



## **Initial Review Resource Guide for IRB Members**

**Purpose:** To provide guidance on how to review an initial review submission.

**Audience:** IRB Members

**Summary:** This resource guide focuses on the review of an initial review application. The guide covers the expedited and full-board review process, as well as the different outcomes that can result from them. Please consult the Table of Contents below to find the information you need.

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## Email Notifications:

### Expedited Review

1. After the IRB Office has finished administrative pre-review of a study submission, the study is ready to be reviewed. If the IRB Office has designated the study for **expedited review**, the reviewer will receive the following email, as shown below. The email contains important study information such as the study number and study title. The reviewer link will directly take you to the reviewer form.

IRB Study Number:

Study Title: Initial Review Application Test # 5

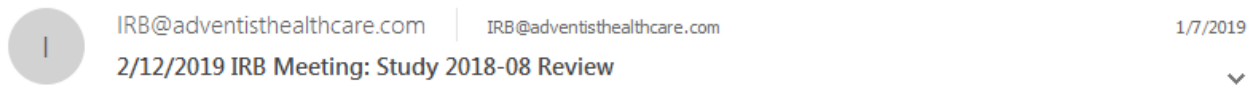
Dear Test IRB Manager, MD,

An initial review for the above referenced study is ready for expedited review. Direct link to the documentation can be accessed here: <https://adventisthealthcare.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=3ca3d81e-64e4-4d24-aa5b-19c1e9b0874a&ReasonGuid=720c2479-da0b-4b8a-bfd7-3582236aac67>.

Thank you.

### Full-Board Review

2. If the IRB Office has designated the study for **full-board review**, the reviewer will receive the following email, as shown below. The reviewer link will directly take you to the reviewer form.



Dear Test IRB Manager, MD,

Will you please present the 2018-08-CREST-H to the IRB on Tuesday, 2/12/2019? Use this link to access the form <https://adventisthealthcare.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=77d6a7ce-8a52-406b-a747-e4d707977b14&ReasonGuid=d39e427b-f4eb-488d-9384-7abf8e7e0a98>.

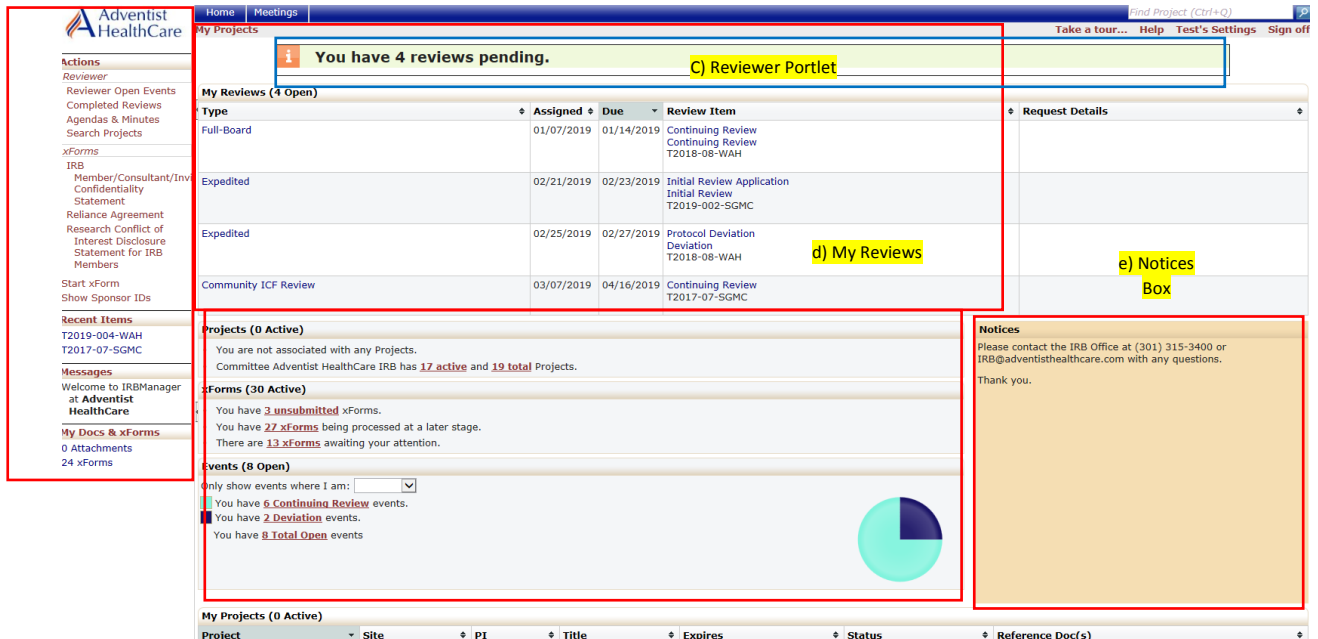
Thank you.

