Adventist HealthCare

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.

Table of Contents:

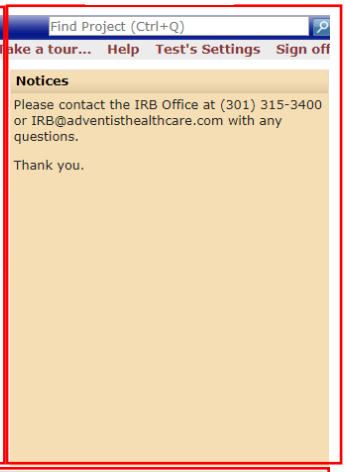
Dashboard Information:

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[2] 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[3], x-forms, and study events[4].
    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.

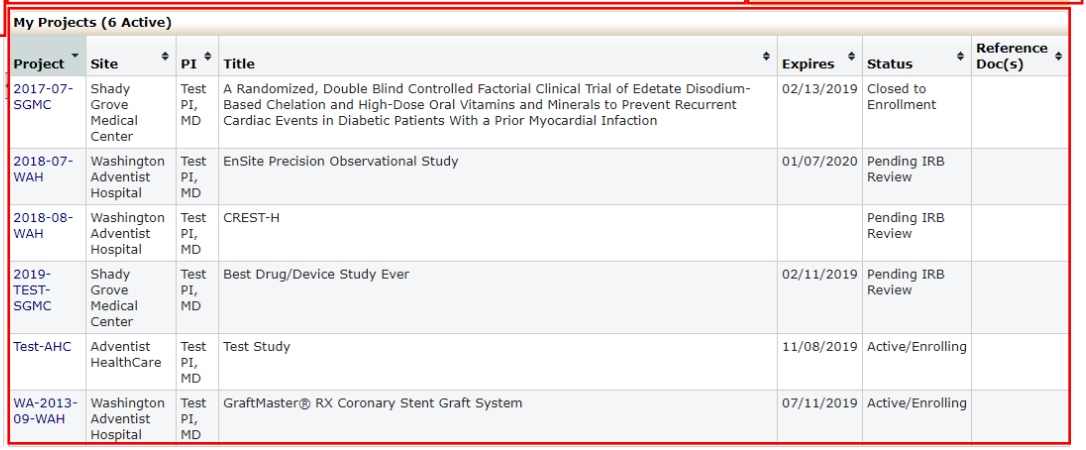
a) Actions Sidebar

b) My Projects Box

c) Notices Box



d) My Projects Table

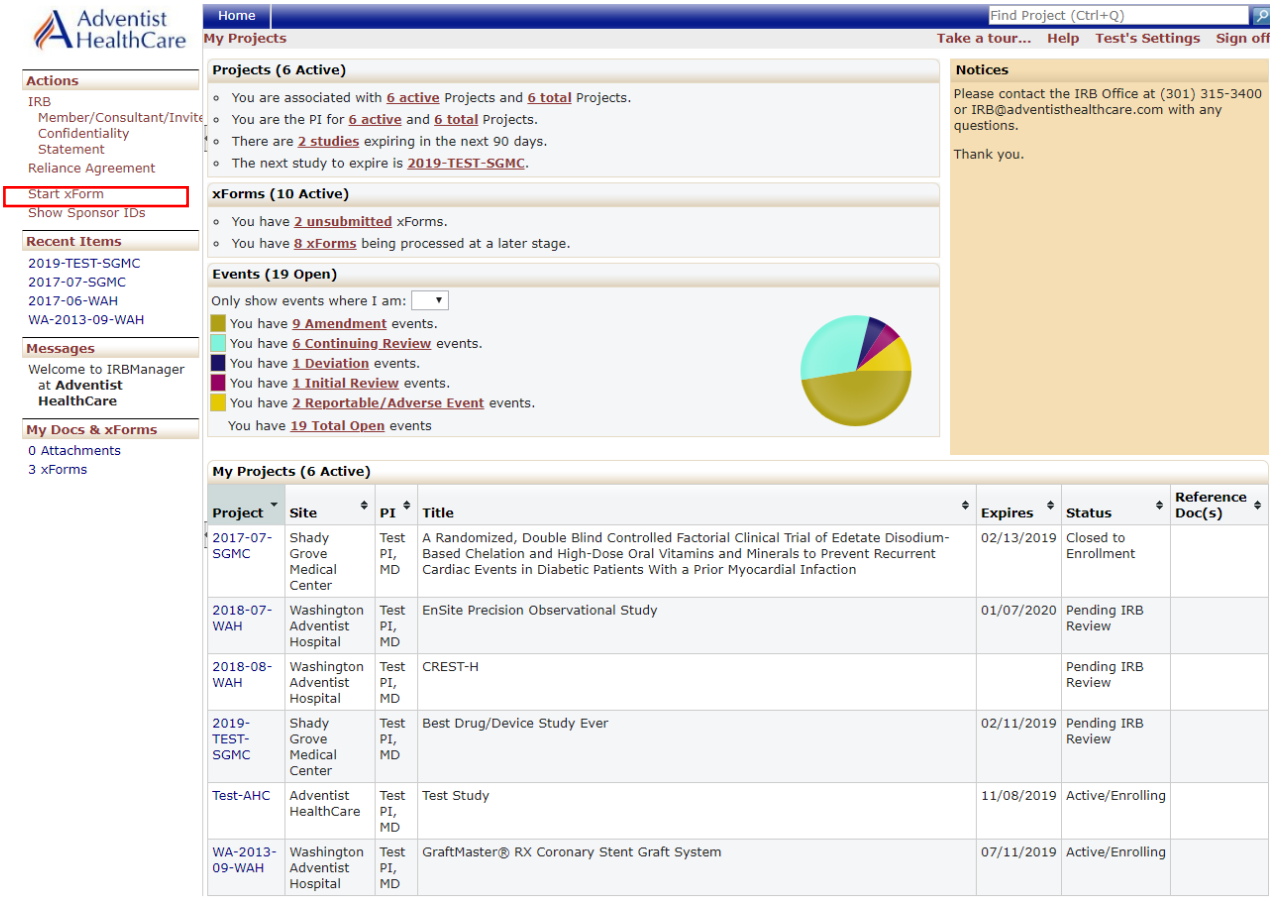


My Projects (6 Active)

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	

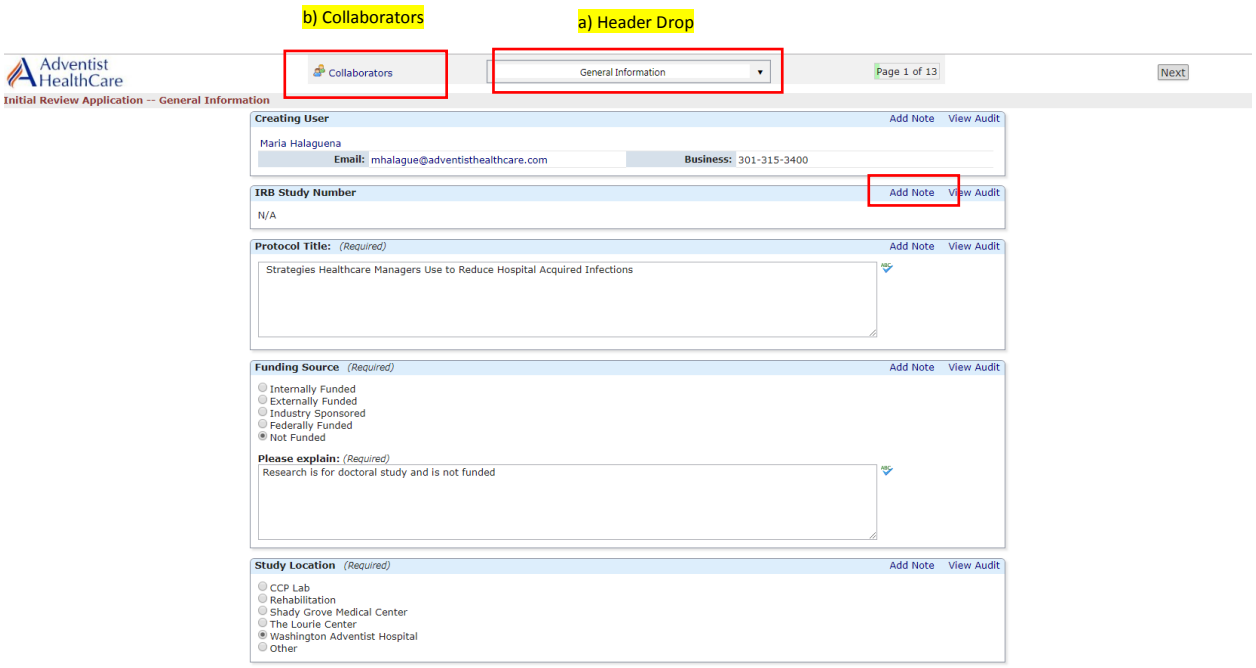
Starting an Initial Review Application:

