Adventist HealthCare

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.

Table of Contents:

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

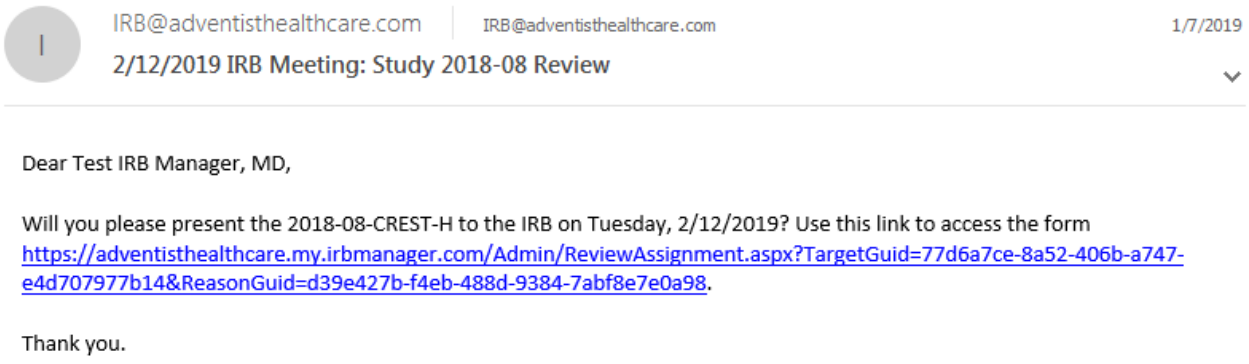
Dear Test IRB Manager, MD,

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.

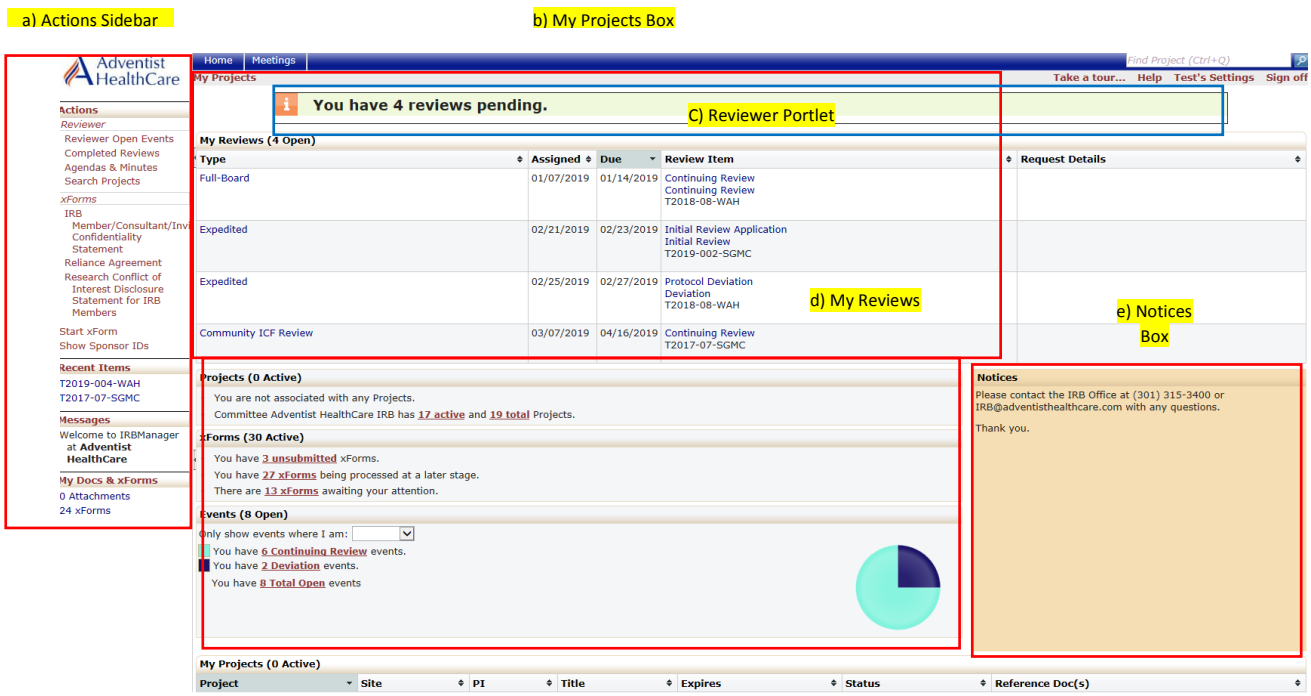
Full-Board Review

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.



