Module 2: Reviewing Online Submissions

Module 2 Objective:
Covers how to review applications for human subject research in eResearch.

Refer to the table of contents below for the topics covered in Module 2.

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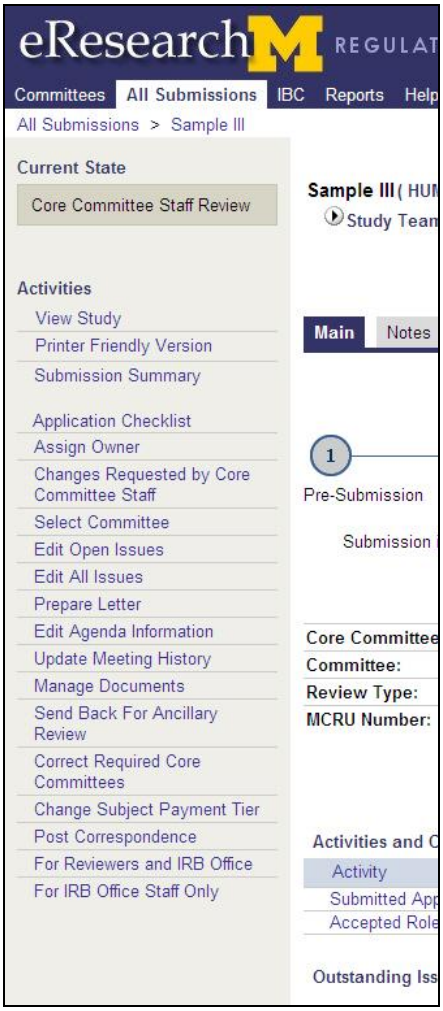
Review Activities

Applications are submitted for review in eResearch. Reviewing online submissions will be covered later in this document.

The actions listed below are some of actions that can be performed from **My Activities** on the workspace:



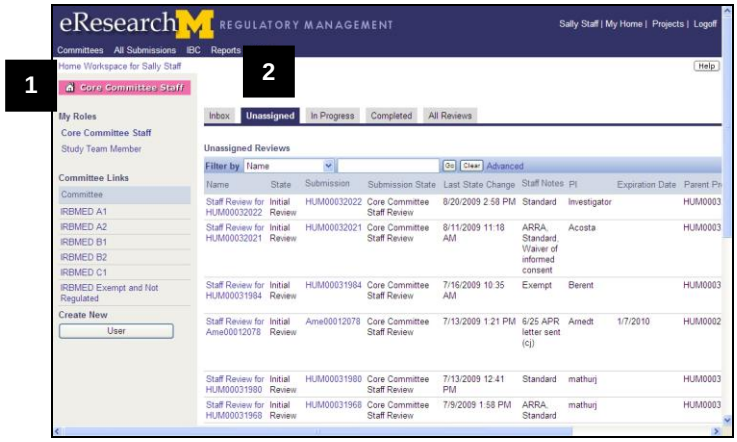
- **Assign Owner**: Changes the owner of the submission.
- **Changes Request by Core Committee Staff**: Notifies the PI that changes to the application are required before they can be approved.
- **Select Committee**: Selects the committee that will be responsible for reviewing the application.

  Note: This only applies to IRBMED, PRC, and MCRU.
- **Edit Identified Issues**: Used to add, change, and delete the outstanding issues for the submission.
- **Prepare Letter**: Used to prepare the submission outcome letter.

  Note: This function is used to prepare any of the letters.
- **Edit Agenda Information**: Used to add staff notes to the agenda and edit conflict of interest information.
- **Manage Documents**: Used to add and/or delete documents that appear under the documents tab in the application workspace.
- **Send Back to Ancillary Review**: Moves the application back to Ancillary Committee Review.
- **Correct Required Core Committees**: Used to send the application to a different IRB.
- **Post Correspondence**: Used to post comments and documents to the study workspace.
- **For Reviewers and IRB/PRC/MCRU Office**: Used to post comments and documents to the study workspace where they can be viewed and/or downloaded by all Core Office Staff, Committee members and Reviewers (comments are not viewable by study team members).
- **For IRB/PRC/MCRU Office Staff Only**: Used to post comments and documents to the study workspace where they can be viewed and/or downloaded by IRB/PRC/MCRU Office Staff only (not viewable by Study Team Member or Committee Members).