2. 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.



Initial Review Application Data Entry:

3. 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 user[5] will be the person who started the x-form.

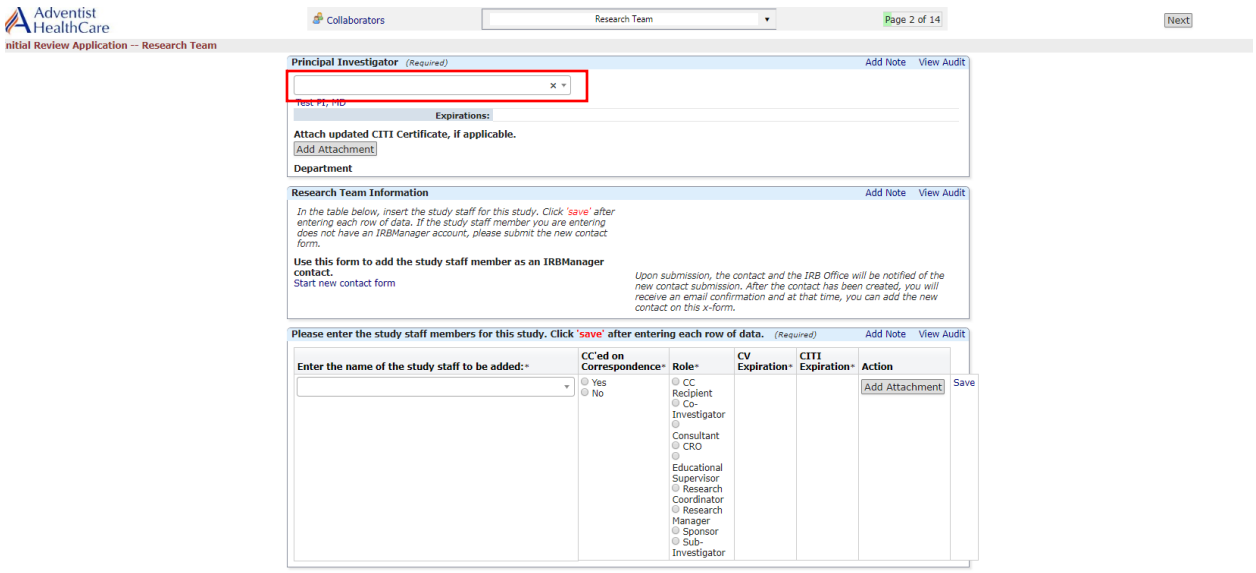


a) The header drop down allows you to skip from one page to the next.
b) The collaborators icon allows you to add others to view, edit, manage, and/or submit the form.
c) You may also add notes to communicate with other collaborators or create notes for yourself.
d) Click 'Next' to move to the next page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

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.

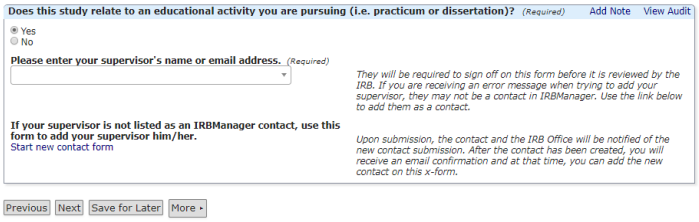
Research Team Data Entry

4. 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.



a) Enter the PI's name or email address and attach any CITI certificates, if applicable.
b) 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.
c) Indicate the study staff member's correspondence status and role.
d) 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.
e) Individual study documents such as CVs, Conflict of Interest Statements, and Certification Forms will be submitted separately from the initial review application.

