



## **Non-Human Subjects Research (NHSR) Resource Guide for IRB Members**

**Purpose:** To provide guidance on how to review a NHSR submission.

**Audience:** IRB Members

**Summary:** This resource guide focuses on the review of a NHSR application. The guide covers the 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.

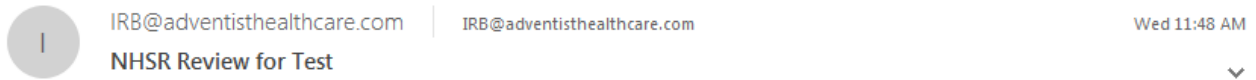
### **Table of Contents:**

- **Email Notifications**
  - **NHSR Review**
- **Dashboard Information**
- **Completing a Review**
  - **NHSR Review**
- **Review Outcomes**
  - **NHSR**
  - **Further IRB Review**
- **Terminology for IRBManager**

**Email Notifications:**

**NHSR Review**

1. After the IRB Office has finished administrative pre-review of a study submission, the study is ready to be reviewed. 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: Test

Study Title: test

Dear IRB Office [IRB@adventisthealthcare.com](mailto:IRB@adventisthealthcare.com),

An NHSR application for the above referenced study is ready for review. Direct link to the documentation can be accessed here: <https://adventisthealthcare.my.irbmanager.com/Admin/ReviewAssignment.aspx?TargetGuid=6e9d1969-4148-4829-9c12-306cf14733ee&ReasonGuid=45944587-eef2-4d0c-acdb-383d0c330538>.

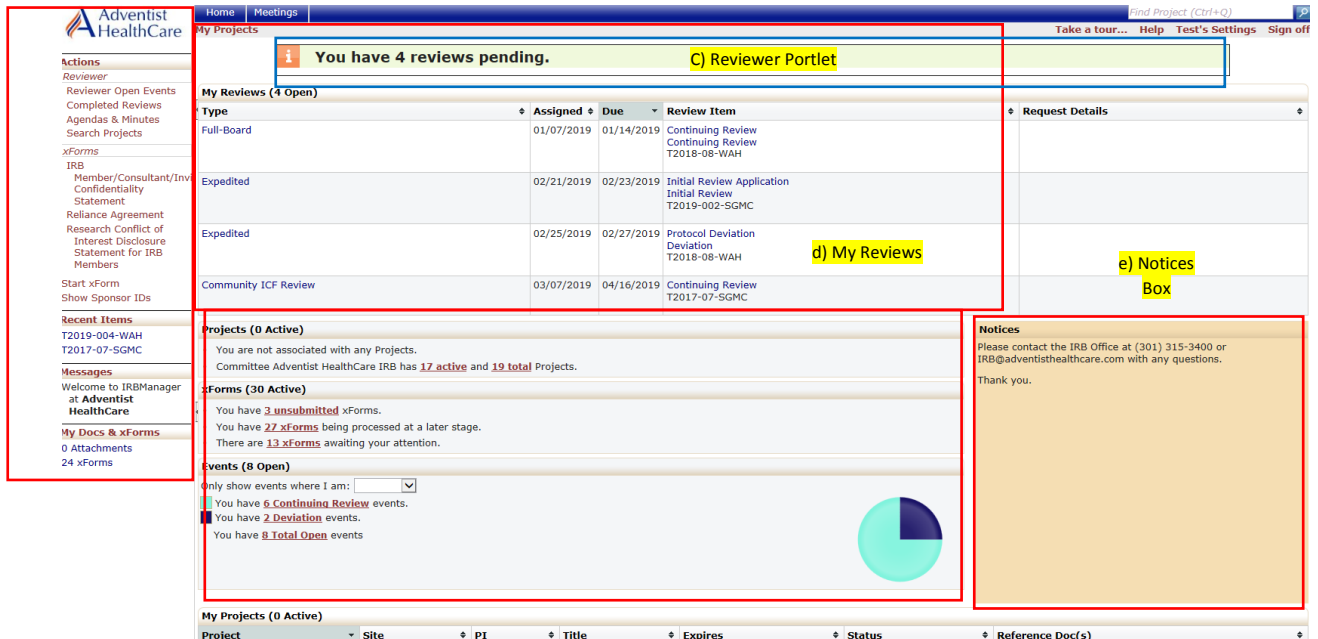
Thank you.

