Continuing Review Resource Guide for IRB Members

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

Audience: IRB Members

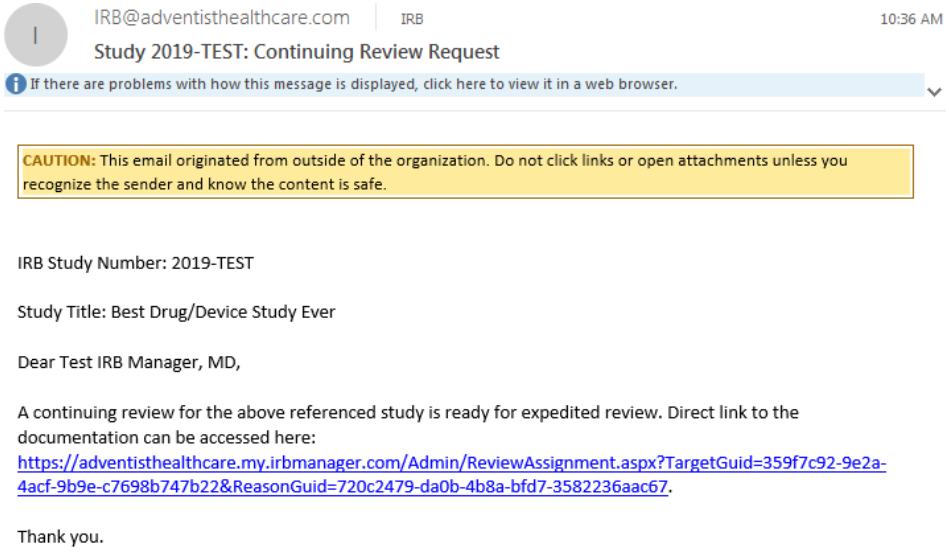
Summary: This resource guide will focus on the review of a continuing review application. The guide will cover the expedited and full-board review process as well as the different outcomes that can result from them. Please consult the Table of Contents below to find the information you need.

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@adventisthealthcare.com IRB 10:36 AM

Study 2019-TEST: Continuing Review Request

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.

IRB Study Number: 2019-TEST

Study Title: Best Drug/Device Study Ever

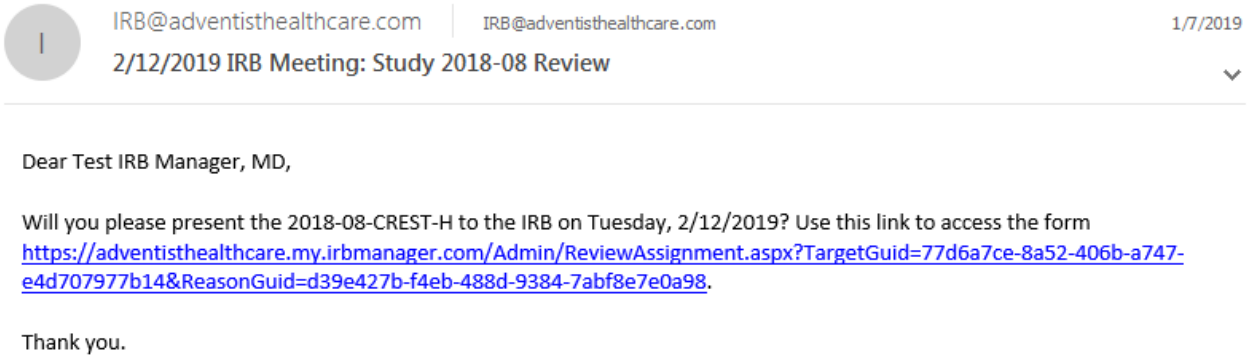
Dear Test IRB Manager, MD,

A continuing 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=359f7c92-9e2a-4acf-9b9e-c7698b747b22&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.



