Preparing a Study Application for Submission

Before a study application can be submitted in eResearch Regulatory Management (eRRM), all required fields on the application must be complete, all members of the Study Team must accept their role, and the application must be moved to ready-to-submit inbox. Complete the following procedures to ensure that the application is ready for submission:

- Application Checklist
- Error Checking
- Notify Study Team Members to Accept Roles
- Move to Ready to Submit Inbox

APPLICATION CHECKLIST

The Application Checklist activity allows study team members to view a list of complete and incomplete sections of the Study Application. Clicking a link on the Application Checklist allows you to jump directly to that section.

After opening the applicable study, complete the following procedure.

eResearch Study Workspace

1. Click Application Checklist from the Activities menu in the Study Workspace.

   Note: The Application Checklist Progress window opens.

2. Click a Section link for which Progress is Incomplete.

   Notes:
   - You will be taken to that section of the Study Application so that you may complete it.
   - You must click Save or Continue in the Study Application in order to save your changes.
   - The Application Checklist Progress window does not update as changes are made. You must close the window and run the activity again in order to see updates in the Progress column.
ERROR CHECKING

eRRM verifies that all required fields are completed on each page of the Study Application whenever you click to move to the next page. Prior to submitting the application, you can display a list of required fields that are not complete (i.e. submission errors) by using:

eResearch Study Application

1. Click at the top of any section of the Study Application to display Error/Warning Messages at the bottom of the screen.

OR

End of Application

1. Click in section 45. End of Application to display Error/Warning Messages in a separate window.

Error/Warning Messages

2. Click the Jump To link to navigate to that section of the Study Application and make applicable changes.

Note: You must click Save or Continue to save the changes you make to the Study Application.

3. Click to update the Error/Warning Messages list.
NOTIFY STUDY TEAM MEMBERS TO ACCEPT ROLES

Study team members, except Principal Investigators and those with an Administrative Staff role, must access eRRM and accept their role before an application can be submitted. This process allows the individual to verify and accept their role on the study team and to maintain compliance with U-M Conflict of Interest policies.

The following procedure demonstrates how to notify study team members of the need for them to accept their role on the study. Email notifications are sent to applicable individuals listed on the study application.

eResearch Study Workspace

1. Click Notify Study Team Members to Accept Roles from the Activities menu in the Study Workspace.

Notify Study Team Members to Accept Roles Window

2. Click the checkbox(es) to select the study team member(s) you wish to notify to accept their role on the study.

3. (Optional) Enter any comments to be included in the notification in the field provided.

4. (Optional) Click the checkbox(es) to select the study team members who should be notified once all study team members have accepted their roles.

5. Click OK.

When study team members who need to accept their role log in to eRRM, they will see a link to the study under Need to Accept Role in the Inbox of their Home Workspace. Once all study team members have accepted their roles on the study, those individuals selected in step 4 will receive an email notification.
MOVE TO READY TO SUBMIT INBOX

A study team member can use the Move to Ready to Submit Inbox activity to alert selected team members that the application is ready to submit. This activity moves the application into the Ready to Submit section of the Principal Investigator’s Inbox (and/or anyone else with access to submit) and sends an email notification.

Important Information

- The application must be complete before using this activity.
- Prior to using this activity, Co-Investigators and Faculty Advisors must accept their roles on the study.

**eResearch Study Workspace**

1. From the Study Workspace, click **Move to Ready to Submit Inbox**.

   OR

2. From the End of Application page within the application, click **Move to Ready to Submit Inbox**

   1. Select the appropriate **Study Team Members** to notify.
   2. If applicable, enter comments that you want included in the email notification (e.g. reminders to accept role for the study).
   3. Click **OK**.
In the Study Workspace, a “Ready to Submit” alert displays in red.

For instructions on how to submit the Study Application, see the Submitting a Completed Application step-by-step procedure.

Removing an Application from the Ready to Submit Inbox

A Remove from Ready to Submit Inbox activity becomes available to use if an application needs to be pulled back to the Require Action by Study Team list in the Inbox.

1. Select the Remove from Ready to Submit Inbox activity.
2. Repeat steps 2-4 from above.

Note: In the Study Workspace, “Ready to Submit” alert disappears (not shown).