Reliance Agreement Application 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 reliance agreement 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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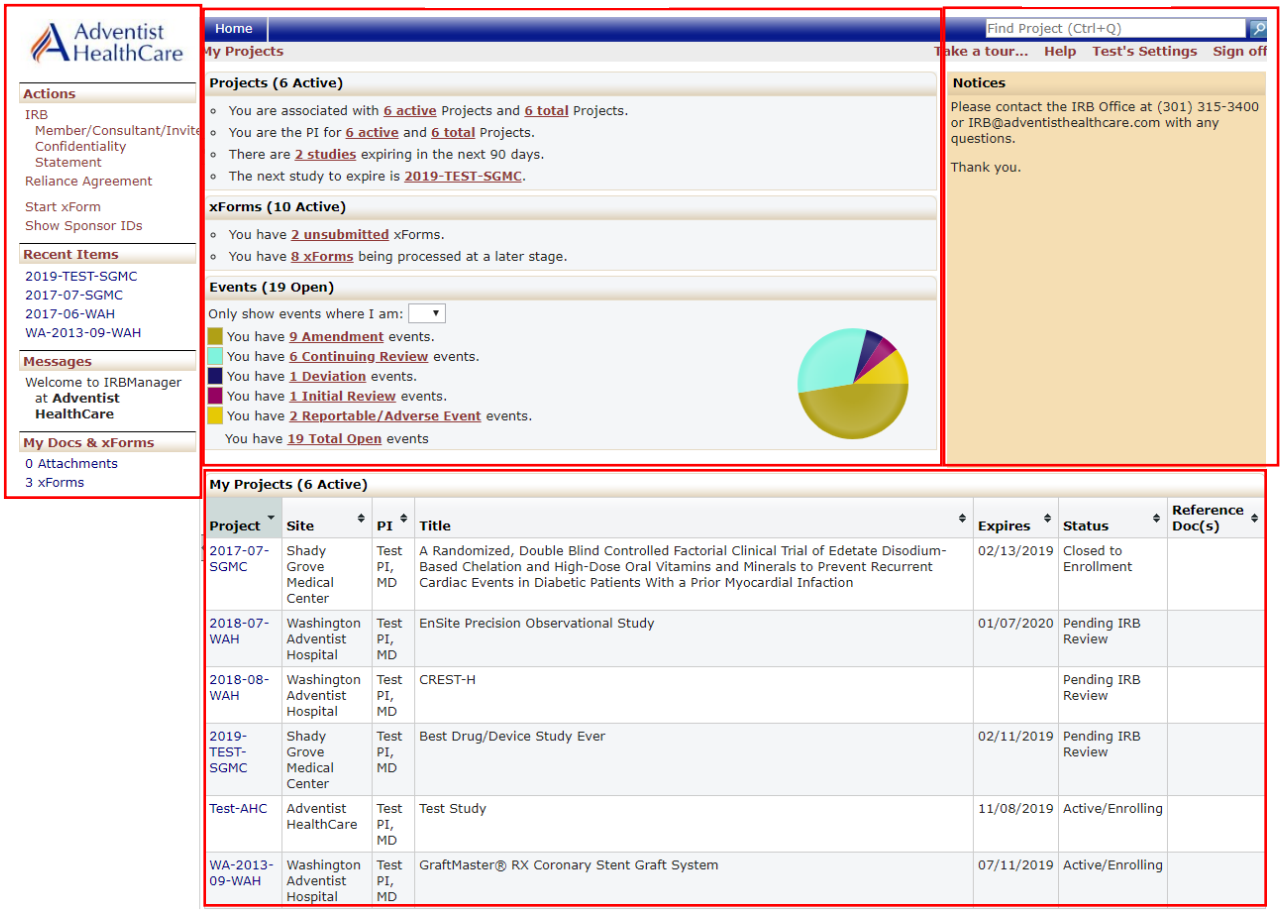
Dashboard Information:

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[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