IRB@adventisthealthcare.com IRB@adventisthealthcare.com 1/7/2019

2/12/2019 IRB Meeting: Study 2018-08 Review

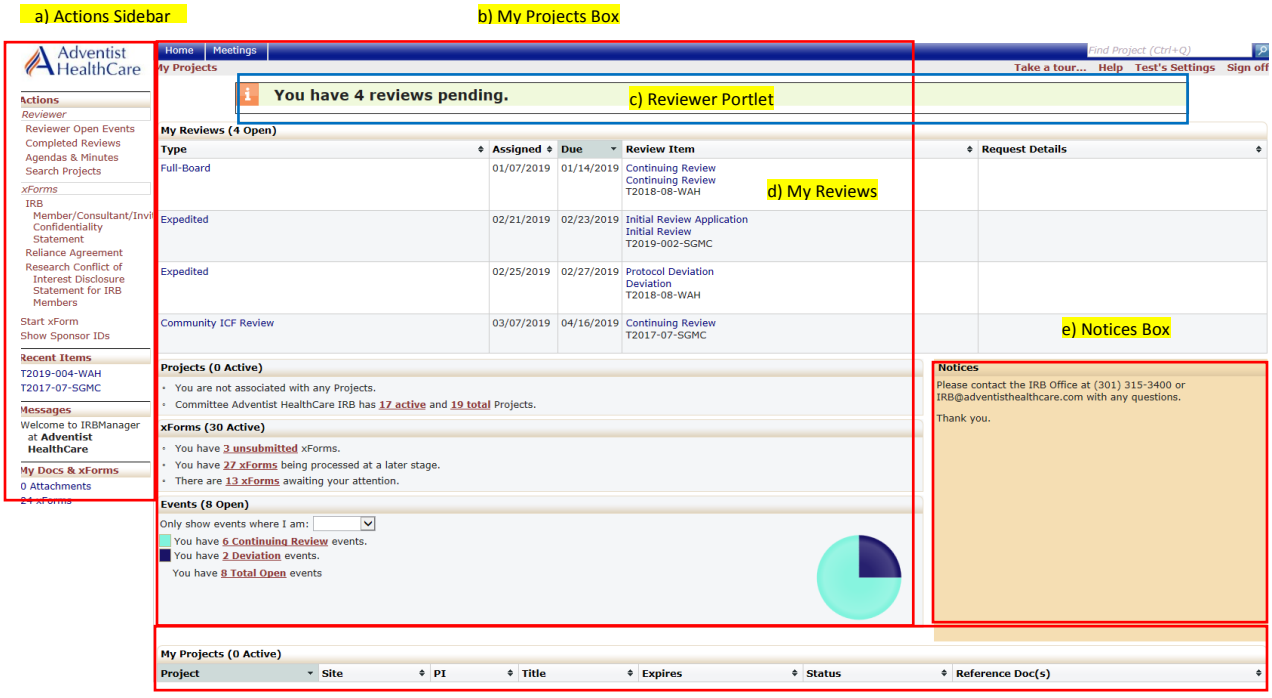
Dear Test IRB Manager, MD,

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.

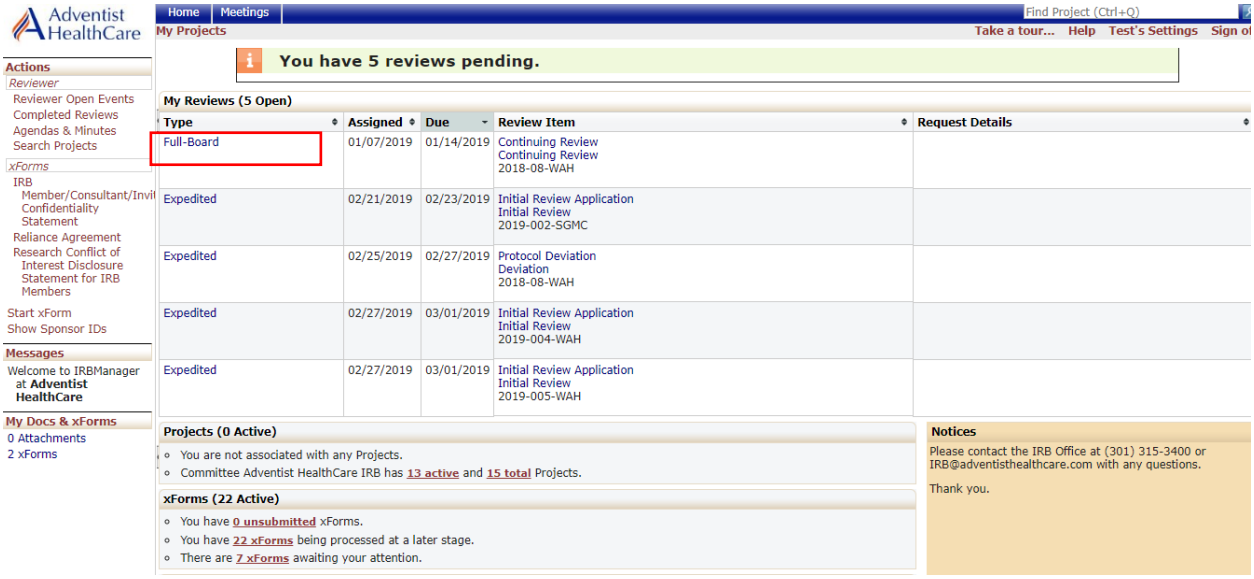
Dashboard Information:

