



Initial Review 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 initial review 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.

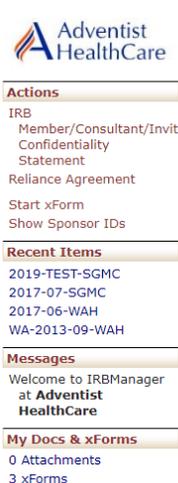
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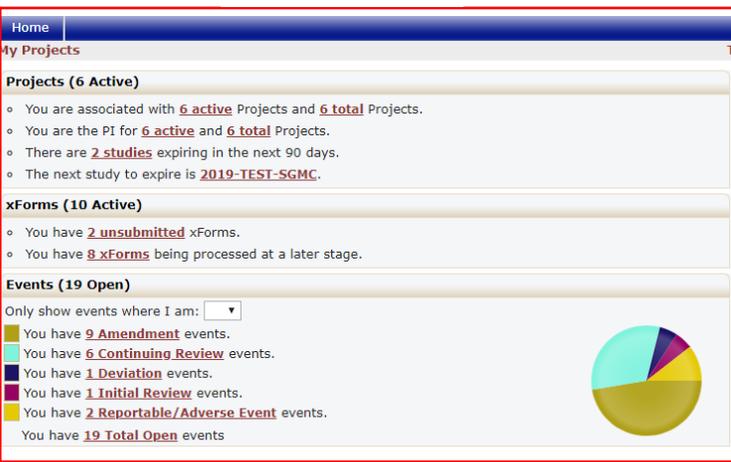
Dashboard Information:

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-forms² 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 projects³, x-forms, and study events⁴.
 - 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.