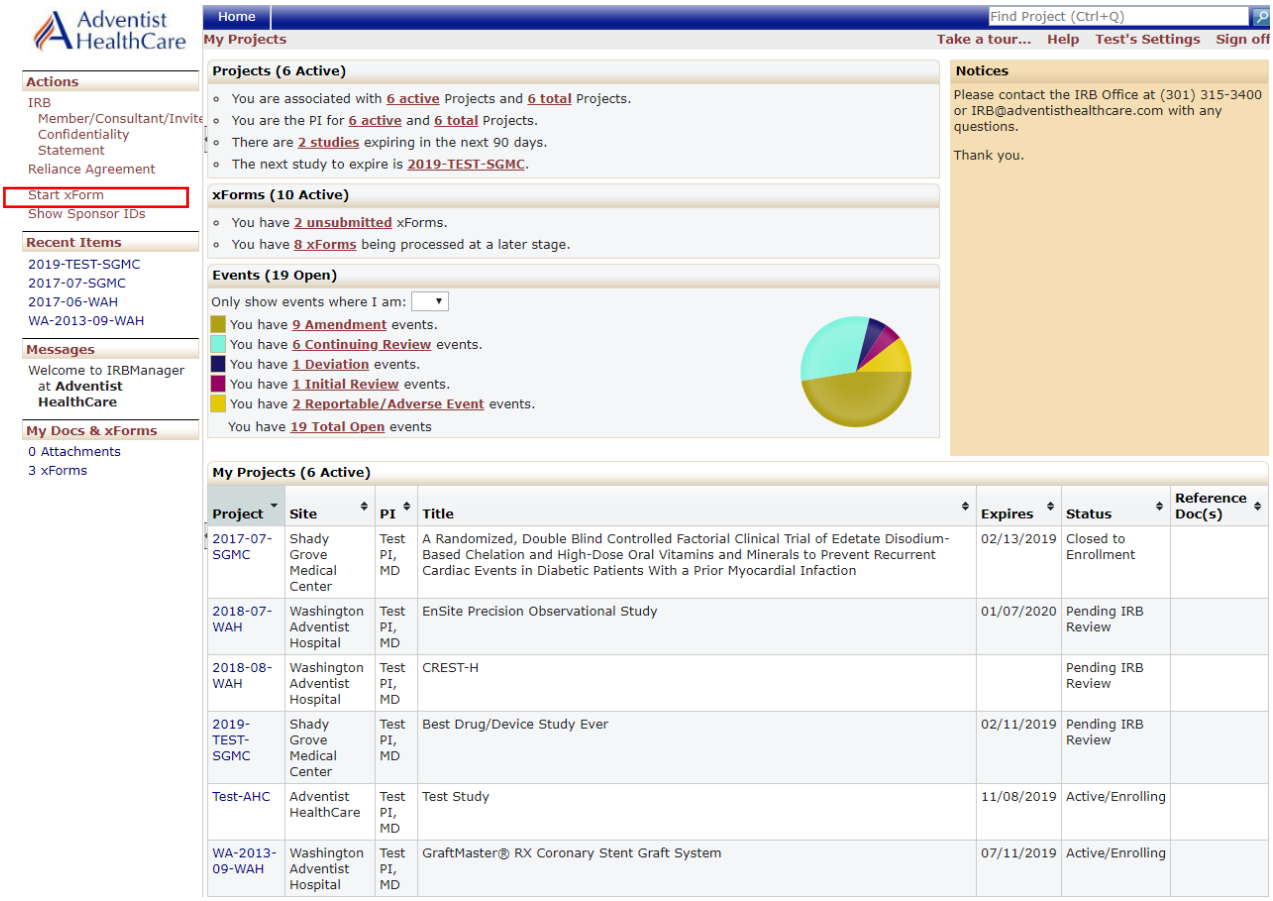
My Projects (6 Active)