Processing New Submissions - Assign an Owner

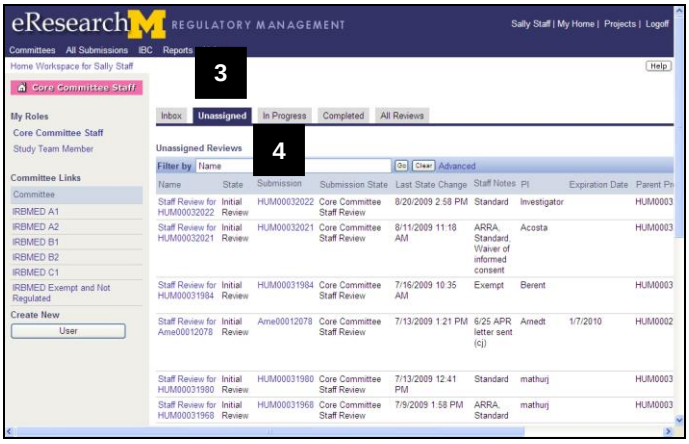
eResearch Study Workspace



1. Verify that **Core Committee Staff** is displayed on the home workspace.
2. Click the **Unassigned** tab.

   Note: All unassigned submissions will appear.

Unassigned Tab

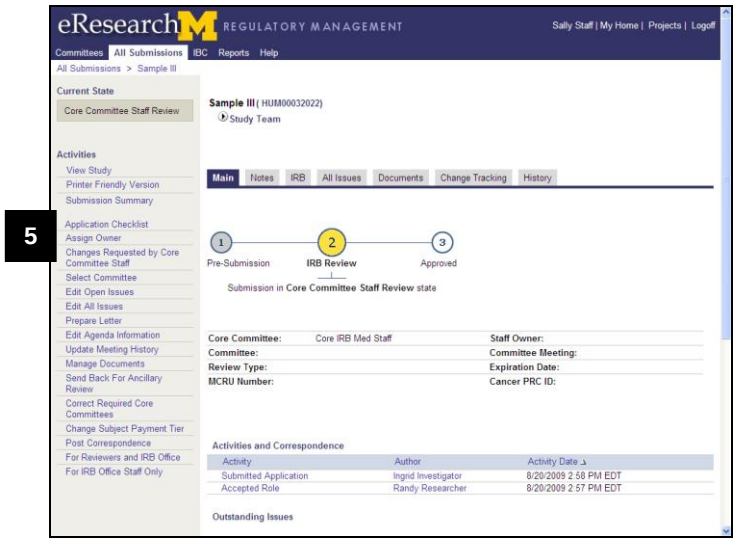


3. All **Unassigned** submissions are now displayed.
4. Click on the **Submission ID** to access the study.

   Important Workspace Information!