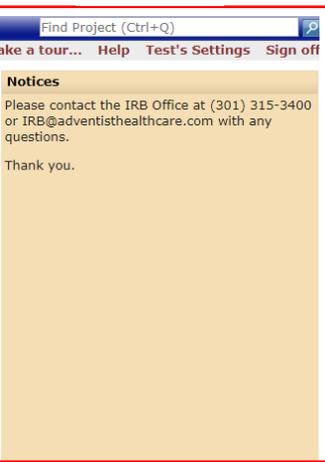
a) Actions Sidebar



b) My Projects Box



c) Notices Box

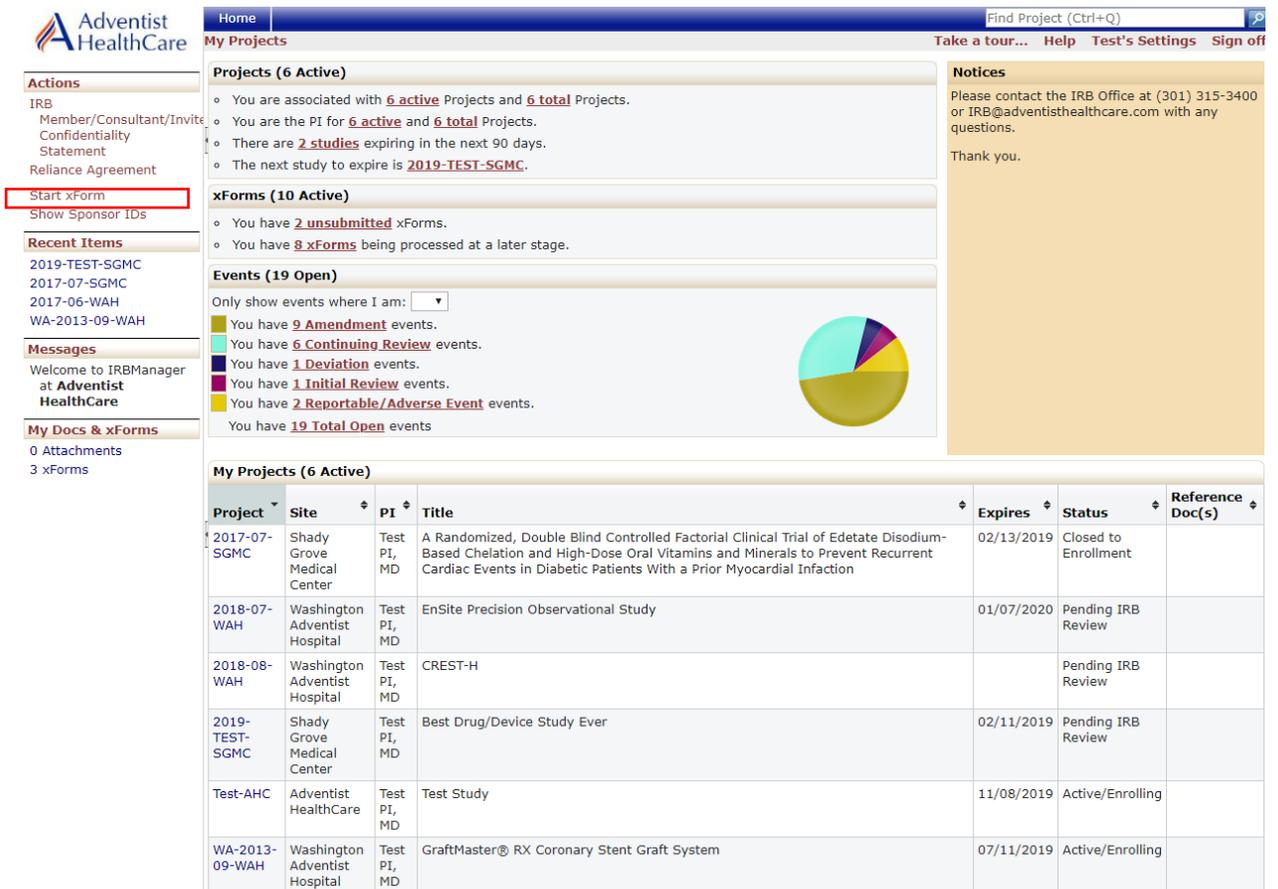


d) My Projects Table

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	

Starting an Initial Review Application:

- To start an initial review application, click 'Start xForm' in the actions side bar of your dashboard. A list of available x-forms will populate. Choose the initial review application.



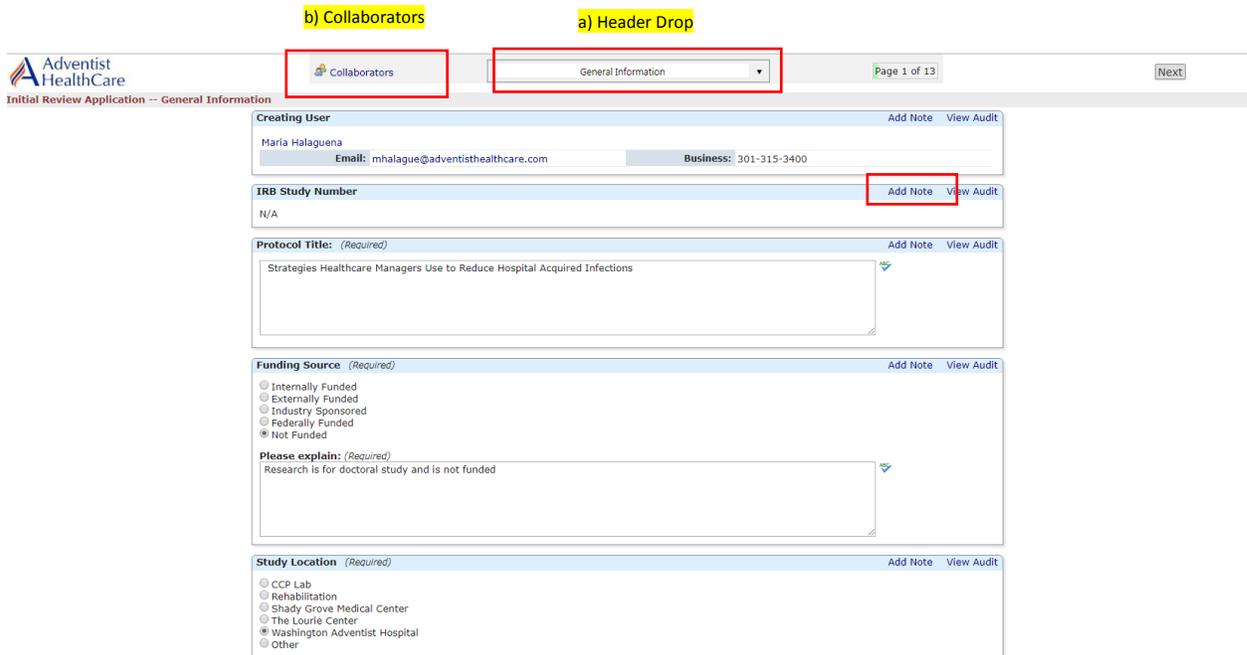
The screenshot shows the IRBManager dashboard with the following sections:

- Actions:** IRB, Member/Consultant/Invite, Confidentiality Statement, Reliance Agreement, **Start xForm** (highlighted), Show Sponsor IDs.
- Recent Items:** 2019-TEST-SGMC, 2017-07-SGMC, 2017-06-WAH, WA-2013-09-WAH.
- Messages:** Welcome to IRBManager at Adventist HealthCare.
- My Docs & xForms:** 0 Attachments, 3 xForms.
- My Projects (6 Active):**
 - Projects (6 Active):** You are associated with 6 active Projects and 6 total Projects. You are the PI for 6 active and 6 total Projects. There are 2 studies expiring in the next 90 days. The next study to expire is 2019-TEST-SGMC.
 - xForms (10 Active):** You have 2 unsubmitted xForms. You have 8 xForms being processed at a later stage.
 - Events (19 Open):** Only show events where I am: [dropdown]. You have 9 Amendment events, 6 Continuing Review events, 1 Deviation events, 1 Initial Review events, 2 Reportable/Adverse Event events, and 19 Total Open events.
- Notices:** Please contact the IRB Office at (301) 315-3400 or IRB@adventisthealthcare.com with any questions. Thank you.
- My Projects (6 Active) 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	

Initial Review Application Data Entry:

- Once you select the initial review application, you will be asked general information about your study such as protocol title, funding source, study location, etc. Your study will not have an associated IRB study number until after the IRB Office has reviewed it. The creating user⁵ will be the person who started the x-form.



- 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.'

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 cannot be left unanswered. You will not be allowed to submit the form until you answer the required questions.

Research Team Data Entry

- The next page will take you to the research team data entry page where you will enter all the study members involved in the study.

Principal Investigator (Required) [Add Note](#) [View Audit](#)

Test PI, MD

Expirations:

Attach updated CITI Certificate, if applicable.
[Add Attachment](#)

Department

Research Team Information [Add Note](#) [View Audit](#)

In the table below, insert the study staff for this study. Click 'save' after entering each row of data. If the study staff member you are entering does not have an IRBManager account, please submit the new contact form.

Use this form to add the study staff member as an IRBManager contact. *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.*

Start new contact form

Please enter the study staff members for this study. Click 'save' after entering each row of data. (Required) [Add Note](#) [View Audit](#)

Enter the name of the study staff to be added:-	CC'ed on Correspondence*	Role*	CV Expiration*	CITI Expiration*	Action
<input type="text" value=""/>	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> CC Recipient <input type="radio"/> Co-Investigator <input type="radio"/> Consultant <input type="radio"/> CRO <input type="radio"/> Educational Supervisor <input type="radio"/> Research Coordinator <input type="radio"/> Research Manager <input type="radio"/> Sponsor <input type="radio"/> Sub-Investigator			<input type="button" value="Add Attachment"/>

- Enter the PI's name or email address and attach any CITI certificates, if applicable.
- In the table below, 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 inputting their name.
- Indicate the study staff member's correspondence status and role.
- 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 the IRB Office.
- Individual study documents such as CVs, Conflict of Interest Statements, and Certification Forms will be submitted separately from the initial review application.

Educational Activity

Does this study relate to an educational activity you are pursuing (i.e. practicum or dissertation)? (Required) [Add Note](#) [View Audit](#)

Yes
 No

Please enter your supervisor's name or email address. (Required)

They will be required to sign off on this form before it is reviewed by the IRB. If you are receiving an error message when trying to add your supervisor, they may not be a contact in IRBManager. Use the link below to add them as a contact.

