



## **Continuing Review 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 focuses on the continuing review application from 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.

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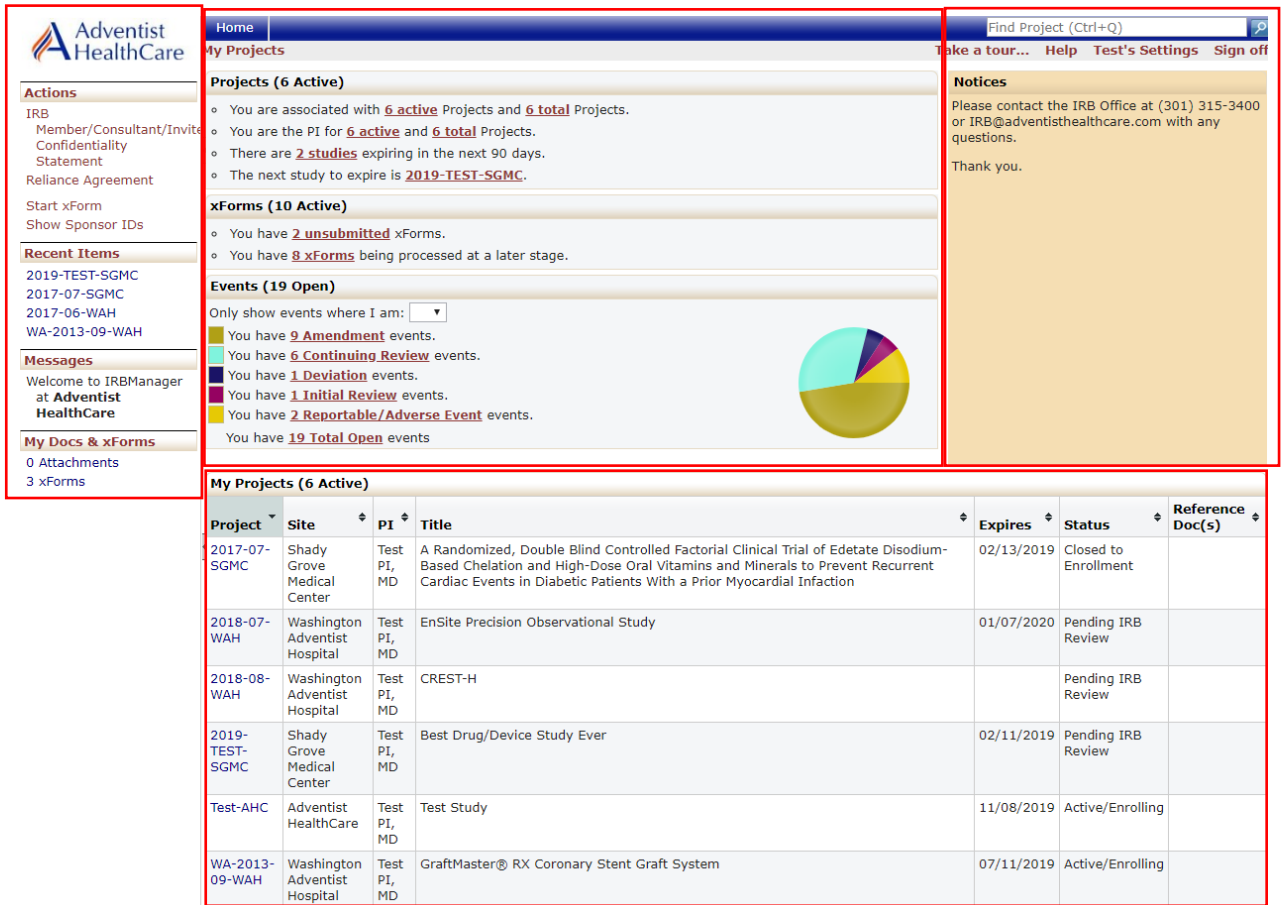
## Dashboard Information:

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<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 Box: Under 'My Projects,' you will see more information on your projects<sup>2</sup>, x-forms, and study events<sup>3</sup>.
  - 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



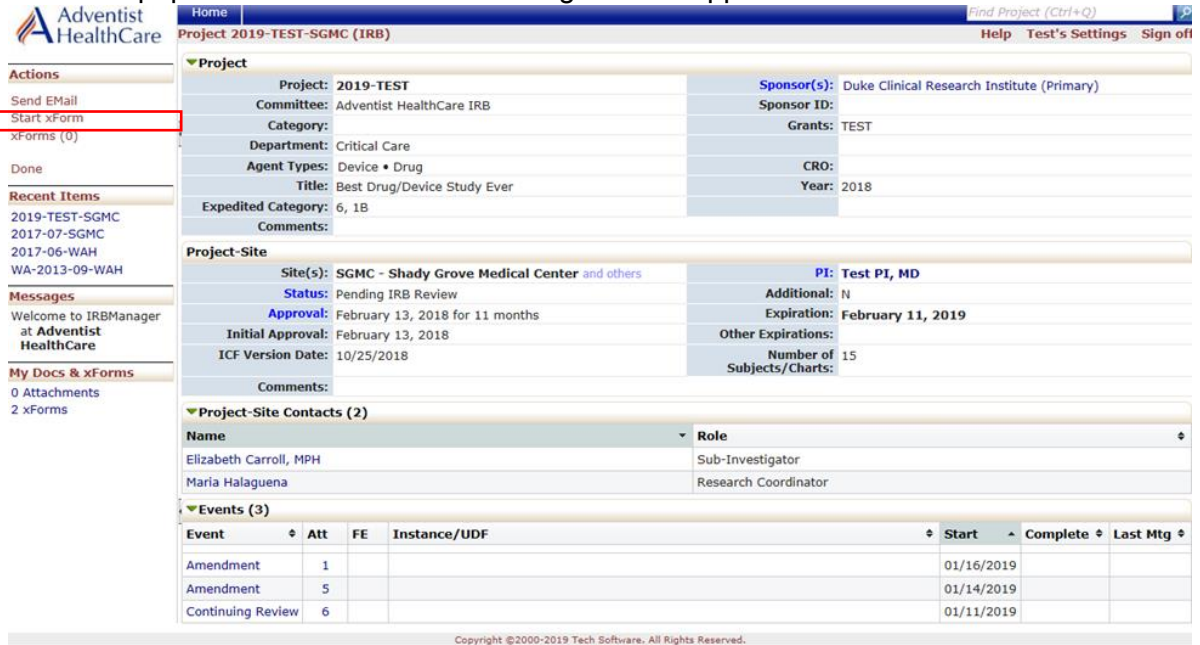
The screenshot displays the IRBManager dashboard interface. On the left is the 'Actions Sidebar' with links for IRB, Start xForm, Recent Items, Messages, and My Docs & xForms. The main area is the 'My Projects Box' which includes summary statistics for Projects (6 Active), xForms (10 Active), and Events (19 Open), along with a pie chart. On the right is the 'Notices Box' with contact information for the IRB Office. Below these sections is a table titled 'My Projects (6 Active)' listing project details.

| 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     |                  |

d) My Projects Table

**Study Profile Information:**

- 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 “Continuing Review Application”.