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

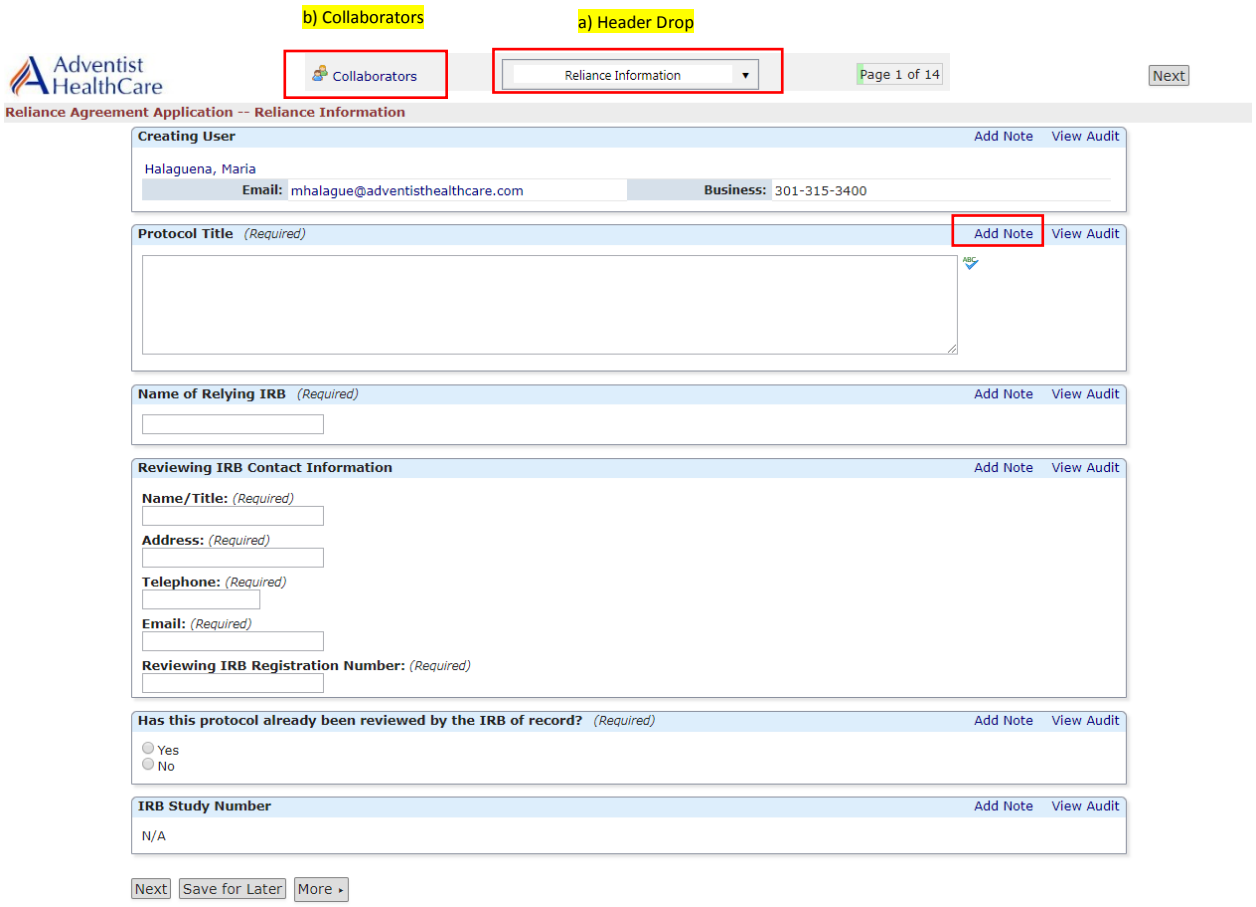
Starting a Reliance Agreement Application:

2. To start a reliance agreement application, click ‘Start xForm’ in the actions side bar of your dashboard. A list of available x-forms will populate. Choose the reliance agreement application.



Reliance Agreement Application Data Entry:

3. Once you select the reliance agreement application, you will be asked the protocol title, relying IRB information, 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.