If your supervisor is not listed as an IRBManager contact, use this form to add your supervisor 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.

- For researchers conducting educational activities, enter your supervisor's name or email address.
- If he/she is not listed as an IRBManager Contact, please submit a New Contact Form by clicking on the 'Start new contact form' link.

Protocol and Associated Documents

- The last question in the initial review application is an attachment question in which you will submit all pertinent study documents (i.e. signed ROE approval, sponsor protocol, DOA, grant, surveys, etc.)

Please upload the following study documents:

Add Note View Audit

- Research Operations Evaluation (ROE) Study Feasibility Decision Form and Checklist
- Informed Consent Form
- Delegation of Authority Log
- Copy of Complete Grant (if applicable)
- Surveys, questionnaires, and assessments
- Other documents

(Required)

Add Attachment

- ✘ test DOA Delegation of Authority Log
- ✘ test ROE Research Operations Evaluation (ROE)
- ✘ test protocol Sponsor Protocol

Previous Next Save for Later More ▾

Investigational Device Form/Investigational Drug Form

8. If the study involves an investigational device or drug, you need to submit the investigational device form or investigational drug form which will populate towards the end of the application.

Request for Waiver of Informed Consent and HIPAA Authorization

9. If you are requesting a waiver or alteration of informed consent or waiver of documentation of informed consent, you need to submit the request for waiver of informed consent and HIPAA Authorization which will populate towards the end of the application.

PI Sign-Off and Admin Pre-Review

10. 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.
11. The PI will receive the following email, as shown below, will include a link to the initial review submission.



Dear Test PI, MD,

Maria Halaguena has submitted an initial review application.

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

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

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



IRB@adventisthealthcare.com | mhalague@adventisthealthcare.com
PI Requested Changes to Initial Review

11:17 AM



Dear Maria Halaguena,

Test PI, MD has reviewed the initial review request for Strategies Healthcare Managers Use to Reduce Hospital Acquired Infections 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. [Initial Review Application](#)

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

13. 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 has to sign off afterwards.

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



IRB@adventisthealthcare.com | mhalague@terpmail.umd.edu
IRB Admin Requesting Changes to the Initial Review

12:16 PM



Study Title: Testing Study Title

Dear Test PI, MD,

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

Please address the following questions:

Submit informed consent form in AHC wording.

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

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.

15. 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 better communicate the required changes to the research study teams. The notes feature 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.

Adventist HealthCare Collaborators Informed Consent Information Page 5 of 15 [Next](#)

Initial Review Application -- Informed Consent Information

Methods of Consent (Required) [Add Note](#) [View Audit](#)

Entered: 03/01/19 By: Maria Halaquena Internal: No
 need to use full consent because of investigational drug

Written informed consent will be obtained from subjects
 Informed consent will be obtained through a method other than a written document (i.e. verbal, survey completion)
 Waiver of informed consent and authorization are requested. No consent/authorization will be obtained.
 Other method.

Please indicate the study staff member(s) responsible for conducting the consent process. (Required) [Add Note](#) [View Audit](#)

[Add Contact](#)

✗ Test PI, MD
 Email: mhalague@terpmail.umd.edu Phone:

Process of Consent [Add Note](#) [View Audit](#)

Entered: 03/01/19 By: Maria Halaquena Internal: No
 change consent environment to reflect use of full consent

Describe the environment and location where informed consent will be solicited. Please address the following:

- Timing of the process (e.g., in relation to hospital admission, surgery, medication, stressful events).
- Involvement of someone other than the investigator(s) to help explain the research.
- Opportunity for prospective subjects to discuss participation in the research with others.
- If the research involves children, describe the process for obtaining assent (and submit the assent form), if applicable, and parental permission/consent.