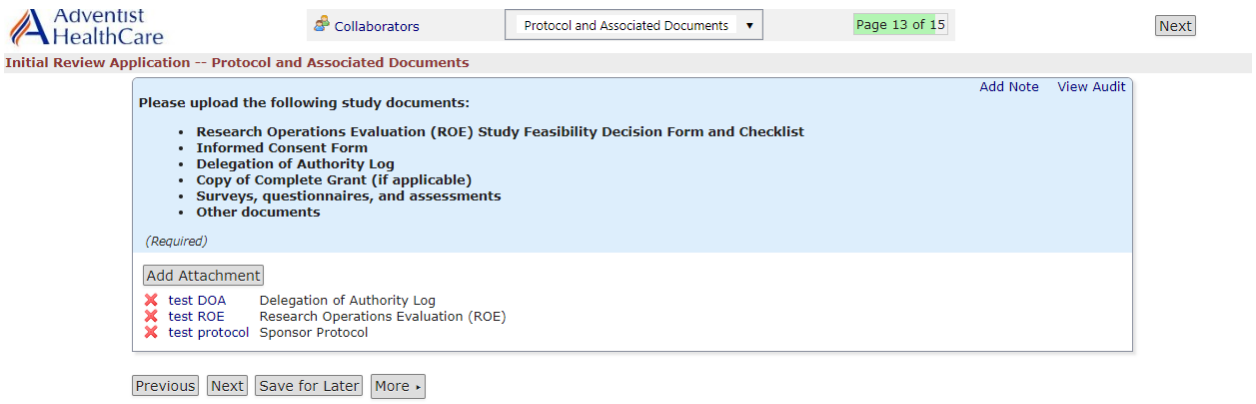
Educational Activity



5. For researchers conducting educational activities, enter your supervisor's name or email address.
6. 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

7. 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.)



Investigational Device Form/Investigational Drug Form

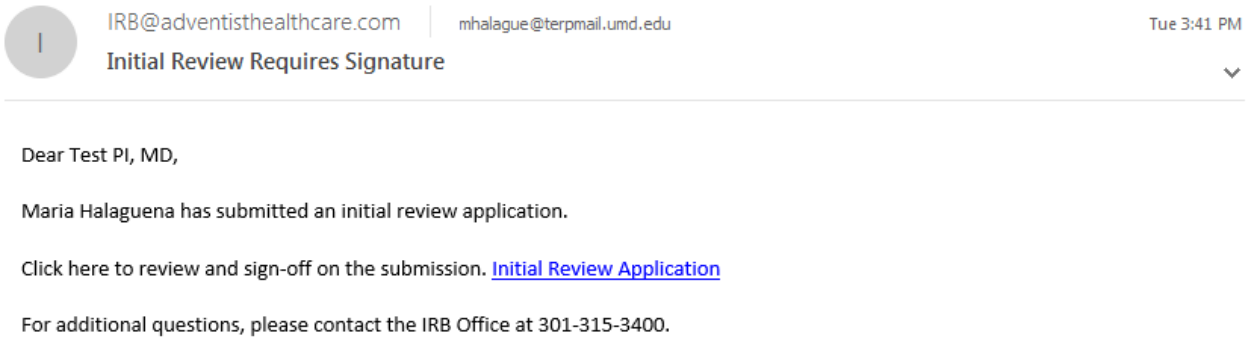
8. If the study involves an investigational device or drug, you need to submit the investigational device form or investigational drug form which will populate towards the end of the application.