**Project**

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

**Project-Site**

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

**Project-Site Contacts (2)**

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

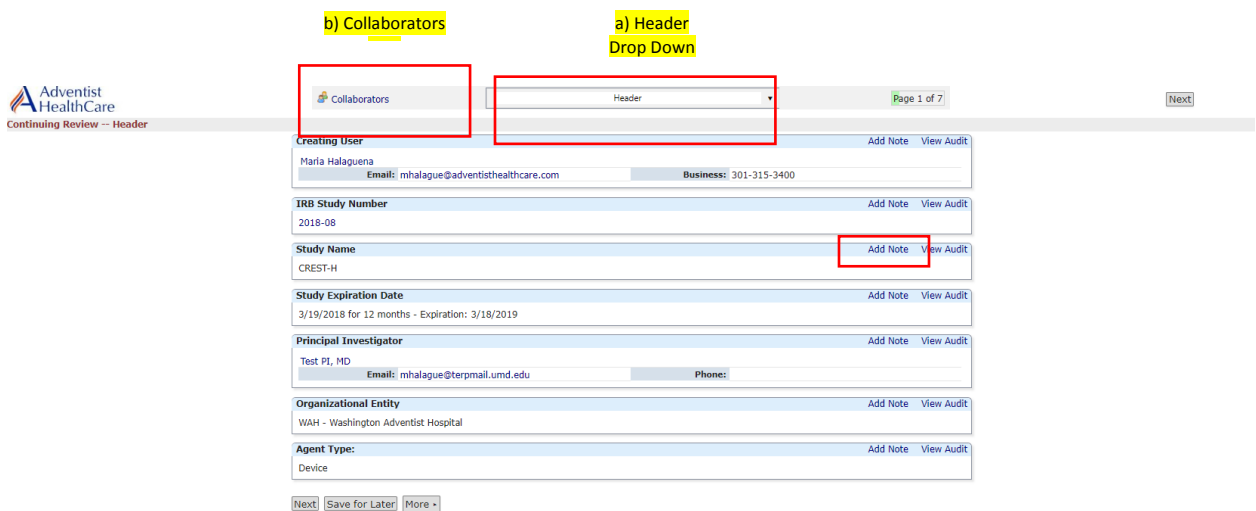
**Events (3)**

| 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 a Continuing Review Application:**

3. Once you select the continuing review application, the Study Header page will populate. The Study Header page contains information on the IRB study number, protocol site<sup>4</sup>, study expiration date, principal investigator, and agent type<sup>5</sup>. The creating user<sup>6</sup> will be the person who started the x-Form.

