both with subtext 'Questionnaires/Surveys/Subject Diaries'. At the bottom of the section are buttons for 'Previous', 'Next', 'Save for Later', and 'More -'.

PI Sign-Off and Admin Pre-Review:

12. 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.
13. The PI will receive the following email, as shown below, which will include information on the amendment type and a link to the amendment application.



Dear Test PI, MD,

Maria Halaguena has submitted an amendment for 2018-08-CREST-H.

Type of amendment: Recruitment Materials.

Click here to review and sign-off on the submission. [Amendment Request Form](#)

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

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



Dear Maria Halaguena,

Test PI, MD has reviewed the amendment request for T2019-006-Initial Review Application Test # 3 and is requesting changes before it can be submitted to the IRB.

PI requested changes:

testing amendment

Click here to access the form and make the changes. [Amendment Request Form](#)

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

15. 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.

16. The IRB Office will review the Amendment Application and if there are any changes requested, you will receive the following email:



IRB Study Number: 2018-07

Study Title: EnSite Precision Observational Study

Dear Test PI, MD,

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

Please address the following questions:

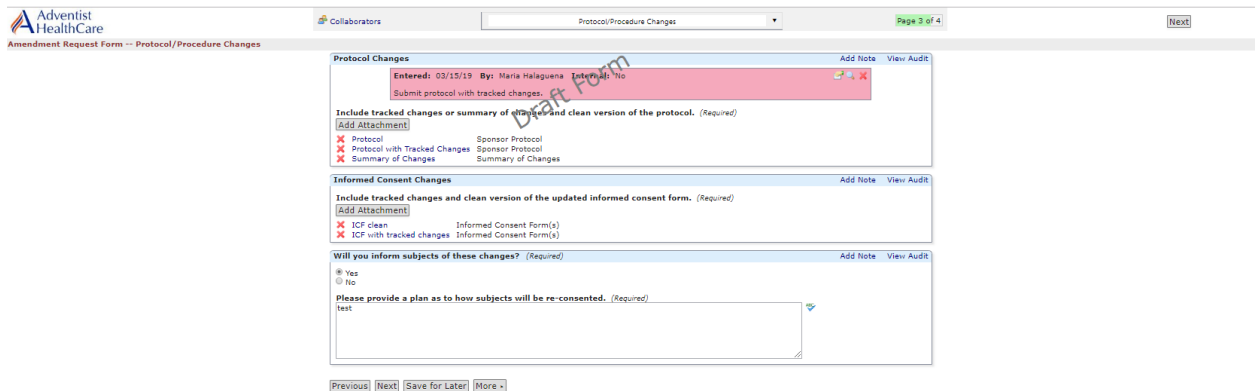
1. Submit word copy of informed consent form.

Click here to access the form. [Amendment Request Form](#)

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.

17. 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 communicate the required changes to the research study teams, which makes 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 the notes internal.



The screenshot shows the 'Amendment Request Form' interface. At the top, it says 'Adventist HealthCare' and 'Collaborators'. The main section is titled 'Protocol/Procedure Changes' and is marked as 'Page 3 of 4'. There are three main sections:

- Protocol Changes:** Includes a header with 'Entered: 03/15/19 By: Maria Halaguena' and 'Submitted: No'. Below it is a red box with the text 'Submit protocol with tracked changes.' and a list of items with red 'X' marks: 'Protocol', 'Protocol with Tracked Changes', and 'Summary of Changes'. There is an 'Add Attachment' button.
- Informed Consent Changes:** Includes a header with 'Include tracked changes and clean version of the updated informed consent form. (Required)'. Below it is a red box with the text 'Submit protocol with tracked changes.' and a list of items with red 'X' marks: 'ICF clean' and 'ICF with tracked changes'. There is an 'Add Attachment' button.
- Will you inform subjects of these changes? (Required):** Includes radio buttons for 'Yes' and 'No', and a text area for 'Please provide a plan as to how subjects will be re-consented. (Required)'. The text area contains the word 'test'.

At the bottom, there are navigation buttons: 'Previous', 'Next', 'Save for Later', and 'More...'.

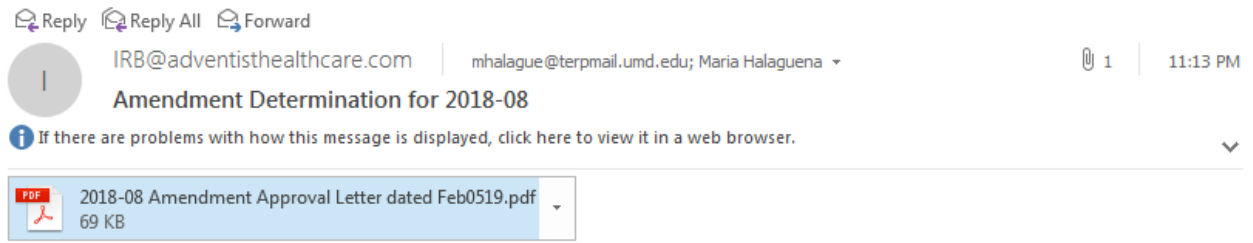
Please note: You cannot submit the form until the changes requested by the IRB Office have been made.

18. After you have made the changes requested by the IRB Office, the form will go to the PI for sign off.
19. If no additional changes are requested by the PI and IRB Office, the Amendment Application is ready to be reviewed by the IRB.

IRB Review:

Expedited Review

20. The type of review is contingent upon the risk-benefit ratio and severity of the changes in the amendment application. If only minor changes are involved, the amendment will most likely be reviewed via expedited review. The study team should receive an outcome letter within 4-5 business days. The determination letter and informed consent form (if applicable) will be sent to the PI and creating user via email, as shown below.