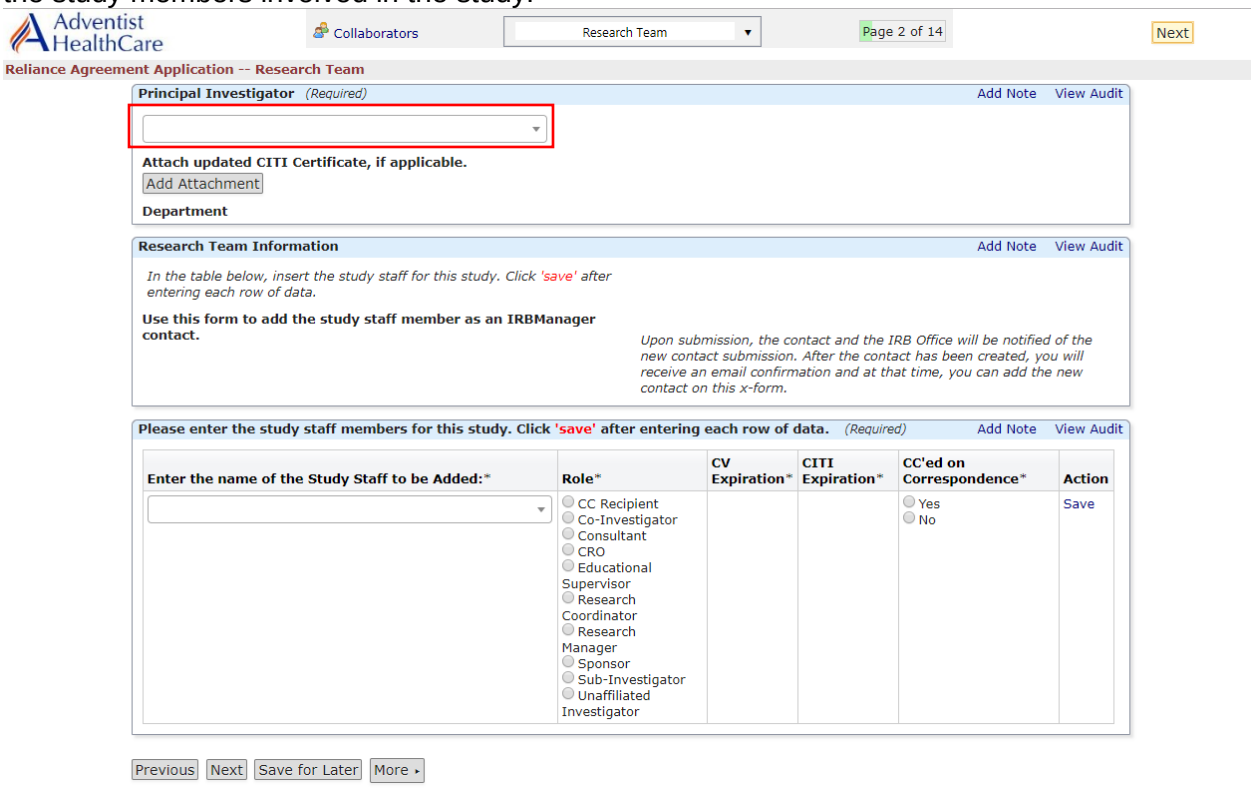


a) The header drop down allows you to skip from one page to the next.
b) The collaborators icon allows you to add others to view, edit, manage, and/or submit the form.
c) You may also add notes to communicate with other collaborators or create notes for yourself.
d) Click 'Next' to move to the next page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

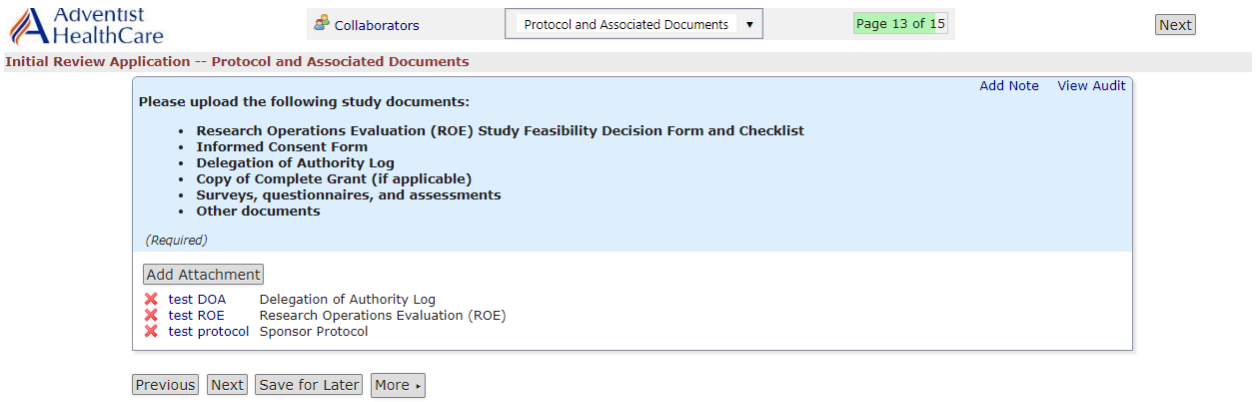
4. The next page will take you to the research team data entry page where you will enter all the study members involved in the study.



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.