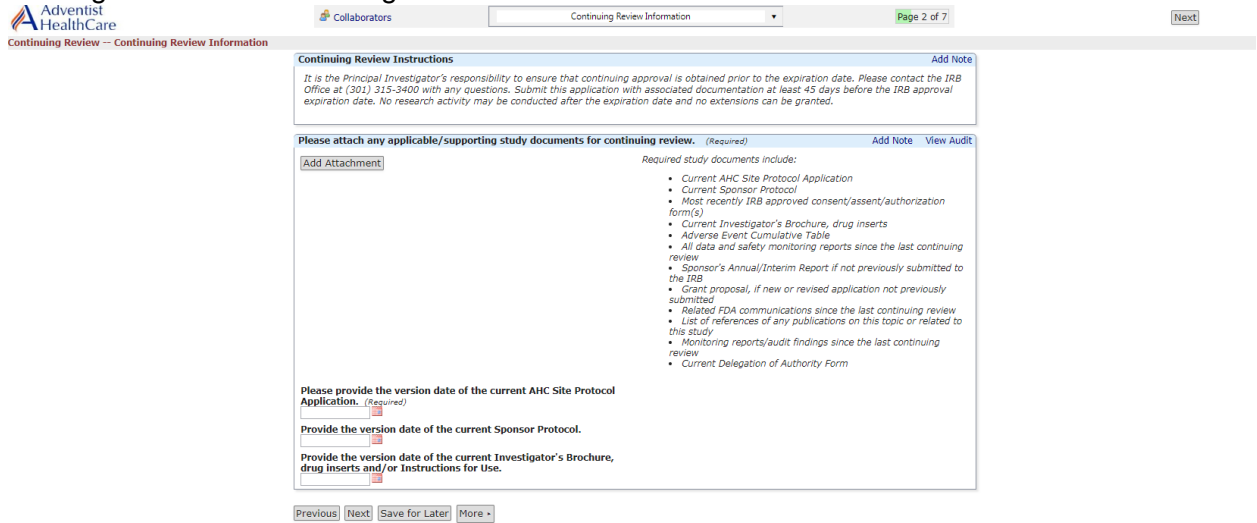


The screenshot displays the 'Continuing Review - Header' page. At the top left is the Adventist HealthCare logo. The page title is 'Continuing Review - Header'. A navigation bar at the top right shows 'Page 1 of 7' and a 'Next' button. The main content area is a form with several sections, each with an 'Add Note' and 'View Audit' link. The sections are: 'Creating User' (Maria Halaguena, Email: mhalague@adventisthealthcare.com, Business: 301-315-3400), 'IRB Study Number' (2018-08), 'Study Name' (CREST-H), 'Study Expiration Date' (3/19/2018 for 12 months - Expiration: 3/18/2019), 'Principal Investigator' (Test PI, MD, Email: mhalague@terpmail.umd.edu, Phone: ), 'Organizational Entity' (WAH - Washington Adventist Hospital), and 'Agent Type' (Device). At the bottom of the form are buttons for 'Next', 'Save for Later', and 'More -'. Two red boxes highlight the 'Collaborators' icon and the 'Header' drop-down menu.

- 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.'

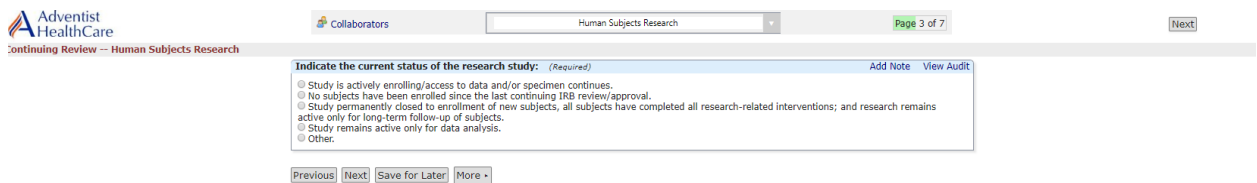
## Continuing Review Application Data Entry:

- The next page will take you to the continuing review information page, where you will attach any applicable/supporting documents for continuing review. In this page, you will provide the dates of the current AHC site protocol application, sponsor protocol, and any investigator brochures or drug inserts.

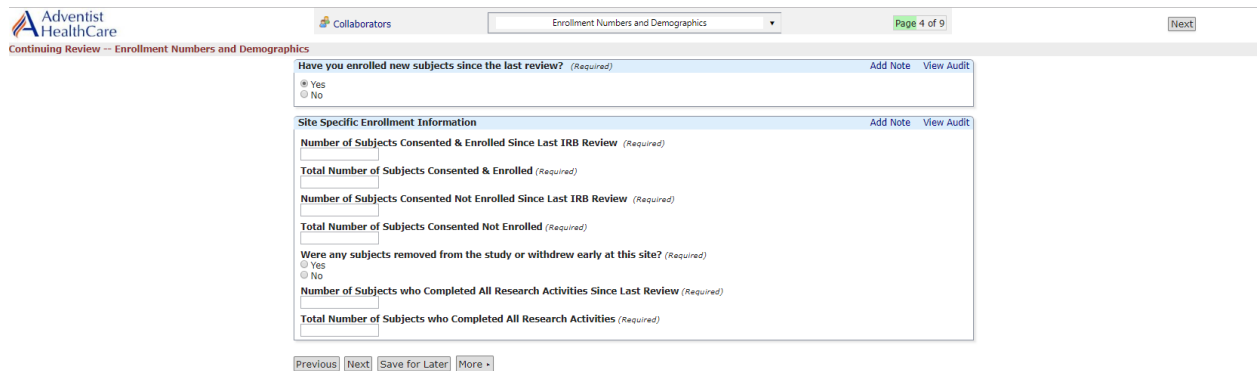


**Please note:** Questions on the x-forms are specifically conditioned based on your responses. In other words, certain questions will appear based on your answer(s) to a previous question(s). Furthermore, questions marked as required cannot be left unanswered. You will not be allowed to submit the form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