Request for Waiver of Informed Consent and HIPAA Authorization

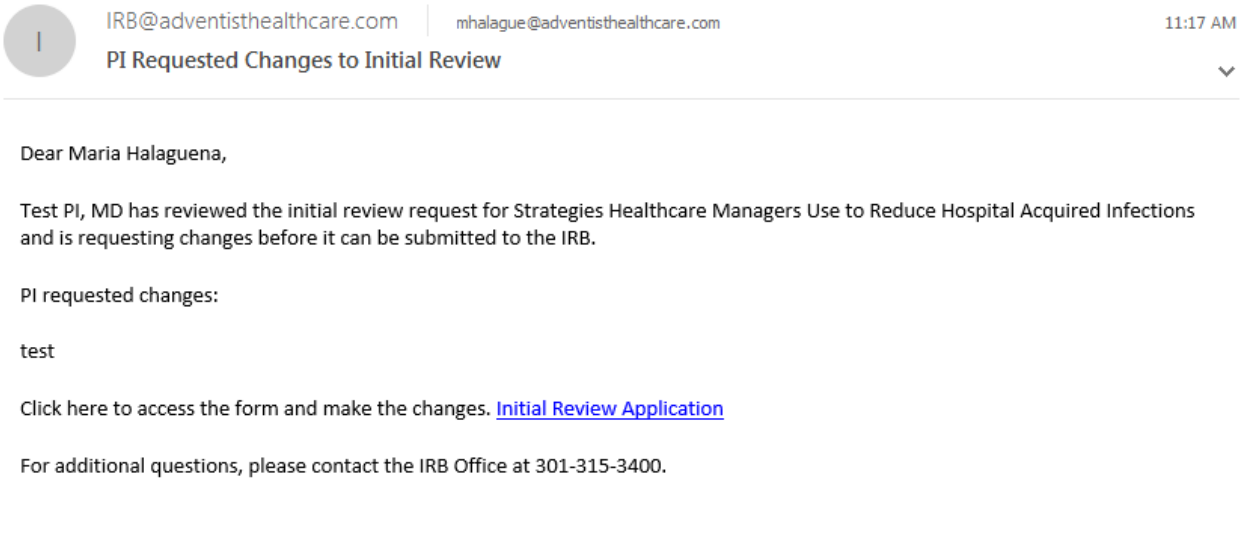
9. If you are requesting a waiver or alteration of informed consent or waiver of documentation of informed consent, you need to submit the request for waiver of informed consent and HIPAA Authorization which will populate towards the end of the application.

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.



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 11:17 AM

PI Requested Changes to Initial Review

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

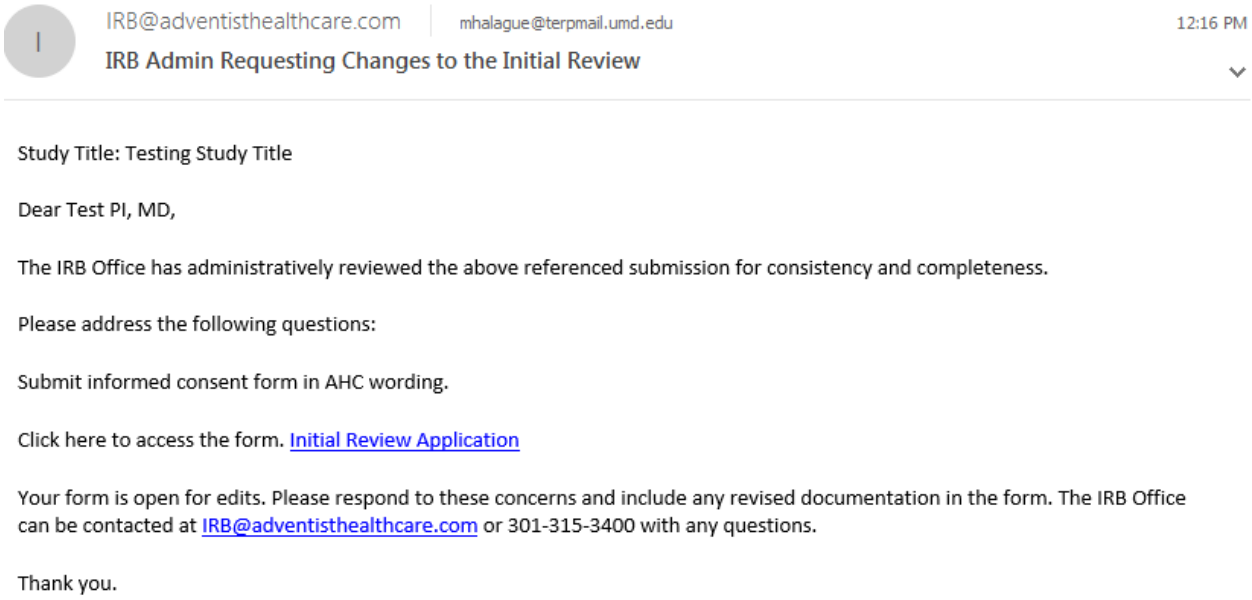
Click here to access the form and make the changes. Initial Review Application