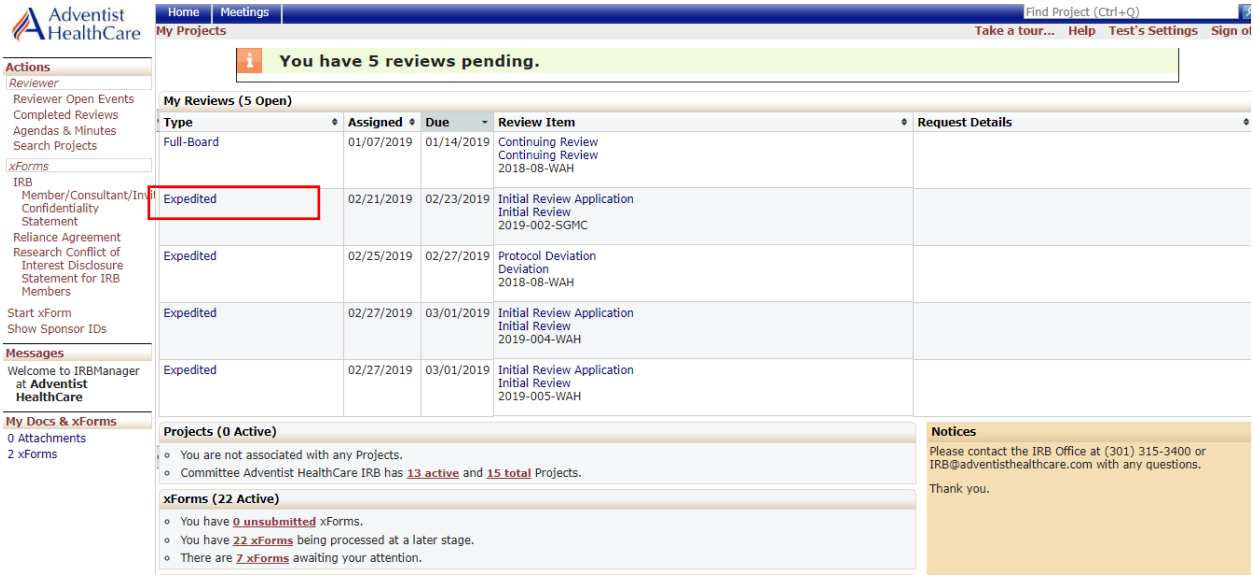
Dashboard Information:

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.



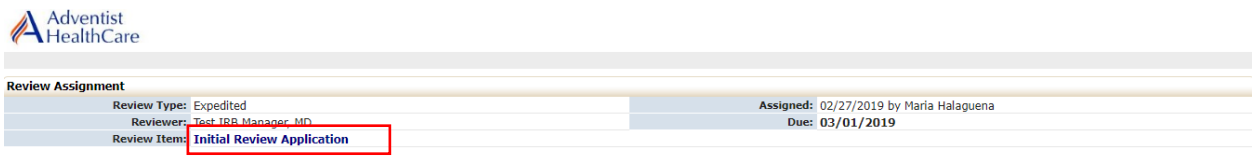
Completing a Review:

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.