## Dashboard Information:

1. When you log into IRBManager, your dashboard will appear. The information on your dashboard can be subdivided into six 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) Reviewer Portlet: Notifications on pending reviews can be found here.
  - d) My Reviews: The table will contain all your review items as well as more information on the item such as the type of review, assigned date, and due date.
  - e) Notices Box: Important IRB information can be found here.
  - f) 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



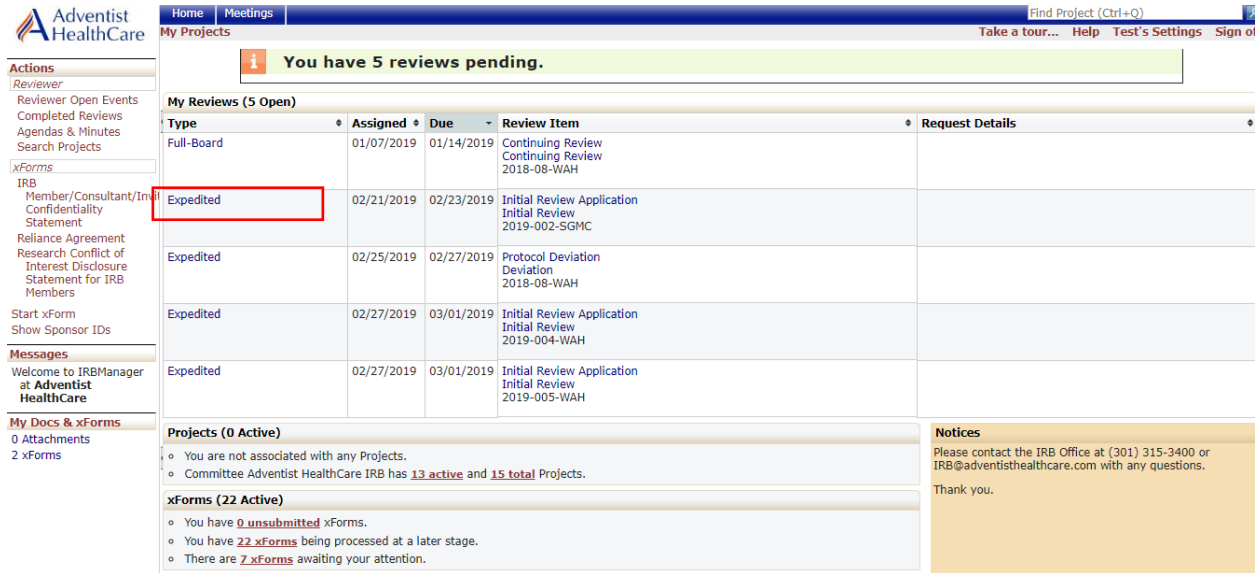
The screenshot shows the IRBManager dashboard interface. The left sidebar (a) contains navigation links for Actions, Reviewer, xForms, and Recent Items. The main content area is divided into several sections: a notification banner (c) for pending reviews, a table of reviews (d), a projects summary (b), and a notices box (e). A pie chart is visible in the lower right of the main area. At the bottom, there is a table header for active projects (f).

Type	Assigned	Due	Review Item	Request Details
Full-Board	01/07/2019	01/14/2019	Continuing Review T2018-08-WAH	
Expedited	02/21/2019	02/23/2019	Initial Review Application T2019-002-SGMC	
Expedited	02/25/2019	02/27/2019	Protocol Deviation T2018-08-WAH	
Community ICF Review	03/07/2019	04/16/2019	Continuing Review T2017-07-SGMC	

f) My Projects Table

### Completing a Review:

- To complete a review, click on the review link on the 'My Reviews' table of your dashboard. The review link will direct you to the reviewer form.