3. 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.



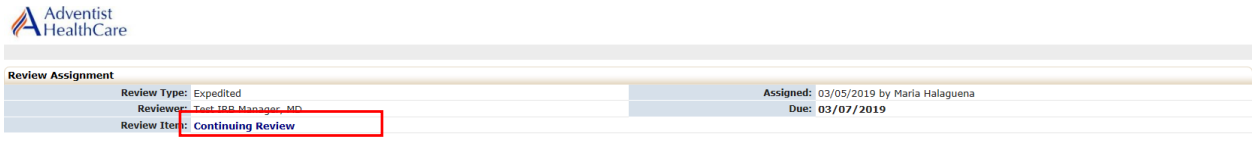
Completing a Review:

4. 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.



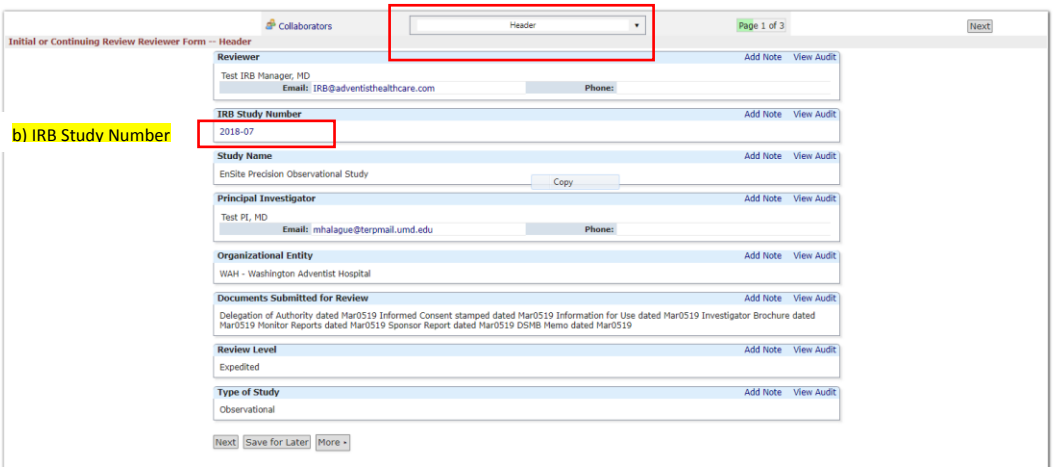
Expedited Review and Full-Board Review

5. You will use the 'Initial or Continuing Reviewer Form' for both expedited and full-board review items. 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 continuing review application submitted by the researcher, click the blue form link and you will be directed to the form.

