This quick reference card outlines how to complete an Ancillary Committee review of a study application and an amendment including:

- Reviewing a New Study Application
- Reviewing an Amendment
- Additional Review Activities

Some committees have unique review processes not detailed here. Always follow your committee’s review guidelines.

### Reviewing a New Study Application

When a new study application is submitted and it requires Ancillary Committee review, you will receive an email notification containing a link to the application. You can also find a link to the application in the Inbox of your Home Workspace.

There are four basic steps to completing the review. The first two steps can be done in any order.

1. View/edit staff notes
2. Assign Ancillary Owner
3. Review the application
4. Submit review decision

#### View Staff Notes

There are two options for viewing notes left by Core Committee Staff and/or other Ancillary Committee members who previously reviewed the application:

- From the Inbox of your Home Workspace, look in the Staff Notes column for the application you are reviewing.
- OR
- From the Study Workspace, click the Edit Inbox Staff Notes activity. Notes entered here appear in the Staff Notes column of your Home Workspace Inbox and can be viewed and edited by all.

#### Assign an Ancillary Owner

1. Click Assign Ancillary Owner from the Activities menu in the submission workspace.
2. Select a person from the Current Ancillary Owner drop-down menu, and then click OK. The Ancillary Committee Owner is displayed in the Study Workspace.

### Review the Application

Use the tips listed below, as applicable, to review the application according to the standard practices of your committee.

A. Click the View Study activity in the Study Workspace to open the application (not shown).
B. Click Continue to navigate to the next page of the application.
C. Click Jump To to navigate to a specific section of the application.
D. Click Print to print (or to view a print-friendly version) of the application.
E. Click Exit to return to the Study Workspace.

### Submit Review Decision

1. Click one of the following activities from the Study Workspace, as applicable:
   - Issue Ancillary Committee Approval
   - No Review Required by Ancillary
   - Ancillary Disapprove
2. Complete any required fields (marked with a red asterisk*).
3. If present, click the checkbox to indicate which Ancillary Committee you represent.
4. (Optional) Click Add to upload any supporting documents.
5. Click OK. You will return to the Study Workspace. Note that “Review Complete” for your committee appears in the progress bar.

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### Reviewing an Amendment

When an existing study is amended, review may be required by your committee. In such a case, you will receive an email notification containing a link to the amendment application. You can also find a link to the application in the **Inbox** of your Home Workspace.

Many of the steps involved in reviewing a new study application are also part of the amendment-review process. As such, the following procedure references details provided in the **Reviewing a New Study Application** section of this quick reference. As you proceed, note that any previous references to the Study Workspace should be interpreted as referring to the Amendment Workspace.

### View/Edit Staff Notes and Assign an Ancillary Owner

1. Read any Staff Notes left by Core Committee Staff and/or other Ancillary Committee members who previously reviewed the amendment. See the **View Staff Notes** section of **Reviewing a New Study Application** for details.
2. Complete the required steps to Assign an Ancillary Owner for the amendment. See the **Assign an Ancillary Owner** section under **Reviewing a New Study Application** for details.

### Review Amendment Info & Changes to Study

1. Click the **View Amendment Forms** activity from the Amendment Workspace. The Amendment Instructions page opens.
2. Click **Continue** to review the information in the Amendment Cover Sheet. Click **Exit** to return to the Amendment Workspace.
3. Click the **View Study** activity to view the amended study application. Click **Continue** or use the **Jump To** menu to navigate through the application. Click **Exit** when finished.
4. Click the **Amendment Audit Trail** activity to review a list of amended items.
5. Click the **Change Log** link to view additional details about the change.
6. Click the **On Page** link to open that section of the amended study application. Repeat steps 5-6 as necessary to review all changes.

### Submit Review Decision

The procedures for submitting a reviewing decision for a study application and amendment are identical. For instructions, see the **Submit Review Decision** section under **Reviewing a New Study Application**. You may also refer to the procedures under **Additional Review Activities** as needed.

### Additional Review Activities

Depending on the circumstances, you may need to use some of the following activities to complete your review. They can be used for reviewing both study applications and amendments.

#### Request Changes from Study Team

1. Click the **Changes Requested by Ancillary Committee** activity.
2. Describe the requested changes in the **Comments** field.
3. (Optional) Click **Add** to upload supporting documents.
4. Click the checkbox indicating the committee you represent, and then click **OK**. The state of the submission becomes **Changes Required by Ancillary Committee** and comments are displayed in the submission workspace under **Activities & Correspondence**.

#### View Submitted Changes

You will receive an email notification when the Study Team submits the requested changes.

1. Read comments left by the Study Team under **Activities & Correspondence** in the submission workspace.
2. Review the changes using the **View Study** and **Amendment Audit Trail** activities, as applicable. Repeat the **Request Changes From Study Team** procedure if further changes are needed.
3. Complete the applicable **Submit Review Decision** procedure.

#### View Adverse Events & Scheduled Continuing Reviews

Use to view an Adverse Event (AE) or Scheduled Continuing Review (SCR) submitted for a study previously reviewed by your committee. Ancillary approval is not required for these submission types.

1. From the submission workspace, click **View Adverse Event** or **View Continuing Review**, as applicable. See the **Review the Application** section under **Reviewing a New Study Application** or details on navigating the form.

#### Ancillary Manage Documents

Use this activity to upload any additional documents to the parent study that would otherwise not be included in the application.

1. Click the **Ancillary Manage Documents** activity.
2. Complete the **Adding a Document** step-by-step procedure.

#### For Ancillary and IRB Office

Use this activity to post comments/documents visible only to other Ancillary Committees and the IRB.

1. Click the **For Ancillary and IRB Office** activity.
2. Enter any **Comments** and **Add** any documents, as applicable.
3. Click the checkboxes to select notification recipients, and then click **OK**. This correspondence appears under the **Ancillary** tab of the submission workspace.

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