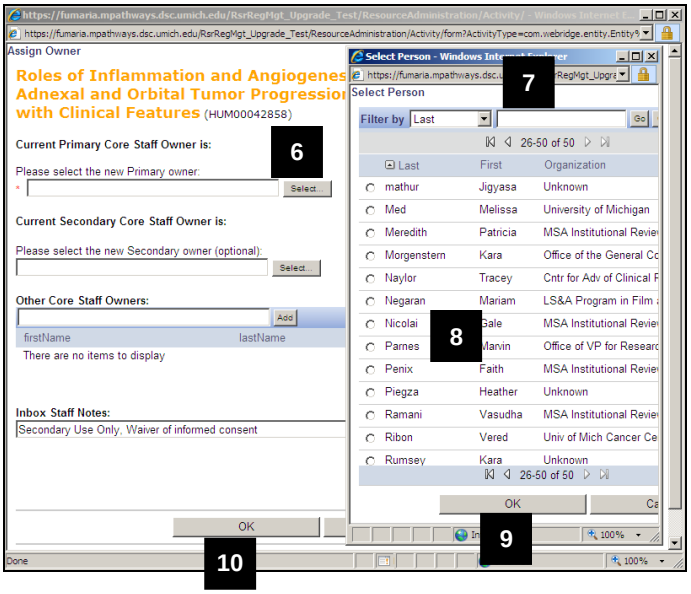
   - You must go to the **Submission ID** to open the study, *not* the Review Name.
   - Clicking on the **Submission ID** takes you directly to the Submission Workspace.
   - All Core Staff reviewing, assigning, approving, etc. is performed from the **Submission ID** area.
   - **Submission State** displays the current state of the Submission.
   - **Staff Notes** displays both the auto-generated and staff edited information about the submission.

Assign Owner



5. Click **Assign Owner**.

Select Person



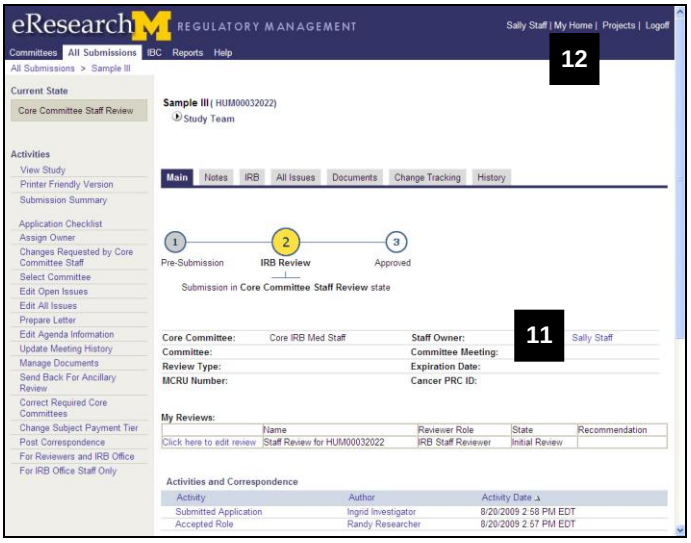
6. Click Select... to assign the Primary Owner.
7. Type the first three letters of the last name and click Go.
8. Select the staff member.
9. Click OK.

   Notes:

   - Individuals are added to the **Select Person** list once they log into eResearch for the first time and have been given the role of IRB staff. If the staff member you are attempting to add does not appear in this list, ask the individual to log into eResearch or use the **New User** activity in the study workspace and then request IRB staff access for that person by contacting the MAIS Help Desk .
   - **Secondary Core Staff Owner** and **Other Core Staff Owners** can be added following the above procedure. However, every staff owner works within the same Staff Reviewer Checklist.

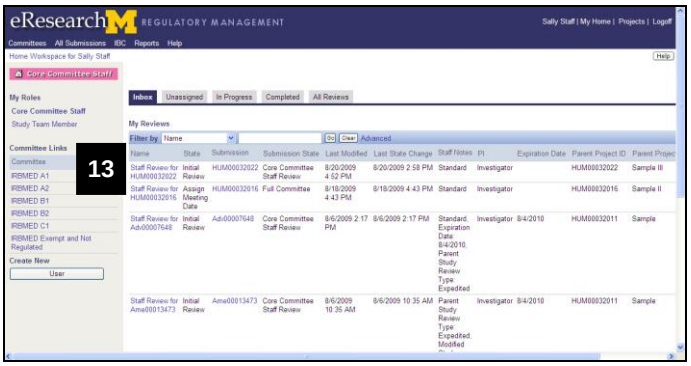
10. Click OK on the **Assign Owner** screen.