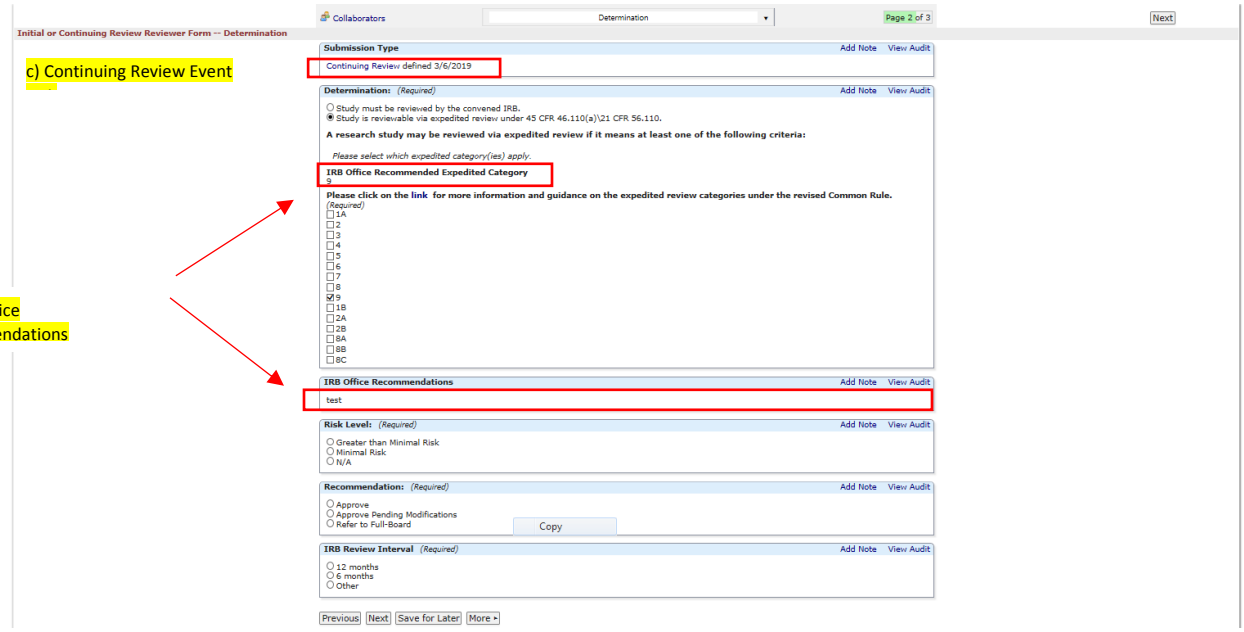


6. The Study Header page will also populate below and it contains more information on the study and submission documents.

a) Header
Drop Down



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 continuing review event link will direct you to the study event where you can see more information such as the continuing review application.
d) Indicate the determination (expedited or refer to full-board).
e) IRB Office Recommendations are available for your convenience and designed to help facilitate reviews. A link to the expedited categories under the revised Common Rule is also available for further guidance.
f) Provide a risk determination level for the study.

g) 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.**

h) Provide an IRB review interval.

i) The next page will ask you questions about the study's informed consent procedures, risks, benefits, and protections. 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.

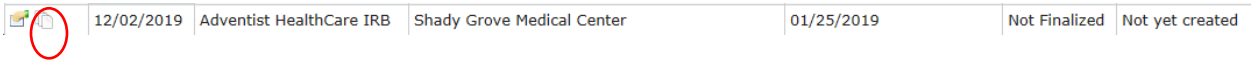
Please note: You will be asked to provide an explanation on certain questions based on your answer. Furthermore, questions marked as required cannot be left unanswered. You will not be allowed to submit the form until you answer the required questions.

j) After completing the reviewer form, you will sign-off by inputting your IRBManager password.

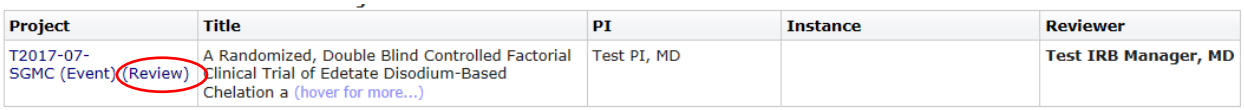
k) The completed reviewer forms can be accessed in the actions side bar by clicking on 'completed reviews.' A list of your completed forms will populate. Choose the reviewer form you need.