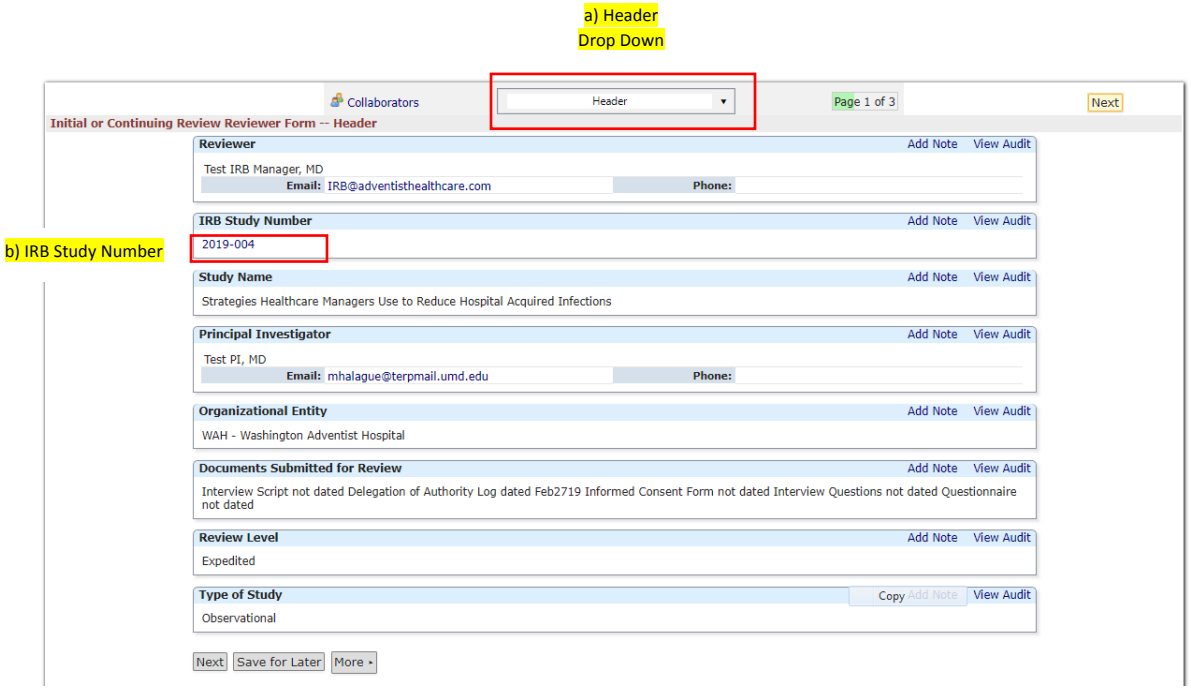


Expedited and Full-Board Review

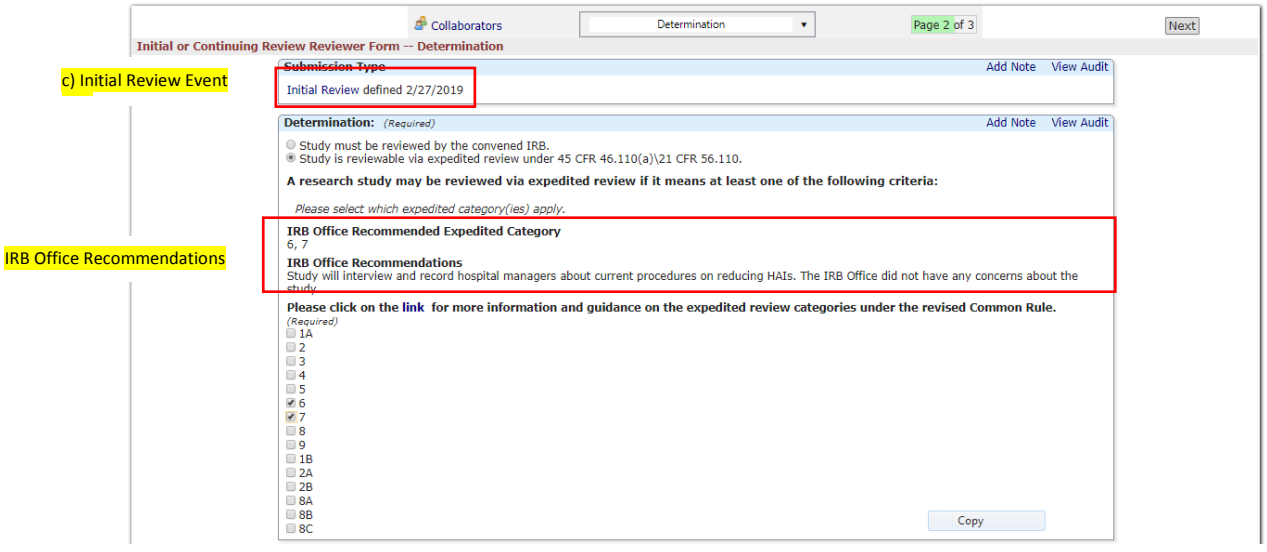
3. You will use the 'Initial Review or Continuing Review Reviewer Form' for both expedited and full-board reviews. The Review Assignment Header contains more information on the review type, review item, assigned date, and due date. If you would like to see the initial review application submitted by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



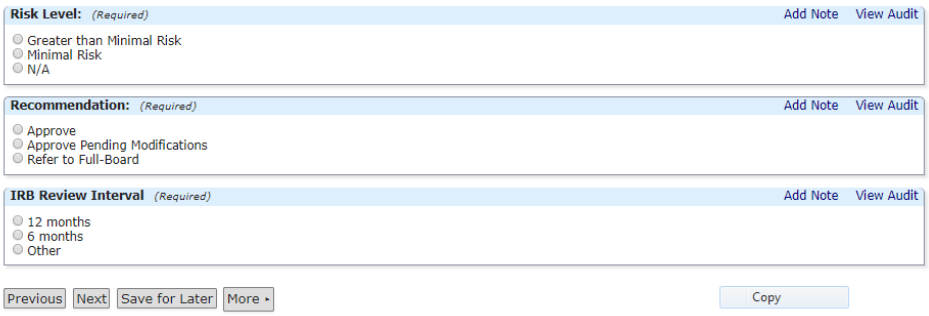
4. The Study Header page will also populate below and it contains more information on the study and submission documents.