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 12:16 PM

IRB Admin Requesting Changes to the Initial Review

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:

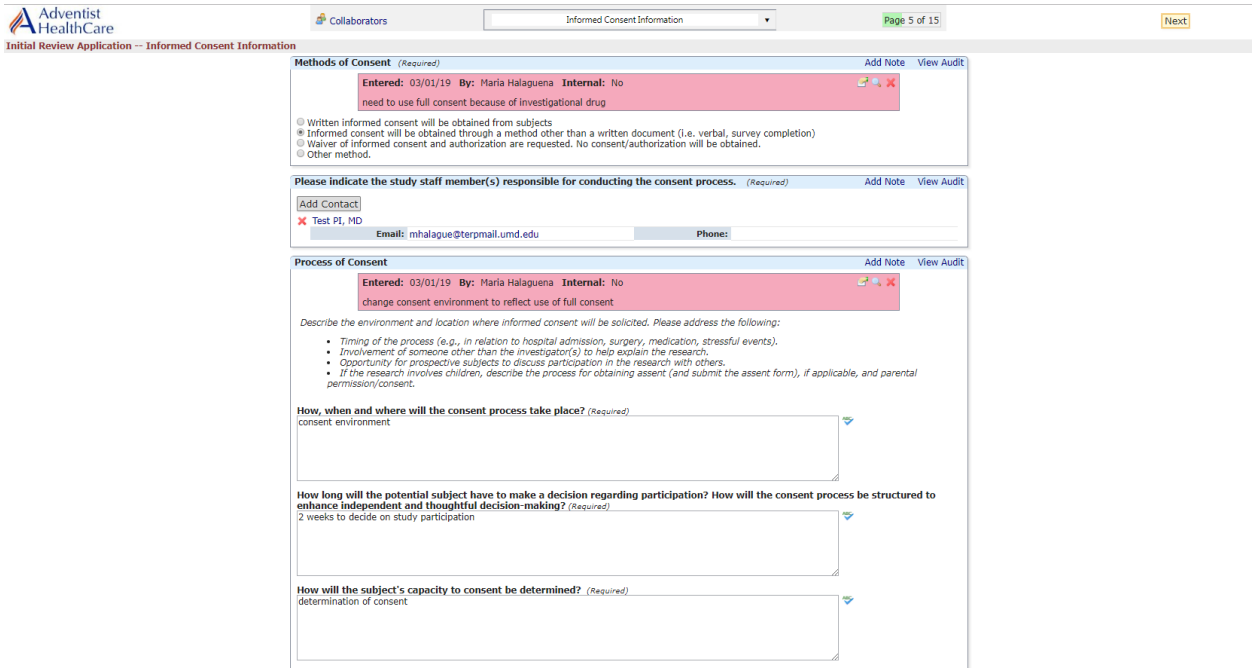
Submit informed consent form in AHC wording.

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.



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

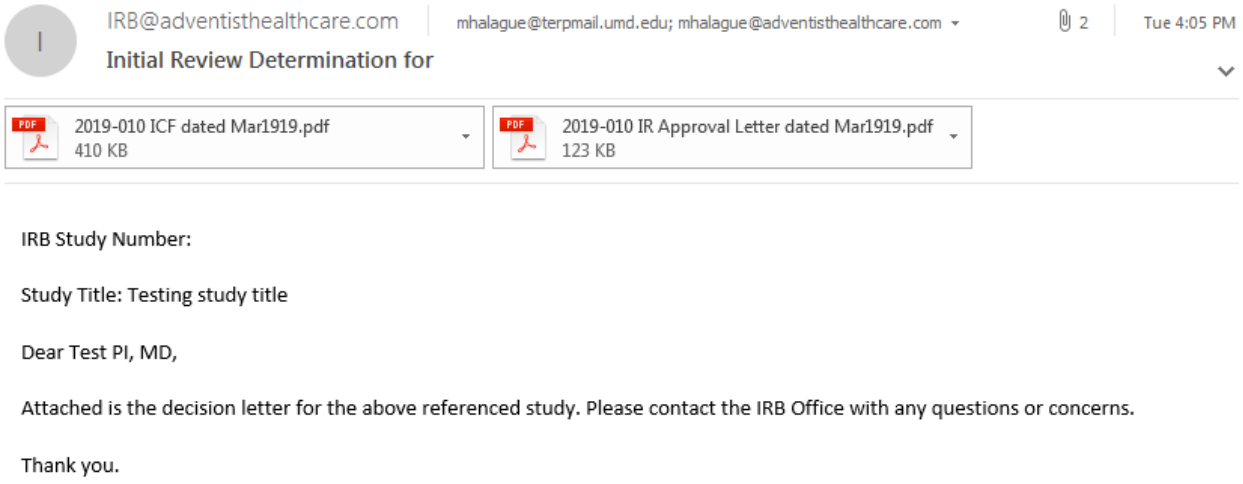
16. After you have made the changes requested by the IRB Office, the form will go to the PI for sign off.