Full-Board Meetings: Community Member ICF Review Form

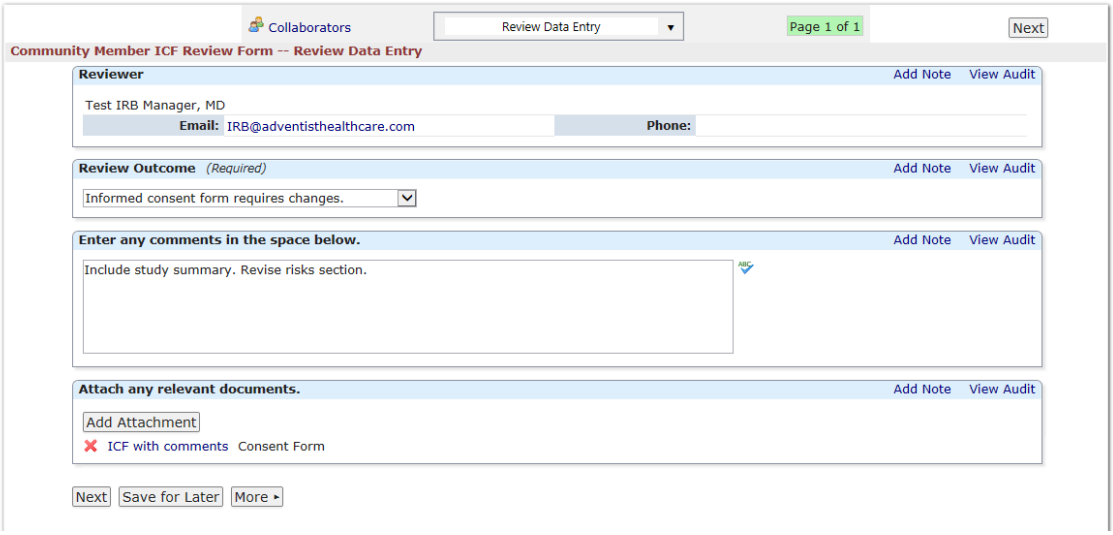
7. The 'Community Member ICF Review Form' is where you can review and make edits to the informed consent form in preparation for the IRB meeting. To access the form, you will go to the meetings tab and click on the pages icon of the meeting date.



8. 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.



9.



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

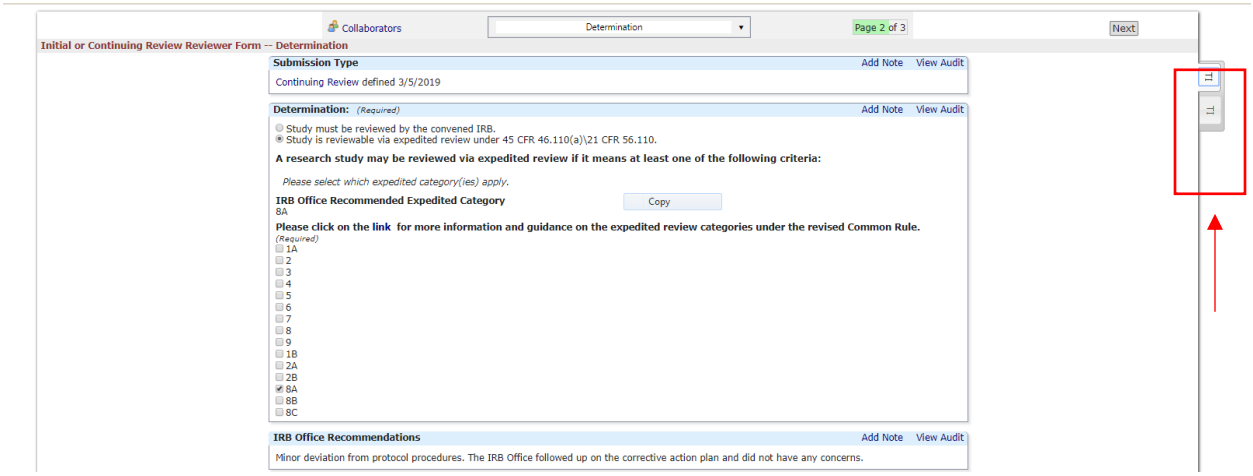
Review Outcomes:

Full Approval

10. 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

11. 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.
12. 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.



a) 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.
b) After reviewing the changes to the continuing 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