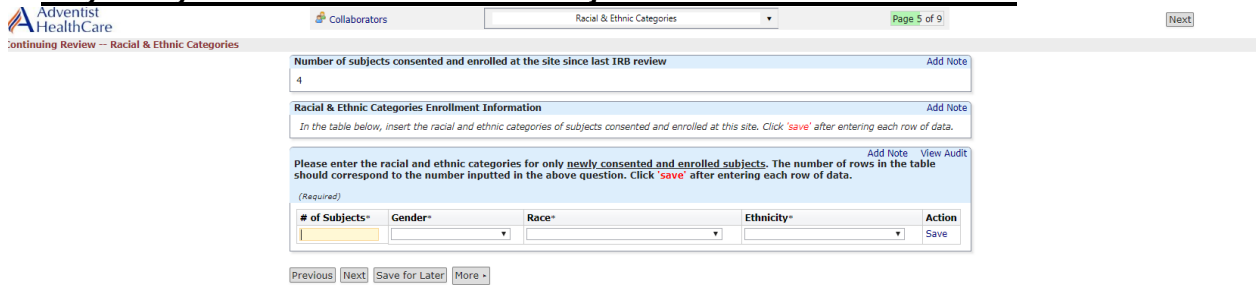
- Indicate the current study status of the research study.



- If the study is actively enrolling, you must provide more information on newly enrolled and consented subjects as well as any subject attrition.



7. After providing the enrollment information, you must provide the racial/ethnic background of **only newly consented and enrolled subjects since the last IRB review.**



Continuing Review -- Racial & Ethnic Categories

Collaborators Racial & Ethnic Categories Page 5 of 9 Next

Number of subjects consented and enrolled at the site since last IRB review Add Note  
4

Racial & Ethnic Categories Enrollment Information Add Note  
In the table below, insert the racial and ethnic categories of subjects consented and enrolled at this site. Click 'save' after entering each row of data.

Please enter the racial and ethnic categories for only newly consented and enrolled subjects. The number of rows in the table should correspond to the number inputted in the above question. Click 'save' after entering each row of data. Add Note View Audit

(Required)

| # of Subjects* | Gender* | Race* | Ethnicity* | Action |
|----------------|---------|-------|------------|--------|
| 1              |         |       |            | Save   |

Previous Next Save for Later More -

- The number for subjects consented and enrolled at the site since the last IRB review is available for your convenience.
  - 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 down.
  - You must save the information entered before adding another row of information.
8. The next following pages will ask you about the protocol and consent process and safety and adverse events.

### **Reportable Event Information**

- If you are reporting any reportable events to the IRB at continuing review, you need to submit the reportable event form. Based on your response(s) to the questions on the safety and adverse events page, the reportable event form will populate towards the end of the continuing review application. From there, you can attach any cumulative tables.
- Please refer to the Reportable Event Resource Guide for Research Personnel and Principal Investigators for more guidance on how to fill out the form.

### **Amendment Information**

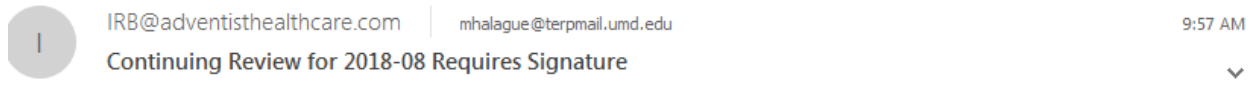
- If you are submitting an amendment with the continuing review application, you need to complete the amendment request form. Based on your response(s) to the questions on the research personnel page, the amendment request form will populate towards the end of the continuing review application.
- Please refer to the Amendment Request Form Resource Guide for Research Personnel and Principal Investigators for more guidance on how to fill out the form.

### **Risk/Benefit Ratio**

- Lastly, you will be prompted to assess the risk/benefit ration prior to submission.

