Adventist HealthCare

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.

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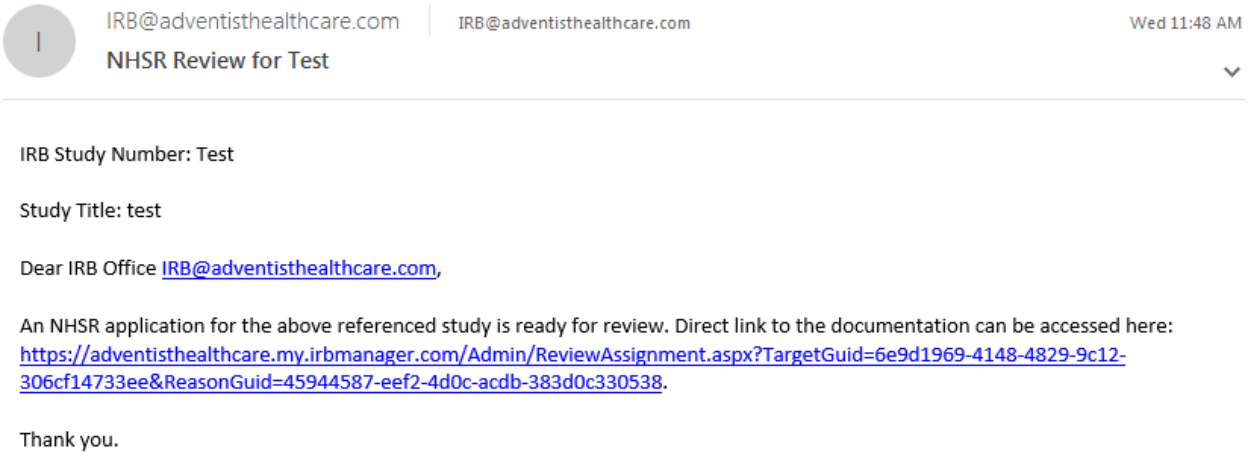
Email Notifications:

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.



I | IRB@adventisthealthcare.com | IRB@adventisthealthcare.com | Wed 11:48 AM

NHSR Review for Test

IRB Study Number: Test

Study Title: test

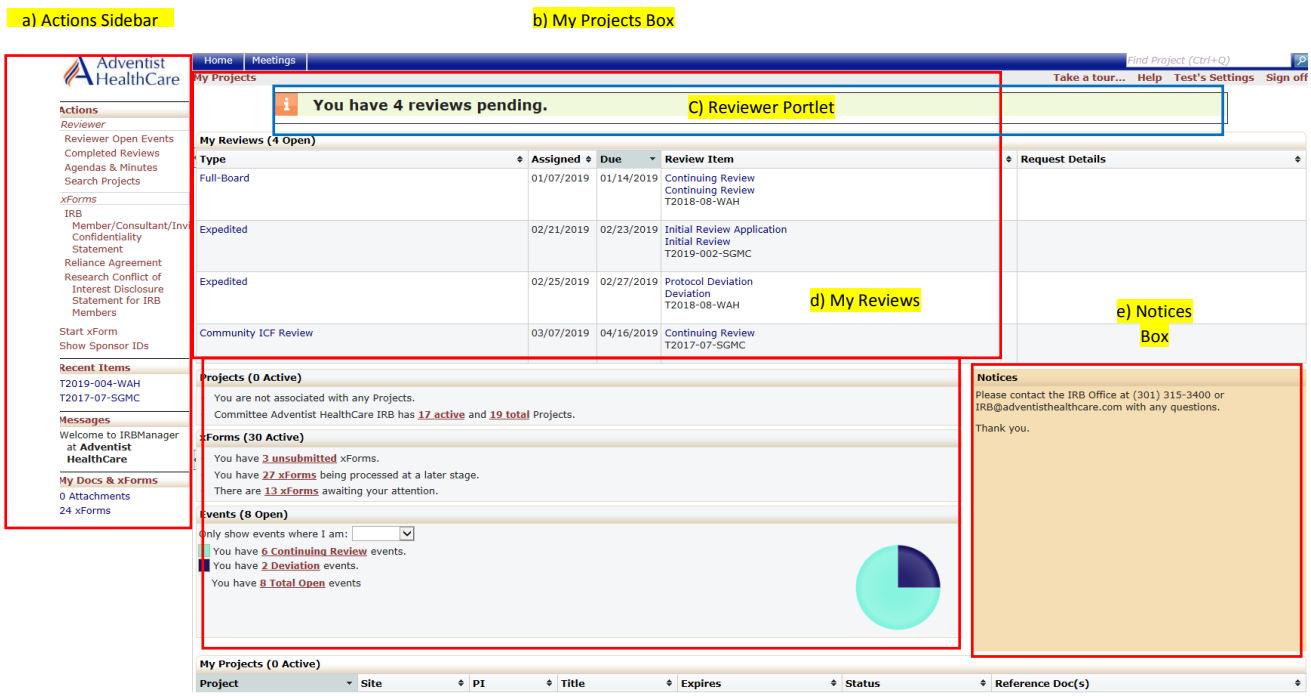
Dear IRB Office IRB@adventisthealthcare.com,

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.

