Core Staff - Submission Review
Quick Reference Card

This quick reference card outlines how to complete a Core Committee Staff Review of a submission (e.g., application, amendment, etc.). It covers:

- Assigning a Core Staff Owner
- Completing the Staff Reviewer Checklist
- Submitting the Staff Reviewer Checklist

Log Into eResearch Regulatory Management

2. Click Regulatory Management Login.
3. Enter your Login ID (Uniqname) and UMICH Password.
4. Verify that the Core Committee Staff role is selected or select it from the My Roles list.

Assigning a Core Staff Owner

The Primary Core Staff Owner is the person responsible for managing the submission throughout the review process. Additional Staff Owners can also be assigned, although all Owners work from the same Reviewer Checklist.

1. Click the Unassigned tab.
2. Click the Submission ID to open the workspace.
3. Click Assign Owner from the Activities menu.
4. Begin typing the last name of the core staff member in the Primary Owner field, then select the name from the matching values that appear in the drop-down list.
5. If applicable, enter a Secondary Owner and/or Other Core Staff Owners.
6. Enter any notes to the Primary Owner in the Inbox Staff Notes field, if applicable.
7. Click OK. The submission moves to the Primary Owner’s Inbox.

 Completing the Reviewer Checklist

Staff Reviewers use the Reviewer Checklist to verify that required submission information is complete and to recommend a review process (e.g., Exempt, Full Committee, etc.).

Tips: At the top of the checklist...
- Click Print Version of Submission to view both the submission and checklist at the same time.
- Click Manage Action Items to access action items on the application (or parent application).

1. Click the Submission ID.
2. Click Click here to edit review under My Reviews under the Main tab. The Staff Reviewer Checklist opens.
3. Verify each Section and corresponding Checklist Item that needs to be reviewed. Click the Section link to open that section of the submission in a separate window.
4. Select Yes or No in response to Condition Met for each Checklist Item.
5. Enter Comments. Comments are required if a condition is not met. Comments are converted to Identified Issues upon submission.
6. Select Yes or No in response to Does this study involve...?
7. Enter any Additional Issues for the study team.
8. Click Add to attach any Supporting review documents.
9. Select your Review Recommendation. Choices will vary depending on the type of submission under review.
10. Click Continue.

Submitting the Staff Reviewer Checklist

The steps for submitting the Staff Reviewer Checklist vary depending on the selected Review Recommendation. After you submit the review, you can edit and resubmit it at any time until the determination is processed and the study team is notified.

The procedures on the following page assume you have completed the Reviewer Checklist and then clicked Continue to navigate to the next page. In most cases, this will be the Submit Review page. You will be asked to provide additional information for Not Regulated, Administratively Approved and Exempt determinations before you are taken to the Submit Review page.
Assign to Expedited Reviewer

1. Click Yes in response to Are you ready to submit your review?
2. Click Finish. You will be taken to the submission workspace.
3. Click Select Committee from the Activities menu.
4. Select the committee responsible for reviewing the submission, and then click OK.
5. Click Expedite from the Activities menu.
6. Click Select, and then choose the reviewer’s name. Click OK.
7. Select the appropriate Reviewer Role from the drop-down menu. Select additional reviewers as needed.
8. (Optional) Enter Inbox Staff Notes and/or Comments for Reviewers.
9. If you are from the IRB, select an Expedited Category. Otherwise, you can skip this step.
10. Click OK. The state of the submission changes to In Expedited Review.

Assign to Full Committee

1. Complete steps 1-4 (as applicable) for Assign to Expedited Reviewer.
2. Click Full Committee from the Activities menu.
3. Select the Agenda Item Type from the drop-down menu.
4. (Optional) Enter Inbox Staff Notes.
5. Click Select under Reviewer Selection, choose the desired reviewer’s name, and select the appropriate Reviewer Role. Repeat as needed until all necessary reviewers are selected.
6. Choose the desired Meeting date.
7. (Optional) Enter Comments for Reviewers.
8. Click OK. The state of the submission changes to Full Committee.

Not Regulated Determination

1. On the Not Regulated Determination page, check the box to indicate the Category being applied to the submission.
2. Click Continue.
3. Click Select Committee from the Activities menu.
4. Select the committee responsible for reviewing the submission, and then click OK.
5. Click Yes in response to Are you ready to submit your review?
6. Click Finish. You will be taken to the submission workspace.
7. Click Not Regulated Determination from the Activities menu. The letter template opens in a pop-up window. Verify the Not Regulated Letter displays or select it from the drop-down list.
8. Review the letter, making any necessary changes, and click OK. The state of the submission changes to Not Regulated.

Request Change or Clarification

1. Click Yes in response to Are you ready to submit your review?
2. Click Finish. You will be taken to the submission workspace.
3. Click Changes Requested by Core Committee Staff from the Activities menu.
4. Enter Comments to the PI describing requested changes.
5. (Optional) Click Add to attach any supporting documents.
6. Click OK. The activity and comments are posted to the Activities & Correspondence list in the submission workspace.

Exempt Determination

1. On the Exempt Determination page, click the radio button to indicate the Exemption Category being applied to the submission.
2. Click Continue.
3. Click Yes in response to Are you ready to submit your review?
4. Click Finish. You will be taken to the submission workspace.
5. Click Exempt Determination from the Activities menu. The letter template opens in a pop-up window. Verify the Exempt Letter displays or select it from the drop-down list.
6. Review the letter, making any necessary changes, and click OK. The state of the submission changes to Approved.
7. Click Finalize Documents from the Activities menu.
8. Select the documents to finalize. Edit dates as needed.
9. Click OK.

Approved Administratively

1. On the Administrative Approval page, click the radio button to indicate the Administrative Approval Category being applied to the submission. Only Amendments and Scheduled Continuing Reviews (SCRs) or Termination Reports may be Approved Administratively.
2. Click Yes in response to Are you ready to submit your review?
3. Click Finish. You will be taken to the submission workspace.
4. Click Approve from the Activities menu. The Approval Letter template opens in a pop-up window.
5. Review the letter, making any necessary changes, and click OK. The state of the submission changes to Approved.
6. Click Finalize Documents from the Activities menu.
7. Select the documents to finalize. Edit dates as needed.
8. Click OK.

No Review Required

1. Click Yes in response to Are you ready to submit your review?
2. Click Finish. You will be taken to the submission workspace.
3. Click No Review Required from the Activities menu. The No Review Required Letter template opens in a pop-up window.
4. Review the letter, making any necessary changes, and click OK. The state of the submission changes to No Review Required.