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.

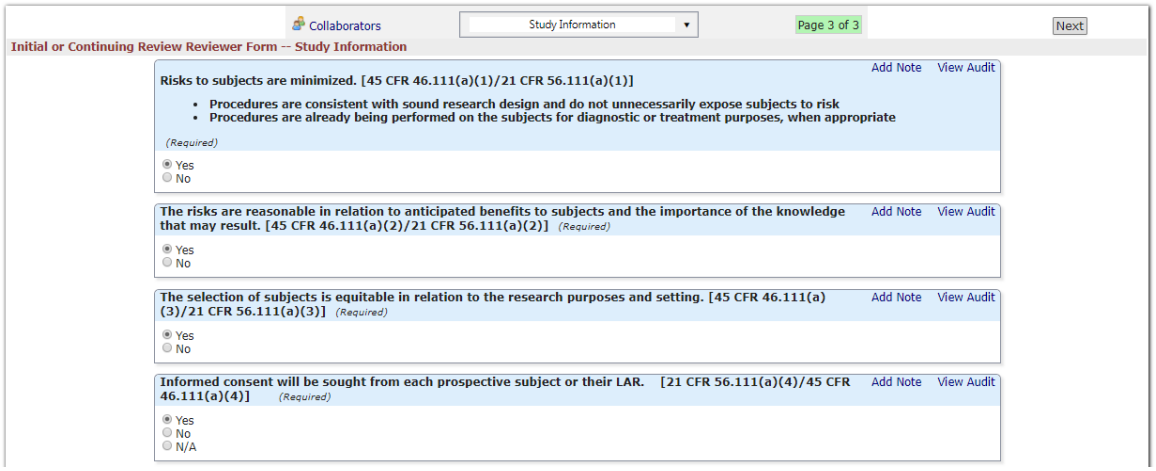


c) The initial review event link will direct you to the study event where you can see more information such as the initial review application.
d) Indicate the study determination (expedited or refer to full-board) for the initial review application.
e) If you determined that the study can be reviewed 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.

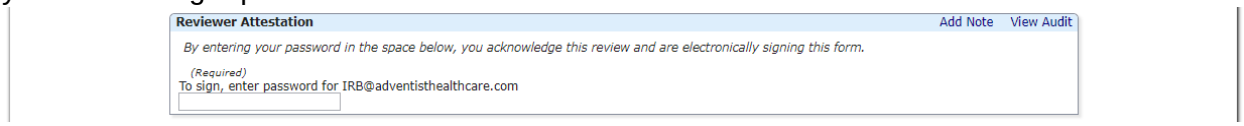


g) Determine the study's risk level.
h) Make recommendations on the approval status of the submission. If the study has been designated for full-board review by the IRB Office, the recommendation you make on the reviewer form is **not the final decision.**
i) Choose the review interval for the study.
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.



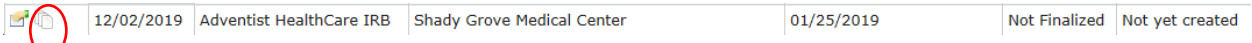
k) After completing the reviewer form, you will sign-off on the reviewer form by entering your IRBManager password.



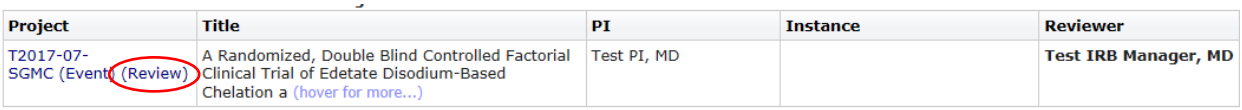
l) The completed reviewer forms can be accessed in the actions side bar by clicking on 'completed reviews.' A list of your completed forms will populate. Choose the reviewer form you need.