**PI Sign-Off and Admin Pre-Review:**

14. 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.
15. The PI will receive the following email, as shown below, which will include a link to the continuing review application.



Dear Test PI, MD,

Maria Halaguena has submitted a continuing review form for 2018-08-CREST-H.

Click here to review and sign-off on the submission. [Continuing Review](#)

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

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



Dear Maria Halaguena,

Test PI, MD has reviewed the continuing review for 2018-08-CREST-H and is requesting changes before it can be submitted to the IRB.

PI requested changes:

Submit revised investigator brochure along with summary of changes..

Click here to access the form and make the changes. [Continuing Review](#)

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

17. 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.

18. The IRB Office will review the continuing review application and if there are any changes requested, you will receive the following email.



IRB Study Number: 2018-08

Study Title: CREST-H

Dear Test PI, MD,

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

Please address the following questions:

Submit word copy of the informed consent form.

Click here to access the form. [Continuing Review](#)

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](mailto:IRB@adventisthealthcare.com) or 301-315-3400 with any questions.

Thank you.

- 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 designating them as internal.

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

- After you have made the changes requested by the IRB Office, the form will go to the PI for sign off.

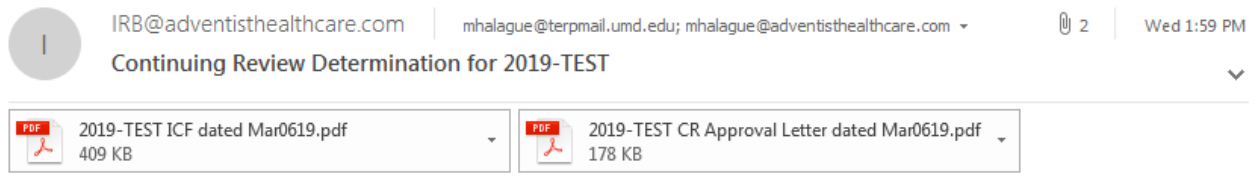


21. If no additional changes are requested by the PI and IRB Office, the continuing review is ready to be reviewed by the IRB.

**IRB Review:**

**Expedited Review**

22. If the continuing review application is reviewed via expedited review and receives a full-approval, 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.



IRB Study Number: 2019-TEST

Study Title: Best Drug/Device Study Ever

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.

23. If the continuing review application 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 Study Number: T2019-007

Study Title: INITIAL REVIEW APPLICATION # 4

Dear Test PI, MD,

The IRB has reviewed the continuing review 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. [Continuing Review Application](#)

Thank you.

### **Referral to Full-Board**

24. If the continuing review is deferred to full-board review, you will receive the email, as shown below, informing you of the referral.



IRB Study Number: 2018-07

Study Name: EnSite Precision Observational Study

Dear Test PI, MD,

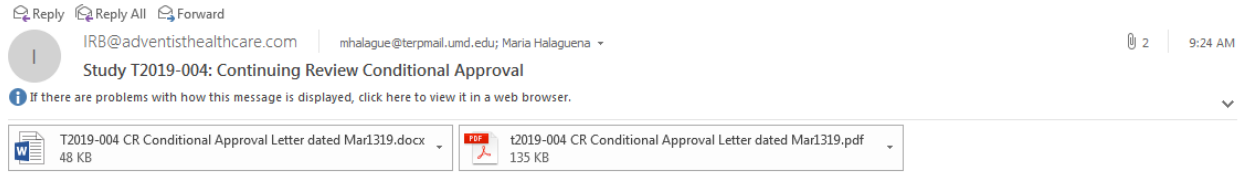
2018-07-EnSite Precision Observational Study was referred for full-board review. Please contact the IRB Office at [IRB@adventisthealthcare.com](mailto:IRB@adventisthealthcare.com) or 301-315-3400 with any questions.

Thank you.

### **Full-Board**

25. 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.

26. If the IRB has determined that modifications are needed to the continuing review, the IRB Office will send an email to the PI and creating user containing the changes requested, as shown below. The form will then go back to data entry and PI sign off.