Protocol and Associated Documents

5. The last question in the reliance agreement request is an attachment question in which you will submit all pertinent study documents (i.e. signed ROE approval, sponsor protocol, reliance authorization agreement, DOA, grant, surveys, etc.)



Investigational Device Form/Investigational Drug Form

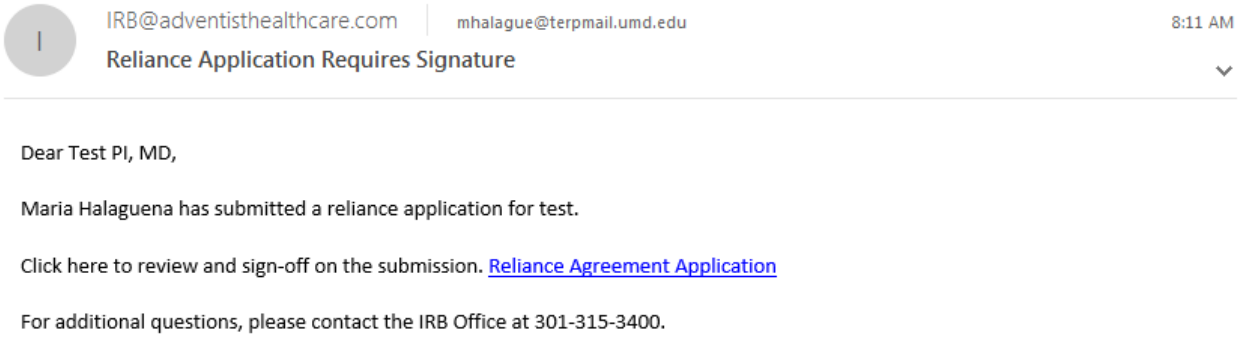
6. If the study involves an investigational device or drug, you need to submit the investigational device form or investigational drug form which will populate towards the end of the application.

Request for Waiver of Informed Consent and HIPAA Authorization

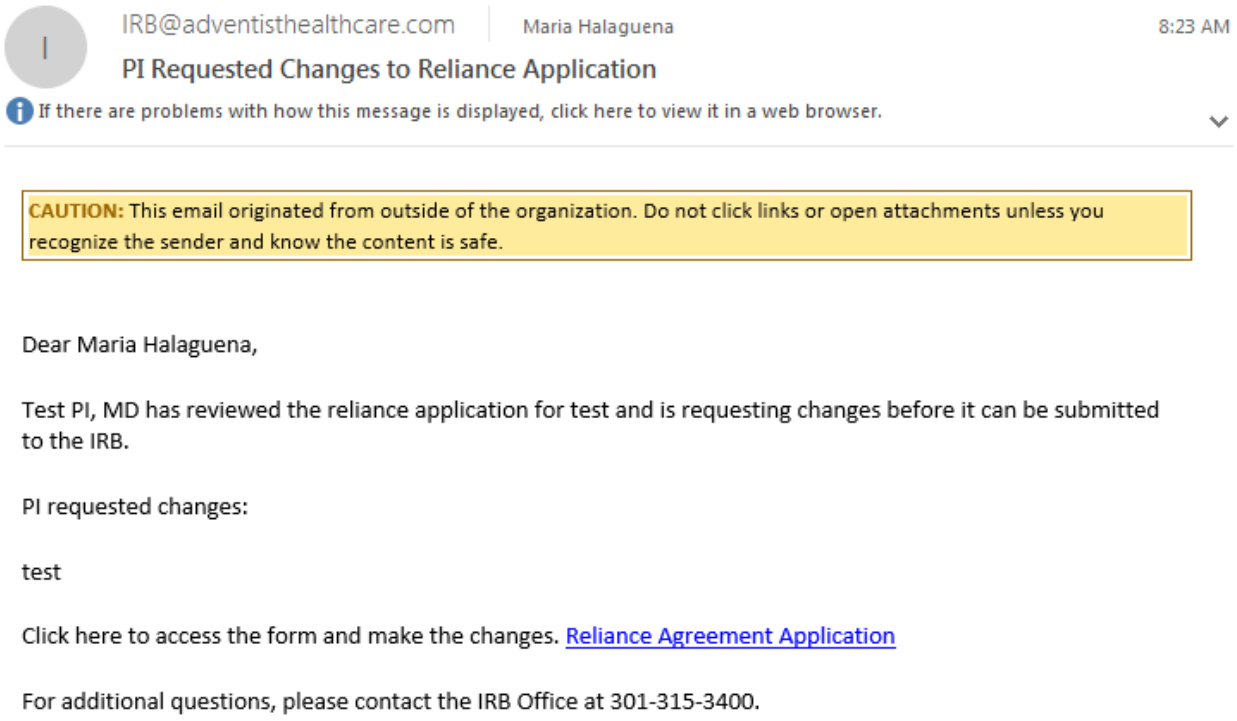
7. If you are requesting a waiver or alteration of informed consent or waiver of documentation of informed consent, you need to submit the request for waiver of informed consent and HIPAA Authorization which will populate towards the end of the application.