**My Reviews (5 Open)**

Type	Assigned	Due	Review Item	Request Details
Full-Board	01/07/2019	01/14/2019	Continuing Review Continuing Review 2018-08-WAH	
<b>Expedited</b>	02/21/2019	02/23/2019	Initial Review Application Initial Review 2019-002-SGMC	
Expedited	02/25/2019	02/27/2019	Protocol Deviation Deviation 2018-08-WAH	
Expedited	02/27/2019	03/01/2019	Initial Review Application Initial Review 2019-004-WAH	
Expedited	02/27/2019	03/01/2019	Initial Review Application Initial Review 2019-005-WAH	

**Projects (0 Active)**

- You are not associated with any Projects.
- Committee Adventist HealthCare IRB has **13 active** and **15 total** Projects.

**xForms (22 Active)**

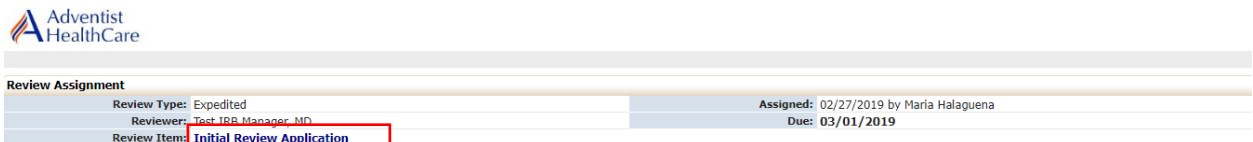
- You have **0 unsubmitted** xForms.
- You have **22 xForms** being processed at a later stage.
- There are **7 xForms** awaiting your attention.

**Notices**

Please contact the IRB Office at (301) 315-3400 or IRB@adventisthealthcare.com with any questions.  
Thank you.

### Expedited and Full-Board Review

- You will use the 'Initial Review or Continuing Review Reviewer Form' for both expedited and full-board reviews. The Review Assignment Header contains more information on the review type, review item, assigned date, and due date. If you would like to see the initial review application submitted by the researcher, click the blue form link and you will be directed to the form.



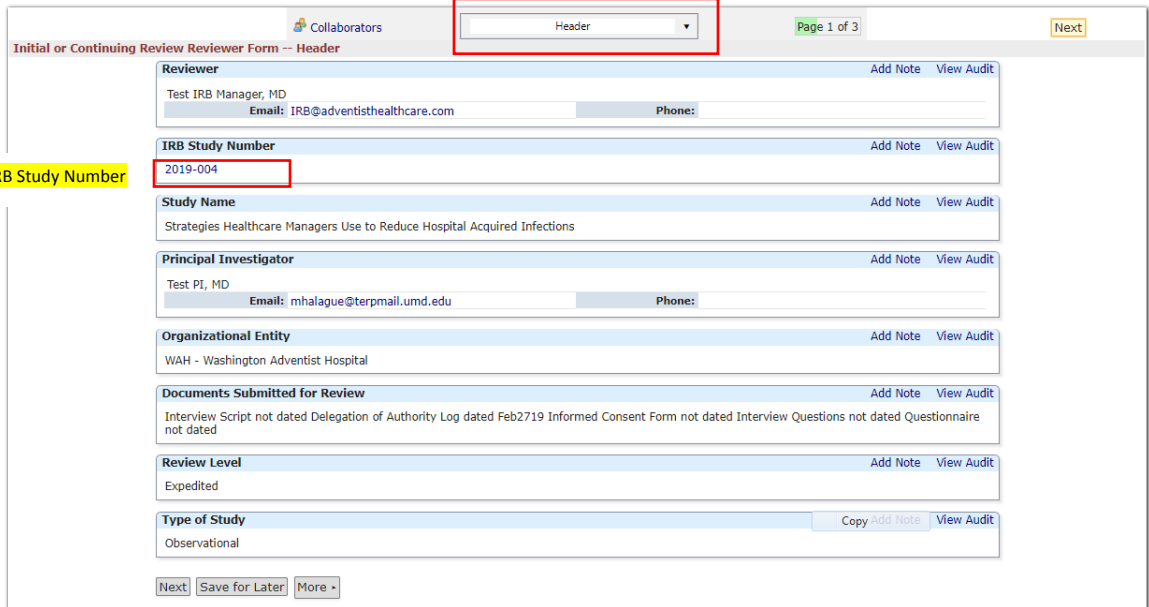
**Review Assignment**

Review Type:	Expedited	Assigned:	02/27/2019 by Maria Halaguena
Reviewer:	Test IRB Manager, MD	Due:	03/01/2019
Review Items:	<b>Initial Review Application</b>		

- The Study Header page will also populate below and it contains more information on the study and submission documents.