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: 2018-08


Study Title: CREST-H

Dear Test PI, MD,

Attached is the decision letter for the above referenced study. Please contact the IRB Office with any questions or concerns.

Thank you.

21. If the amendment request receives a determination other than a full-approval, you will receive an email, as shown below, prompting you to make revisions to your application. 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 and the IRB will conduct a second review.

 IRB@adventisthealthcare.com | mhalague@adventisthealthcare.com Wed 10:38 AM
Study T2019-007 Amendment Requires Changes

IRB Study Number: T2019-007

Study Title: INITIAL REVIEW APPLICATION # 4

Dear Test PI, MD,

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


test

Please click the form link to access the form and make changes. [Amendment Request Form](#)

Thank you.

Referral to Full-Board

22. If the amendment is deferred 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

23. 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.

 IRB@adventisthealthcare.com | mhalague@terpmail.umd.edu; mhalague@adventisthealthcare.com 2 4:43 PM
Amendment Determination for T2017-07

 T2017-07 ICF dated Mar2119.pdf 408 KB
 T2017-07 Amendment Approval Letter dated Mar2119.pdf 134 KB

IRB Study Number: T2017-07

Study Title: 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

Dear Test PI, MD,


Attached is the determination letter for the above referenced study. Please contact the IRB Office with any questions or concerns.

Thank you.

24. If the IRB has determined that modifications are needed to the Amendment Application, the IRB Office will send an email to the PI and creating user of the changes requested, as shown below. 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.
25. To view the determination letter and stamped informed consent form within IRBManager, go to the study profile and click on the 'amendment 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 the amendment type and a link to the amendment application.

 IRB@adventisthealthcare.com | mhalague@terpmail.umd.edu 10:27 AM
Amendment for 2018-08 Requires Signature

Dear Test PI, MD,

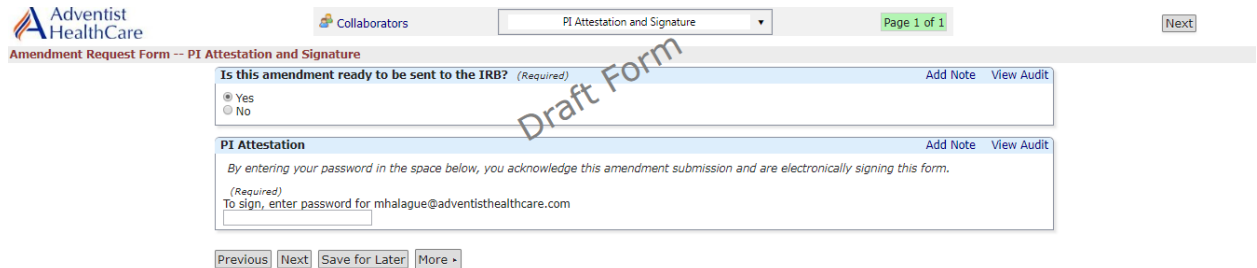
Maria Halaguena has submitted an amendment for 2018-08-CREST-H.

Type of amendment: PI Change.

Click here to review and sign-off on the submission. [Amendment Request Form](#)

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

- 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.
- If you agree with the changes put forth in the submission, you will electronically sign-off on the document by inputting your IRBManager password.



Adventist HealthCare

Collaborators

PI Attestation and Signature

Page 1 of 1

Next

Amendment Request Form -- PI Attestation and Signature

Is this amendment ready to be sent to the IRB? (Required) Add Note View Audit

Yes

No

PI Attestation Add Note View Audit

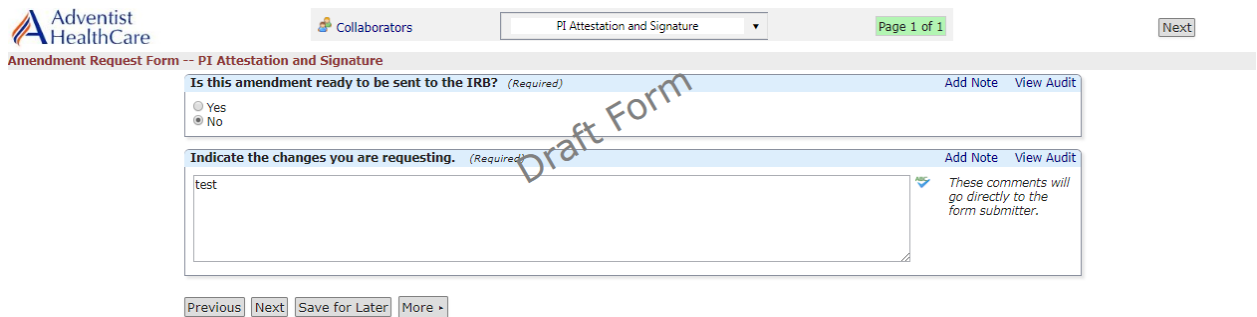
By entering your password in the space below, you acknowledge this amendment submission and are electronically signing this form.

(Required)

To sign, enter password for mhalague@adventisthealthcare.com

Previous Next Save for Later More -

- 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.



Adventist HealthCare

Collaborators

PI Attestation and Signature

Page 1 of 1

Next

Amendment Request Form -- PI Attestation and Signature

Is this amendment ready to be sent to the IRB? (Required) Add Note View Audit

Yes

No

Indicate the changes you are requesting. (Required) Add Note View Audit

test

These comments will go directly to the form submitter.

Previous Next Save for Later More -

- 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:

- 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
- ⁴Protocol site output: where the study will primarily take place. There may be more than one site listed.
- ⁵Agent type: description of the nature of the study or the investigational aspect of the study (e.g., observational, specimen review, drug, device, etc.)
- ⁶Creating user: the study staff member who started the x-form data entry