PI Sign-Off and Admin Pre-Review

8. 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.
9. The PI will receive the following email, as shown below, will include a link to the reliance agreement application.



10. 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 | Maria Halaguena 8:23 AM

PI Requested Changes to Reliance Application

If there are problems with how this message is displayed, click here to view it in a web browser.

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.

Dear Maria Halaguena,

Test PI, MD has reviewed the reliance application for test and is requesting changes before it can be submitted to the IRB.

PI requested changes:

test

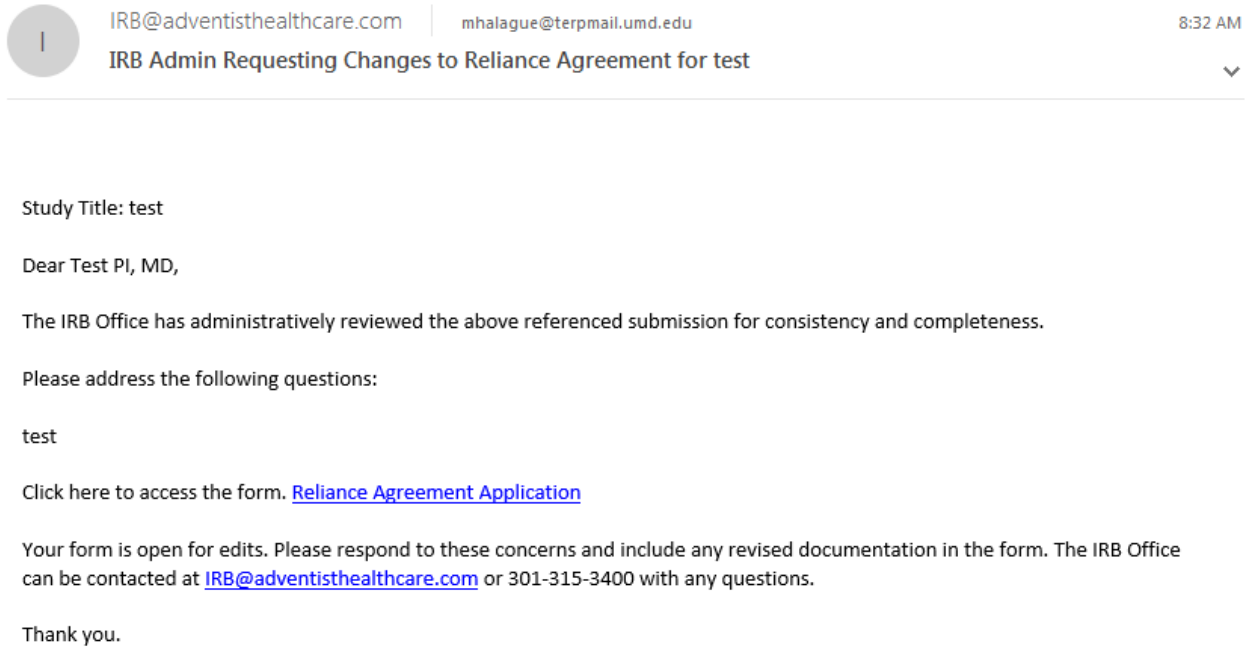
Click here to access the form and make the changes. Reliance Agreement Application

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

11. 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.