## 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



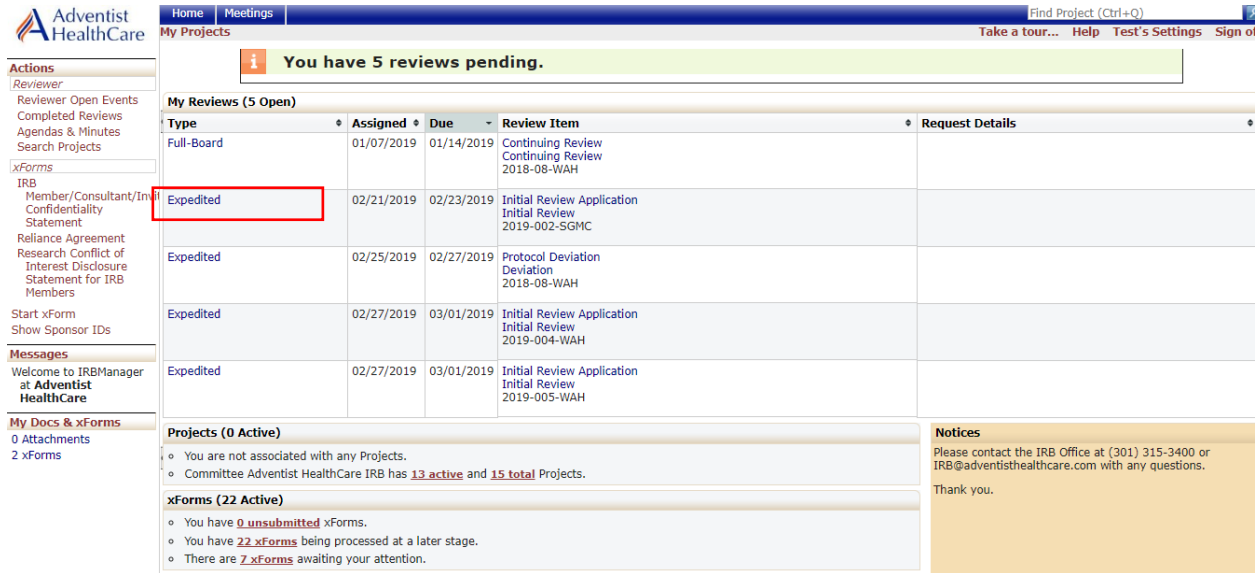
The screenshot shows the IRBManager dashboard interface. The left sidebar (a) contains navigation links for Actions, Reviewer, Open Events, Completed Reviews, Agendas & Minutes, Search Projects, xForms, IRB, Member/Consultant/Inv, Confidentiality Statement, Reliance Agreement, Research Conflict of Interest Disclosure Statement for IRB Members, Start xForm, Show Sponsor IDs, Recent Items, Messages, Welcome to IRBManager at Adventist HealthCare, My Docs & xForms, Attachments, and xForms. The main content area (b) features a 'My Projects' section with a notification 'You have 4 reviews pending.' and a 'C) Reviewer Portlet' box. Below this is a 'My Reviews (4 Open)' table with columns for Type, Assigned, Due, Review Item, and Request Details. The table contains four rows of review items. A 'd) My Reviews' label points to the table. To the right is an 'e) Notices Box' with contact information for the IRB Office. At the bottom, there is a 'My Projects (0 Active)' table (f) with columns for Project, Site, PI, Title, Expires, Status, and Reference Doc(s). A pie chart is visible in the lower right of the dashboard area.

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

### NHSR Review

- You will use the 'Non-Human Subjects Reviewer Form' for 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 NHSR application submitted by the researcher, click the blue form link and you will be directed to the form.

Review Assignment	
Review Type:	NHSR/Not Research
Reviewer:	IRB@adventisthealthcare.com, IRB Office
Assigned:	04/10/2019 by Halaguena, Maria
Due:	04/12/2019
Review Item:	<b>Non-Human Subjects Research Application</b>

4. 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

View xForm - Non-Human Subjects Research Reviewer Form

Hide Help Text

**NHSR/Not Research Reviewer Form**

Reviewer Form  
- Submitted 4/10/2019 11:56:36 AM ET by IRB@adventisthealthcare.com, IRB Office

**Header**

**Reviewer** [View Audit](#)

IRB@adventisthealthcare.com, IRB Office  
 Email: IRB@adventisthealthcare.com Phone:

**IRB Study Number** [View Audit](#)

IRB

**Study Name** [View Audit](#)

test

**Principal Investigator** [View Audit](#)

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

**Organizational Entity** [View Audit](#)

WAH - Washington Adventist Hospital

**Documents Submitted for Review** [View Audit](#)

test protocol dated April 10, 2019 test proposal dated April 10, 2019 test document dated April 10, 2019

**Review Level** [View Audit](#)

NHSR/Not Research

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

c) NHSR Event Link

<b>Determination</b>	
<b>Submission Type</b>	<a href="#">View Audit</a>
NHSR defined 4/10/2019	
<b>Determination:</b>	
Study is determined to not be human subjects research.	
A research project will be considered human subjects research if it meets the following definition:	
1. <b>Human subject</b> means a living individual about whom an investigator (whether professional or student) conducting research:	
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or	
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. [45 CFR 46.102]	
<b>IRB Office Recommendations</b>	
test	
<b>Recommendation NHSR</b>	<a href="#">View Audit</a>
Not Human Subjects Research	
<b>Reviewer Attestation</b>	
By entering your password in the space below, you acknowledge this NHSR review and are electronically signing this form.	
Signed Wednesday, April 10, 2019 11:56:34 AM ET by IRB@adventisthealthcare.com, IRB Office	

f) IRB Office Recommendations

- c) The NHSR event link will direct you to the study event where you can see more information such as the NHSR application.
- d) Indicate the study determination (NHSR or further IRB review) for the NHSR application.
- e) If you determined that the study is NHSR, the definition of human subjects research will populate below for further guidance in making your determination.
- f) IRB Office Recommendations are also available for your convenience and designed to help facilitate reviews.
- g) After completing the reviewer form, you will sign-off on the reviewer form by entering your IRBManager password.

<b>Reviewer Attestation</b>	<a href="#">Add Note</a>	<a href="#">View Audit</a>
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		
<input type="text"/>		

- h) 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.

### Review Outcomes:

#### NHSR

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

**Further IRB Review**

6. If you determined that the study needs to be reviewed further by the IRB, the form will move back to the IRB Office for processing and ultimately to the researcher. The changes made to the application will determine next steps and the type of review.

**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