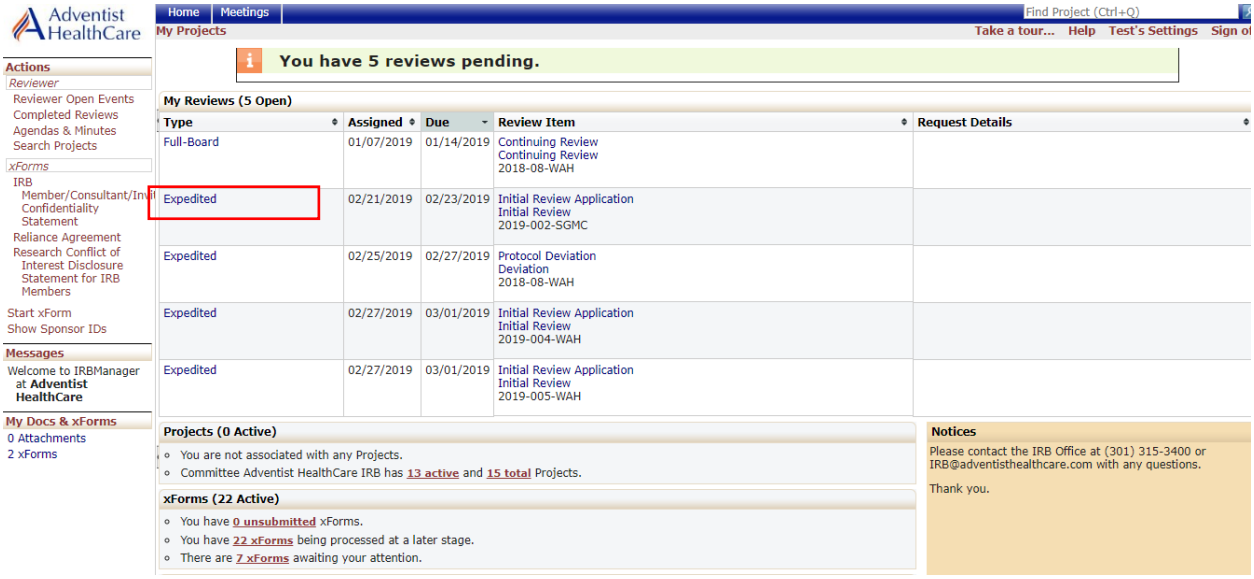
Dashboard Information:

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[1] 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[2], x-forms, and study events[3].
    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.



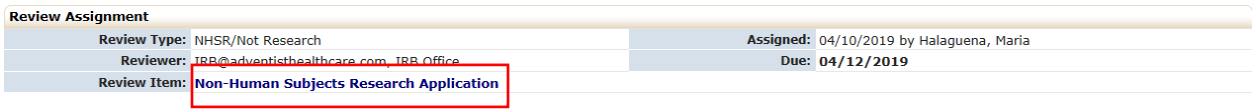
Completing a Review:

2. 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.