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



IRB@adventisthealthcare.com mhalague@terpmail.umd.edu 8:32 AM

IRB Admin Requesting Changes to Reliance Agreement for test

Study Title: test

Dear Test PI, MD,

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

Please address the following questions:

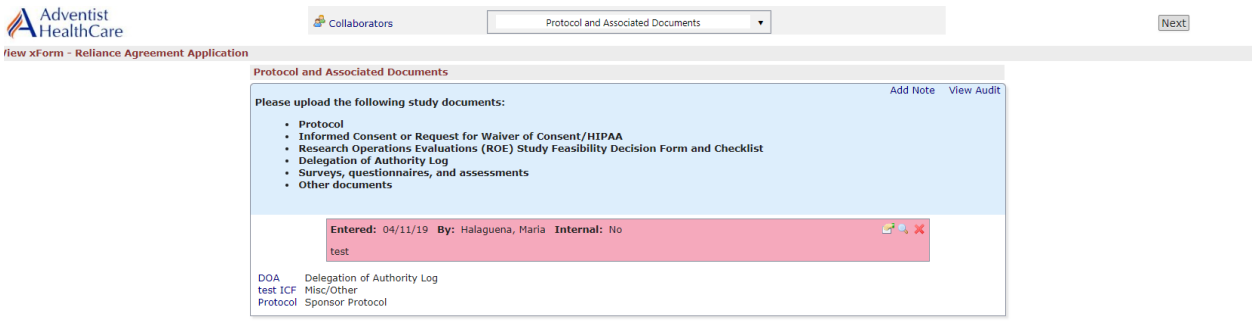
test

Click here to access the form. Reliance Agreement 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.

13. 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.

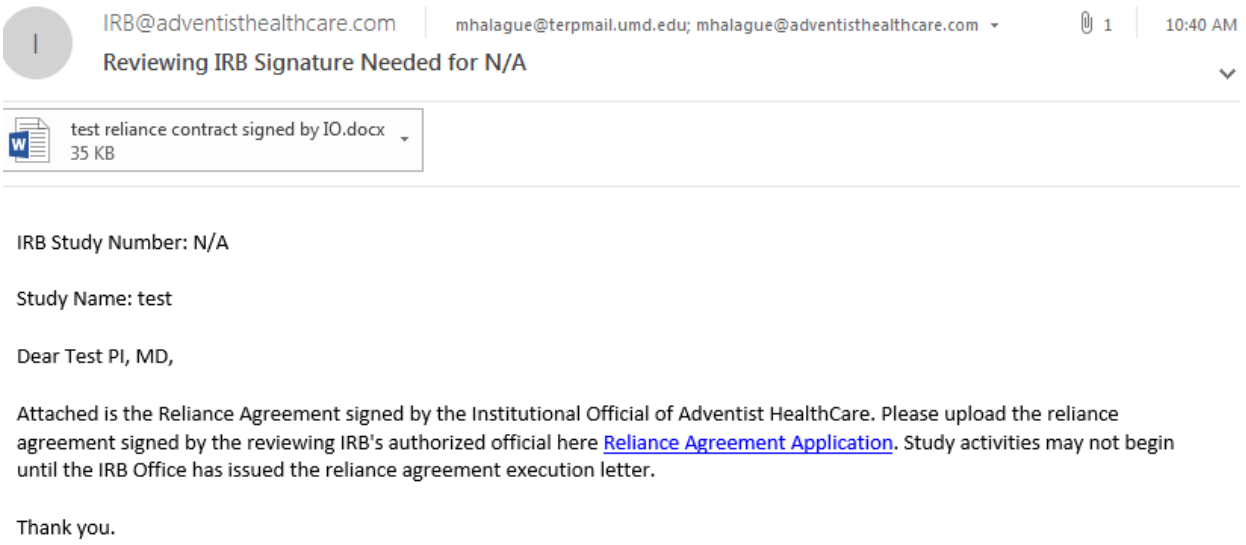
14. After you have made the changes requested by the IRB Office, the form will go to the PI for sign off.

Institutional Sign-Off:

15. If no additional changes are requested by the PI and IRB Office, the reliance authorization agreement is ready to be signed by the Institutional Official.

Please note: Institutional Official sign-off of the reliance authorization agreement will be processed outside IRBManager.

16. Once the IRB Office receives the signed agreement, it will be sent to the PI and research team in an email, as shown below. The PI will be required to submit the reliance authorization agreement signed by the reviewing IRB's authorization official.