**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: T2019-004

Study Title: Strategies Healthcare Managers Use to Reduce Hospital Acquired Infections

Dear Test PI, MD,

Attached is the continuing review conditional approval letter for the above referenced study. Please respond to the IRB's concerns within the letter (attached in Microsoft Word for your convenience) and include any revised documentation.

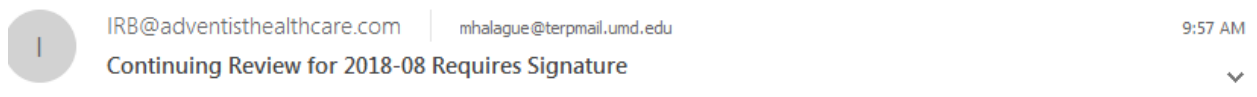
Please contact the IRB office at [IRB@adventisthealthcare.com](mailto:IRB@adventisthealthcare.com) or (301) 315-3400 with any questions.

Thank you.

27. 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](mailto:IRB@adventisthealthcare.com) informing you an x-form has been completed by a research staff member. The email will include a link to the continuing review application.



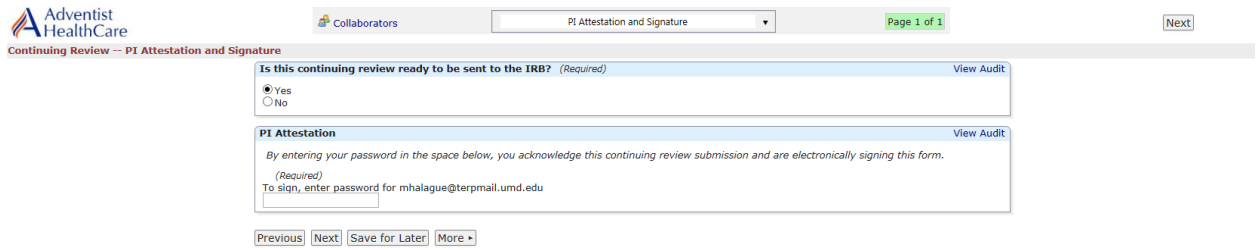
Dear Test PI, MD,

Maria Halaguena has submitted a continuing review form for 2018-08-CREST-H.

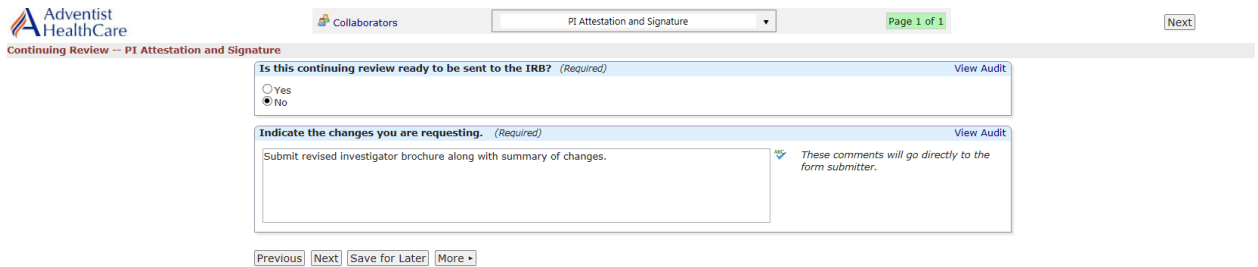
Click here to review and sign-off on the submission. [Continuing Review](#)

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

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.
3. If you agree with the submission information entered, 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:**

- <sup>1</sup>X-forms: online version of the currently existing submission documents with slight 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 event
- <sup>4</sup>Protocol site output: where the study will primarily take place. There may be more than one site listed.
- <sup>5</sup>Agent type: description of the nature of the study or the investigational aspect of the study (e.g., observational, specimen review, drug, device, etc.)
- <sup>6</sup>Creating user: the study staff member who started the x-form data entry .