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.

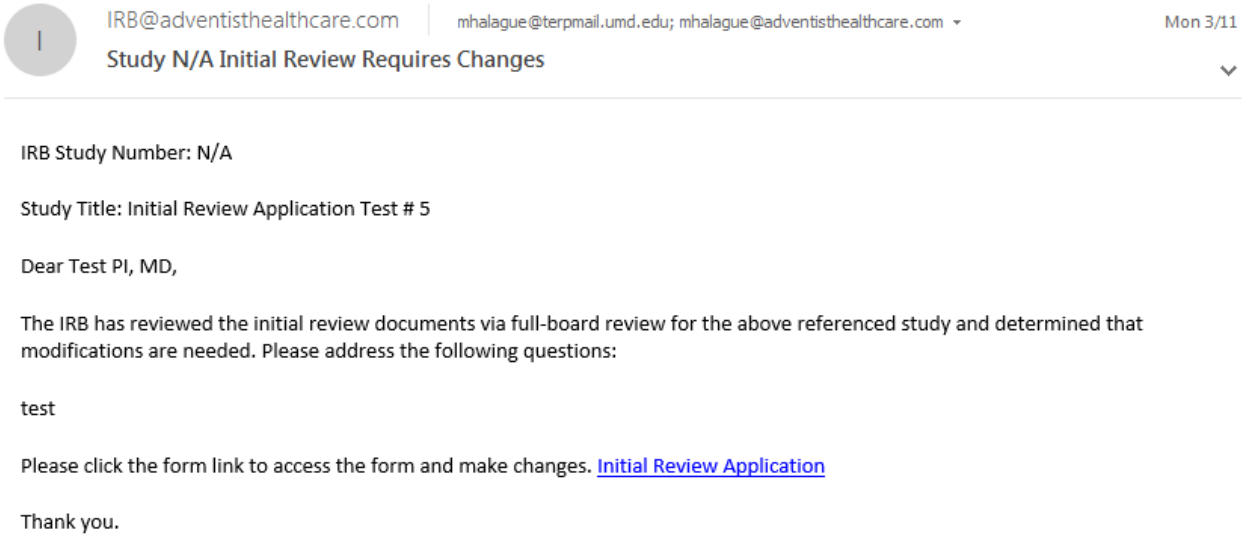
IRB Review:

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.