I IRB@adventisthealthcare.com mhalague@terpmail.umd.edu; mhalague@adventisthealthcare.com 1 10:40 AM

Reviewing IRB Signature Needed for N/A

test reliance contract signed by IO.docx
35 KB

IRB Study Number: N/A

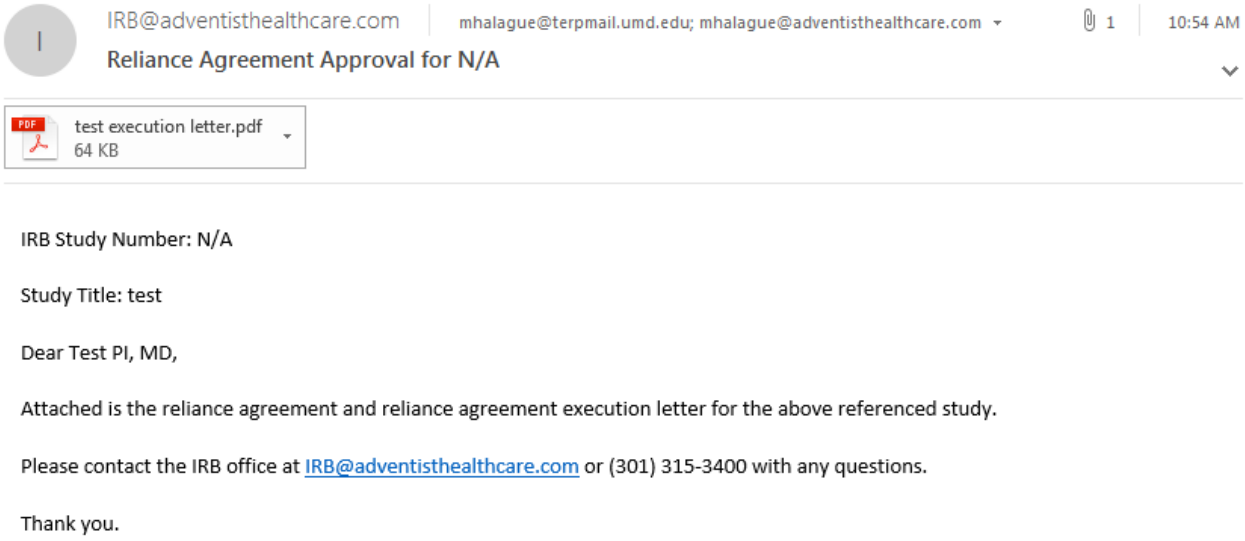
Study Name: test

Dear Test PI, MD,

Attached is the Reliance Agreement signed by the Institutional Official of Adventist HealthCare. Please upload the reliance agreement signed by the reviewing IRB's authorized official here Reliance Agreement Application. Study activities may not begin until the IRB Office has issued the reliance agreement execution letter.

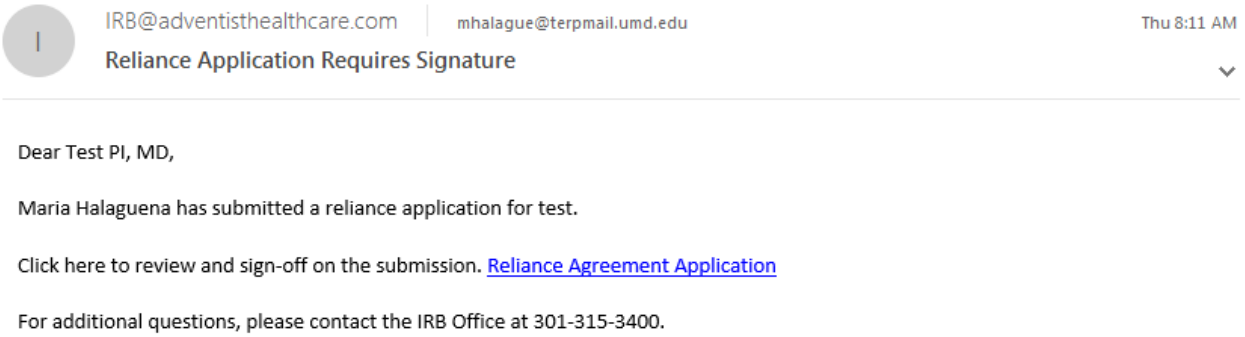
Thank you.

17. Click on the blue reliance agreement application link to submit the signed agreement by reviewing IRB's authorization official.
18. The execution letter will be sent to the PI and research team in an email, as shown below.



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 reliance agreement 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