a) Header  
Drop Down

b) IRB Study Number



Initial or Continuing Review Reviewer Form -- Header

Collaborators Header Page 1 of 3 Next

**Reviewer** Add Note View Audit  
Test IRB Manager, MD  
Email: IRB@adventisthealthcare.com Phone:

**IRB Study Number** Add Note View Audit  
2019-004

**Study Name** Add Note View Audit  
Strategies Healthcare Managers Use to Reduce Hospital Acquired Infections

**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

**Documents Submitted for Review** Add Note View Audit  
Interview Script not dated Delegation of Authority Log dated Feb2719 Informed Consent Form not dated Interview Questions not dated Questionnaire not dated

**Review Level** Add Note View Audit  
Expedited

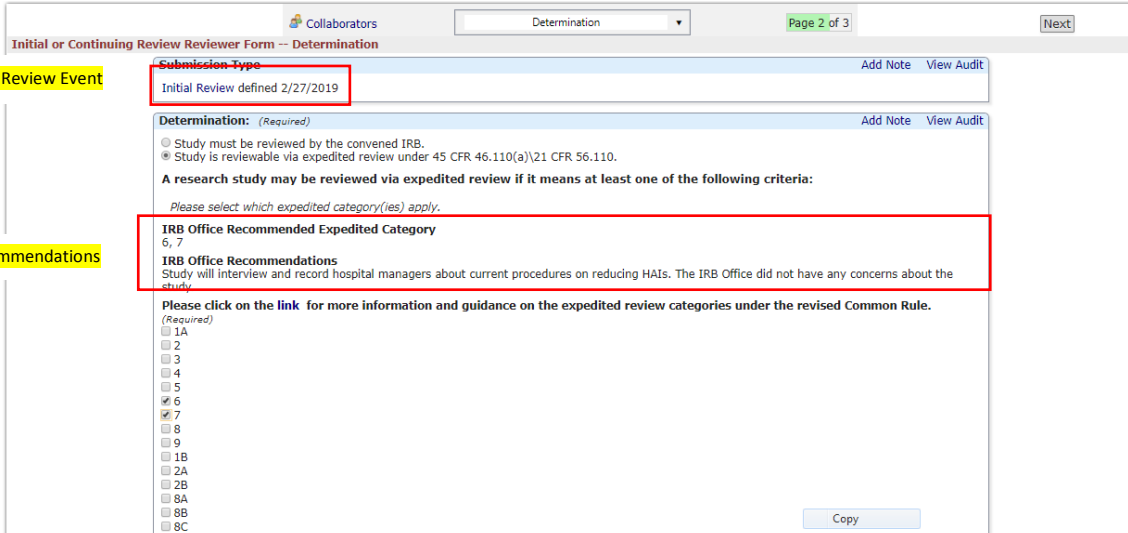
**Type of Study** Copy Add Note View Audit  
Observational

Next Save for Later More -

- The header drop down allows you to skip from one page to the next.
- If you want more information on the study, click the blue IRB study number link.

c) Initial Review Event

IRB Office Recommendations



Initial or Continuing Review Reviewer Form -- Determination

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**Submission Type** Add Note View Audit  
Initial Review defined 2/27/2019

**Determination: (Required)** Add Note View Audit  
 Study must be reviewed by the convened IRB.  
 Study is reviewable via expedited review under 45 CFR 46.110(a)\21 CFR 56.110.  
**A research study may be reviewed via expedited review if it means at least one of the following criteria:**  
 Please select which expedited category(ies) apply.

**IRB Office Recommended Expedited Category**  
6, 7

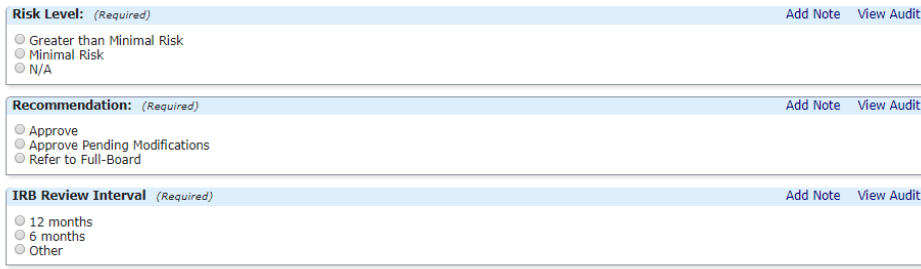
**IRB Office Recommendations**  
Study will interview and record hospital managers about current procedures on reducing HAIs. The IRB Office did not have any concerns about the study.