NHSR Review

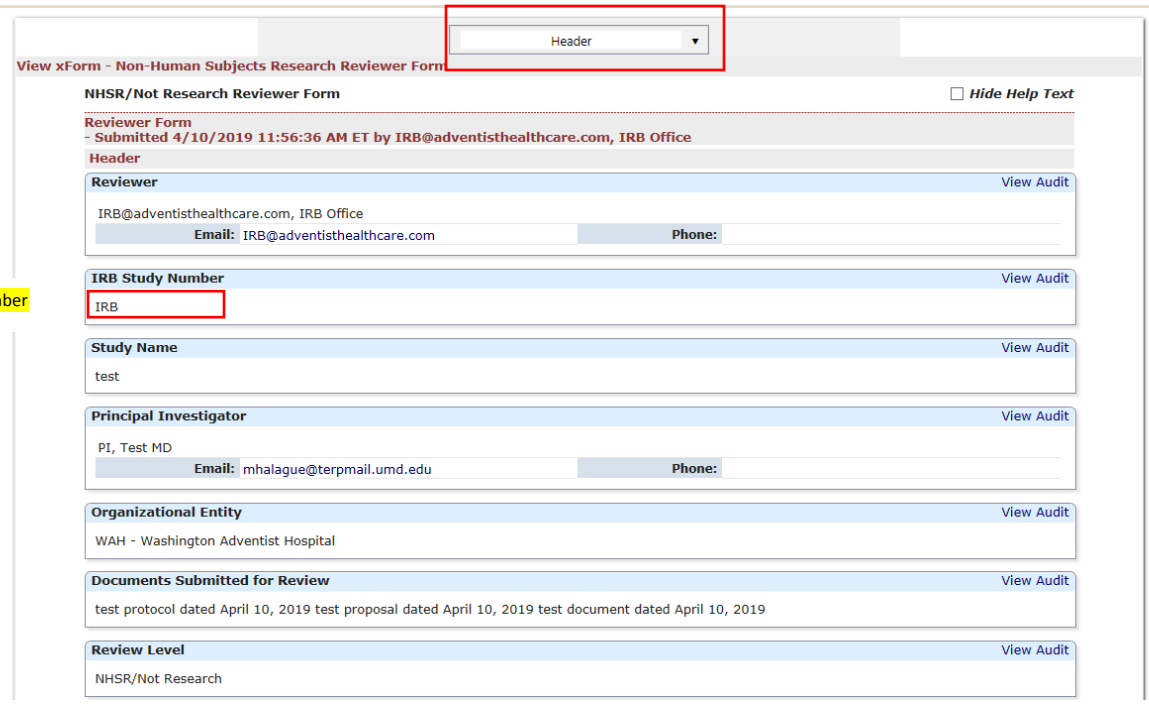
3. You will use the 'Non-Human Subjects Reviewer Form' for reviews. The Review Assignment Header contains more information on the review type, review item, assigned date, and due date. If you would like to see the NHSR application submitted by the researcher, click the blue form link and you will be directed to the form.



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

a) Header Drop Down

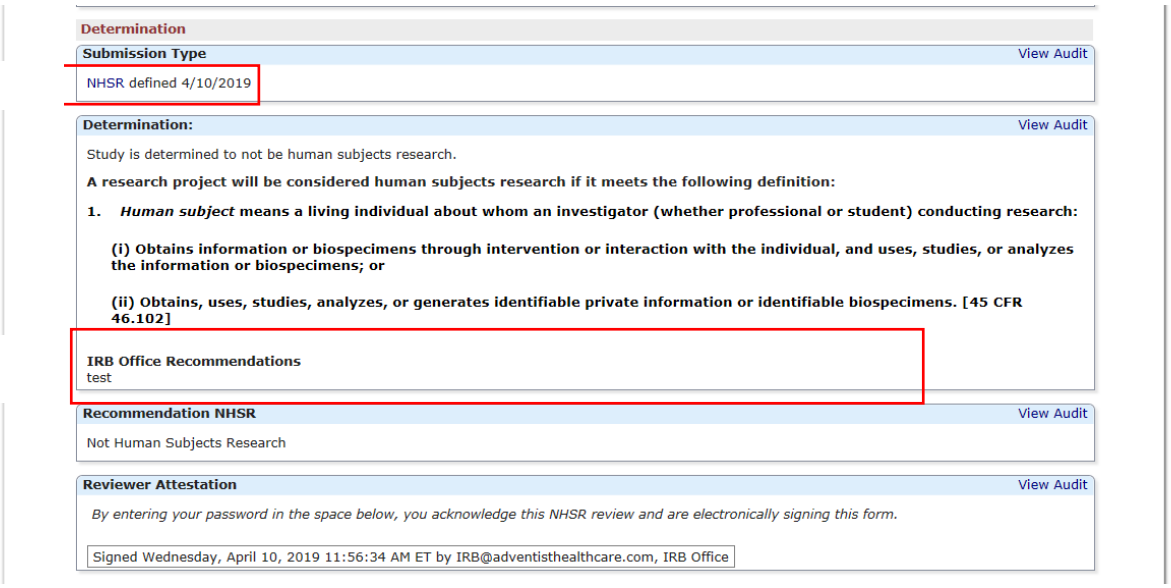
b) IRB Study Number



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

f) IRB Office Recommendations



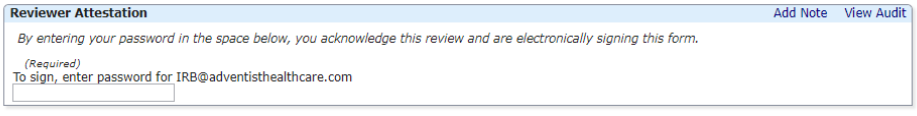
c) The NHSR event link will direct you to the study event where you can see more information such as the NHSR application.

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.



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:

- [1]X-forms: online version of the currently existing submission documents with slight modifications
- [2]Projects: research studies
- [3]Study Events/Events: actions or reviews for research studies. Examples include amendments, continuing review, and reportable event