How, when and where will the consent process take place? (Required)
 consent environment

How long will the potential subject have to make a decision regarding participation? How will the consent process be structured to enhance independent and thoughtful decision-making? (Required)
 2 weeks to decide on study participation

How will the subject's capacity to consent be determined? (Required)
 determination of consent

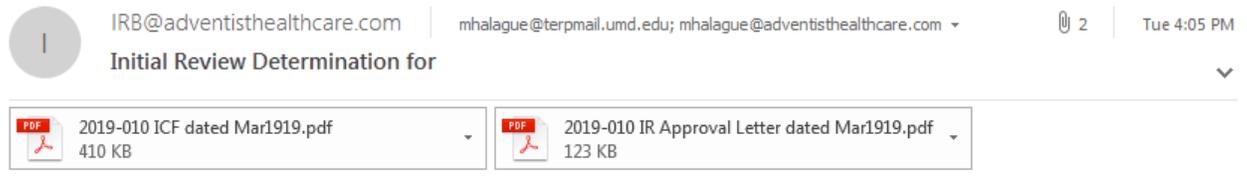
Please note: You cannot submit the form until the changes requested by the IRB Office have been made.

16. After you have made the changes requested by the IRB Office, the form will go to the PI for sign off.
17. If no additional changes are requested by the PI and IRB Office, the initial review application is ready to be reviewed by the IRB.

IRB Review:

Expedited Review

18. If the initial review application is 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.



IRB Study Number:

Study Title: Testing study title

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.

19. If the initial 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: N/A

Study Title: Initial Review Application Test # 5

Dear Test PI, MD,

The IRB has reviewed the initial review documents via full-board 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. [Initial Review Application](#)

Thank you.

Referral to Full-Board

20. If the initial 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 or 301-315-3400 with any questions.

Thank you.

Full-Board

21. 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.
22. If the IRB has determined that modifications are needed to the initial review application, 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.
23. To view the determination letter and stamped informed consent form within IRBManager, go to the study profile and click on the 'initial review' 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 a link to the initial review application.



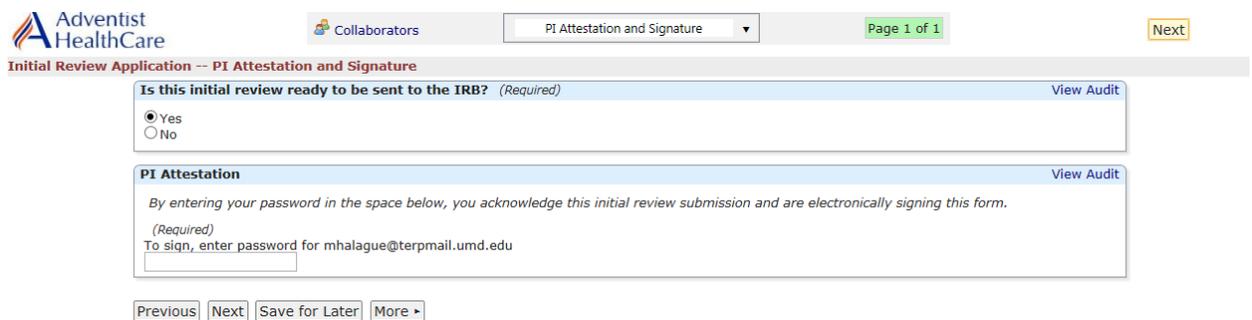
Dear Test PI, MD,

Maria Halaguena has submitted an initial review application.

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

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 information entered, 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

Initial Review Application -- PI Attestation and Signature

Is this initial review ready to be sent to the IRB? (Required) View Audit

Yes
 No

PI Attestation View Audit

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

(Required)
To sign, enter password for mhalague@terpmail.umd.edu

Previous Next Save for Later More >

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.



Adventist HealthCare Collaborators PI Attestation and Signature Page 1 of 1 Next

Initial Review Application -- PI Attestation and Signature

Is this initial review ready to be sent to the IRB? (Required) View Audit

Yes
 No

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

test

These comments will go directly to the form submitter.

Previous Next Save for Later More >

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:

- ¹Educational Activity: Research projects often led by AHC employees pursuing further education. Common examples include evaluating a standard process and conducting interviews.
- ²X-forms: online version of the currently existing submission documents with slight modifications
- ³Projects: research studies
- ⁴Study Events/Events: actions or reviews for research studies. Examples include amendments, continuing review, and reportable event
- ⁵Creating user: the study staff member who started the x-form data entry