Please click on the link for more information and guidance on the expedited review categories under the revised Common Rule.  
(Required)

1A  
 2  
 3  
 4  
 5  
 6  
 7  
 8  
 9  
 1B  
 2A  
 2B  
 8A  
 8B  
 8C

Copy

- c) The initial review event link will direct you to the study event where you can see more information such as the initial review application.
- d) Indicate the study determination (expedited or refer to full-board) for the initial review application.
- e) If you determined that the study can be reviewed via expedited review, choose the appropriate expedited category(ies). A link to expedited review categories is available for further guidance.
- f) IRB Office Recommendations are also available for your convenience and designed to help facilitate reviews.



The screenshot shows a web form with three sections, each with a title, a '(Required)' label, and 'Add Note' and 'View Audit' links.

- Risk Level: (Required)**
  - Greater than Minimal Risk
  - Minimal Risk
  - N/A
- Recommendation: (Required)**
  - Approve
  - Approve Pending Modifications
  - Refer to Full-Board
- IRB Review Interval (Required)**
  - 12 months
  - 6 months
  - Other

At the bottom of the form, there are navigation buttons: 'Previous', 'Next', 'Save for Later', 'More >', and a 'Copy' button.

- g) Determine the study's risk level.
- h) Make recommendations on the approval status of the submission. If the study has been designated for full-board review by the IRB Office, the recommendation you make on the reviewer form is **not the final decision**.
- i) Choose the review interval for the study.
- j) The next page will prompt you to answer questions about the study's risks, benefits, protections for subjects' privacy and confidentiality, and informed consent or use of a waiver of informed consent. In this section, you can also make required or recommended recommendations. Your recommendations will go to the IRB Office and then ultimately to the research team.

**Please note:** You will be asked to provide an explanation on certain questions based on your answer. Furthermore, questions marked as required cannot be left unanswered. You will not be allowed to submit the form until you answer the required questions.

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Initial or Continuing Review Reviewer Form -- Study Information

**Risks to subjects are minimized. [45 CFR 46.111(a)(1)/21 CFR 56.111(a)(1)]** Add Note View Audit

- Procedures are consistent with sound research design and do not unnecessarily expose subjects to risk
- Procedures are already being performed on the subjects for diagnostic or treatment purposes, when appropriate

(Required)

Yes  
 No

**The risks are reasonable in relation to anticipated benefits to subjects and the importance of the knowledge that may result. [45 CFR 46.111(a)(2)/21 CFR 56.111(a)(2)]** Add Note View Audit

(Required)

Yes  
 No

**The selection of subjects is equitable in relation to the research purposes and setting. [45 CFR 46.111(a)(3)/21 CFR 56.111(a)(3)]** Add Note View Audit

(Required)

Yes  
 No

**Informed consent will be sought from each prospective subject or their LAR. [21 CFR 56.111(a)(4)/45 CFR 46.111(a)(4)]** Add Note View Audit

(Required)

Yes  
 No  
 N/A

- k) After completing the reviewer form, you will sign-off on the reviewer form by entering your IRBManager password.

**Reviewer Attestation** Add Note View Audit

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

(Required)

To sign, enter password for IRB@adventisthealthcare.com

- l) The completed reviewer forms can be accessed in the actions side bar by clicking on 'completed reviews.' A list of your completed forms will populate. Choose the reviewer form you need.

### **Full-Board Meetings: Community Member ICF Review Form**

5. The 'Community Member ICF Review Form' is where you can review and make edits to the informed consent form in preparation for the IRB meeting. To access the form, you will go to the meetings tab and click on the pages icon of the meeting date.

	12/02/2019	Adventist HealthCare IRB	Shady Grove Medical Center	01/25/2019	Not Finalized	Not yet created
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6. You will see the meeting's agenda and all the review items. To review a study's informed consent form, click on the review link next to the event link. The review link will take you the 'Community Member ICF Review Form' where you can input all your comments and attach any relevant study documents.