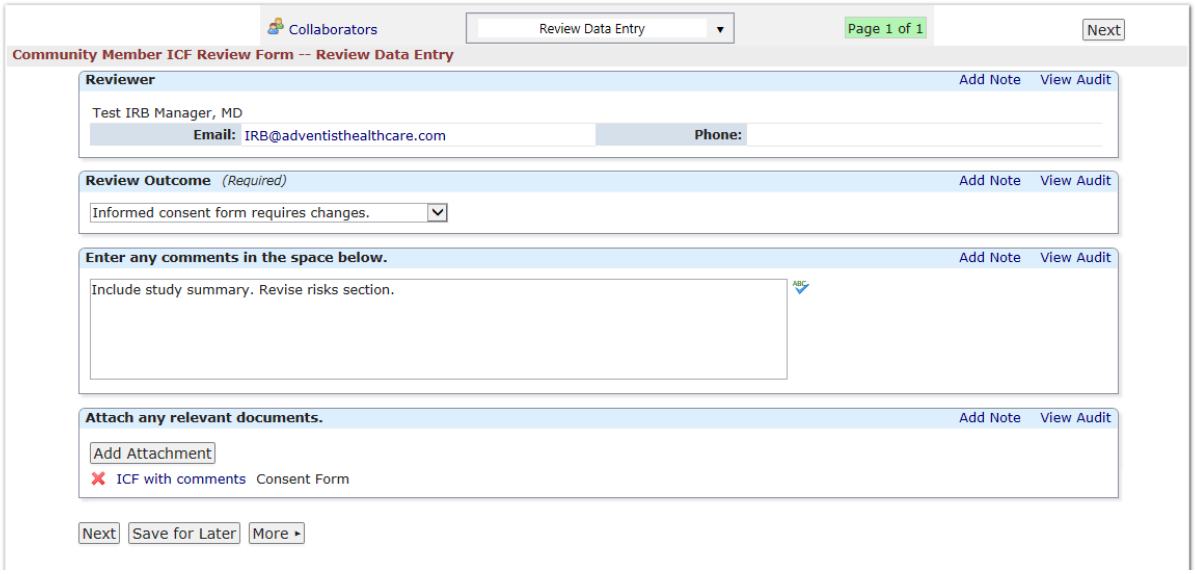
Full-Board Meetings: Community Member ICF Review Form

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.



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.



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.

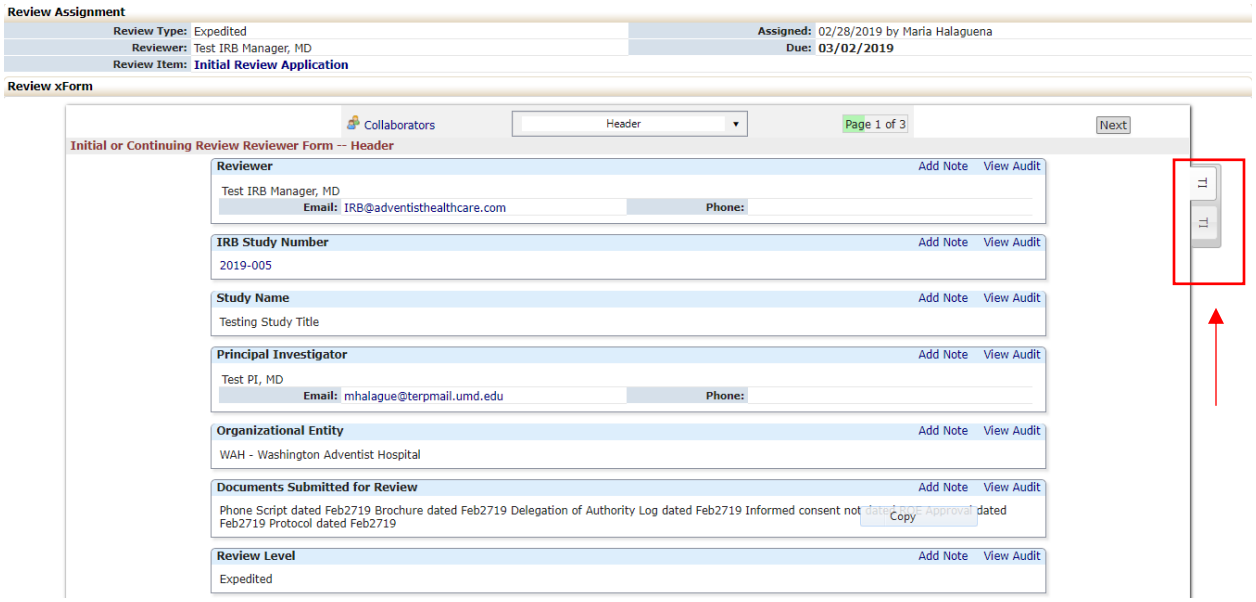
Review Outcomes:

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.



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:

- [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