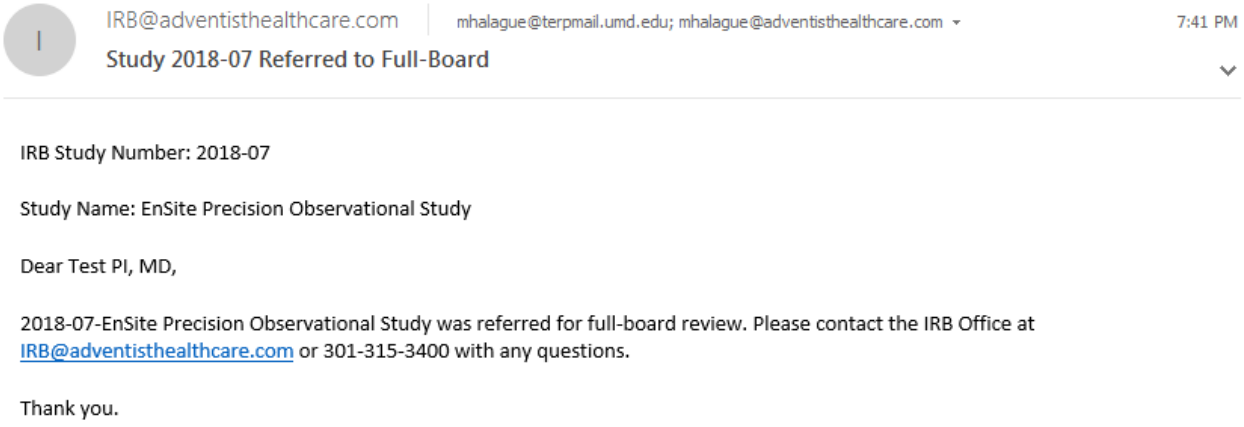


19. If the initial review application receives a determination other than a full-approval, you will receive an email, as shown below, prompting you to make revisions to your application. To make the changes, click on the blue form link. After you have made revisions, the form will go to the PI for sign-off and the IRB will conduct a second review.



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@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.

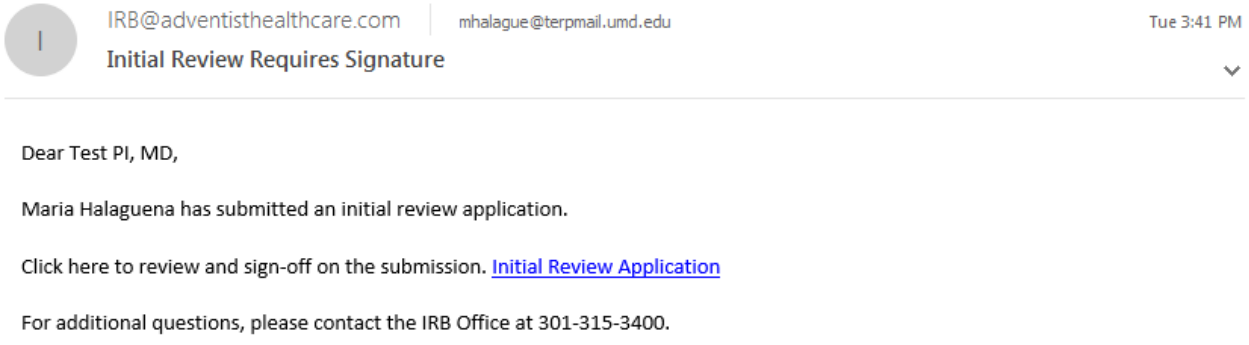
Thank you.

Full-Board

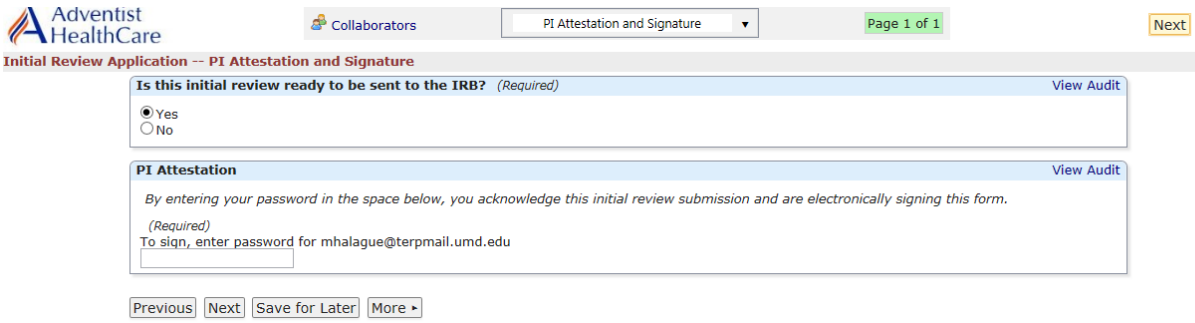
21. After the convened IRB meeting, the PI and creating user will receive an email containing the determination letter and informed consent form (if applicable) within two days of the IRB meeting.
22. If the IRB has determined that modifications are needed to the initial review application, the IRB Office 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.



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.



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