Project	Title	PI	Instance	Reviewer
T2017-07-SGMC (Event) <a href="#">(Review)</a>	A Randomized, Double Blind Controlled Factorial Clinical Trial of Edetate Disodium-Based Chelation a <a href="#">(hover for more...)</a>	Test PI, MD		Test IRB Manager, MD


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**Community Member ICF Review Form -- Review Data Entry**

**Reviewer** [Add Note](#) [View Audit](#)  
Test IRB Manager, MD  
Email: IRB@adventisthealthcare.com Phone:

**Review Outcome (Required)** [Add Note](#) [View Audit](#)

**Enter any comments in the space below.** [Add Note](#) [View Audit](#)  
 

**Attach any relevant documents.** [Add Note](#) [View Audit](#)  
  
 ICF with comments Consent Form

- 7.
- m) Decide on a review outcome (i.e. requires changes vs no changes necessary).
  - n) If you have any comments, enter them in the text box.
  - o) Attach any relevant documents.



## Review Outcomes:

### Full-Approval

8. After the study has been granted full-approval, no further action is required and the reviewer form moves back to the IRB Office for processing.

### Conditional Approval/Deferral/Disapproval

9. If a study is conditionally approved or does not receive full-approval, the comments and suggestions you indicated on the reviewer form will be sent to the IRB Office for processing and ultimately to the research team.
10. After study changes have been made, you will receive an email notification to conduct a second review of the study. Click on the blue form link and it will take you back to the reviewer form.

**Review Assignment**

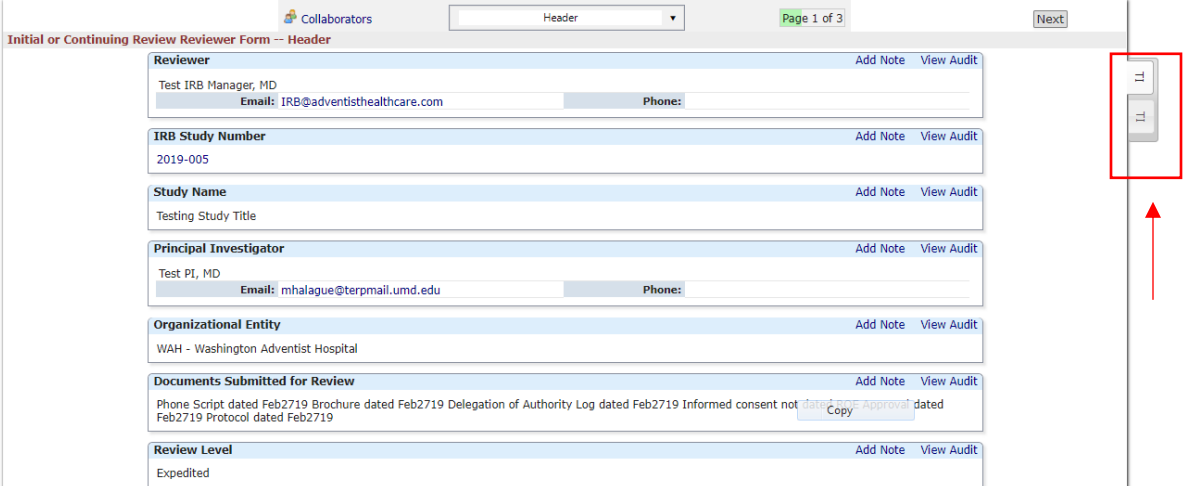
<b>Review Type:</b> Expedited	<b>Assigned:</b> 02/28/2019 by Maria Halaquena
<b>Reviewer:</b> Test IRB Manager, MD	<b>Due:</b> 03/02/2019
<b>Review Item:</b> Initial Review Application	

**Review xForm**

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**Initial or Continuing Review Reviewer Form -- Header**

<b>Reviewer</b> Add Note View Audit
Test IRB Manager, MD Email: IRB@adventisthealthcare.com Phone:
<b>IRB Study Number</b> Add Note View Audit
2019-005
<b>Study Name</b> Add Note View Audit
Testing Study Title
<b>Principal Investigator</b> Add Note View Audit
Test PI, MD Email: mhalague@terpmail.umd.edu Phone:
<b>Organizational Entity</b> Add Note View Audit
WAH - Washington Adventist Hospital
<b>Documents Submitted for Review</b> Add Note View Audit
Phone Script dated Feb2719 Brochure dated Feb2719 Delegation of Authority Log dated Feb2719 Informed consent not dated Copy Approval dated Feb2719 Protocol dated Feb2719
<b>Review Level</b> Add Note View Audit
Expedited



- p) You will have access to the initial reviewer form you answered earlier. The tabs to the side of the reviewer form show you the current and previous reviewer form, respectively.
- q) After reviewing the changes to the initial review application, complete the reviewer form and sign-off.

**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