eResearch Study Workspace



11. Verify the name of the owner now assigned to the study.
12. Click **My Home** to return to your **Home Workspace**.

eResearch Home Workspace



13. If you selected yourself as the owner, the study now appears in your **Inbox**.

Reviewing Online Submissions

Important Information

- Applications can be assigned for review in eResearch in one of four ways:
    - **Not Regulated Determination** – The submission does not require IRB approval. A letter is prepared and sent to the study team, and the submission is stored in the **Exempt & Not Regulated** section of eResearch. (See page 26)
    - **Exempt Determination** –IRB Staff determines that the submission is exempt from review. (See page 23)
    - **Expedite Review** – The submission requires review by a selected committee member only. The committee is selected and a designated reviewer is assigned. The submission is not scheduled for a review meeting. (See page 14)
    - **Single Member Review** – Adverse Event
    - **Full Committee** – The submission requires review by the full IRB committee. A committee is selected and primary and secondary reviewers are assigned. You can also assign additional reviewers as needed. The submission is scheduled for review at a meeting. Meeting decisions are recorded in eResearch by the Core Staff. (See page 29)

Reviewing Online Submissions involves two major components:

- Complete Staff Reviewer Checklist
- Process Review Decision (review types listed above)

Staff Reviewer Checklist

Important Information:

Reviewing a submission requires two major components:

- Complete Staff Reviewer Checklist
- Process the review decision

This procedure details how to complete the Staff Reviewer Checklist. The last section of the Staff Reviewer Checklist differs based on whether you select:

- Not Regulated Determination
- Exempt Determination
- Expedite Review
- Single Member Review
- Full Committee

eResearch Home Workspace

1. Select the submission to review by its Submission ID.

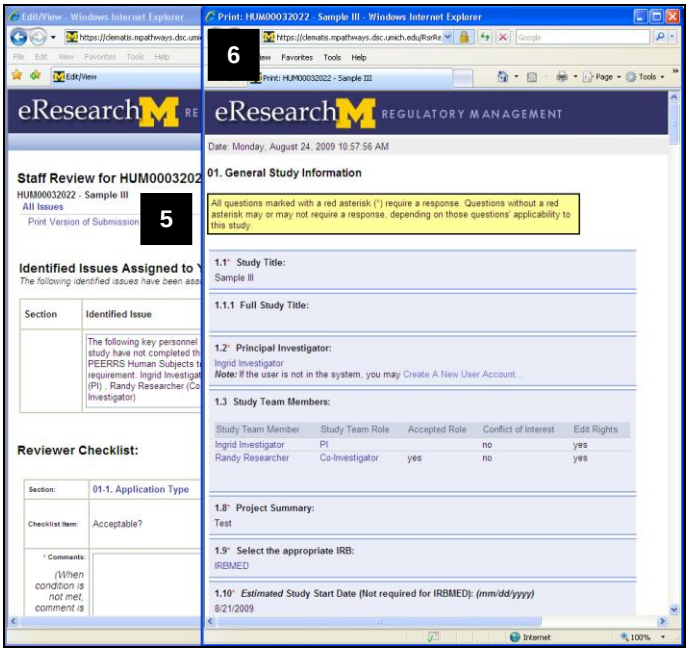
   Important Workspace Information!

   - You must go to the **Submission ID** to open the study, *not* the Review Name.
   - Clicking on the **Submission ID** takes you directly to the **Submission Workspace**.
   - All Core Staff reviewing, assigning, approving, etc. is performed from the **Submission Workspace**.
   - **Submission State** displays the current state of the Submission.
   - **Staff Notes** displays the last action that was performed on the submission.

Study Workspace

2. Verify the current state is **Core Committee Staff Review**.
3. The following information is displayed:
   - **Submission Information** – This area displays information such as the Study Team Member, Core Committee, Staff Owner, Committee Information and Required Ancillary Approvals.
   - **My Reviews** – This section shows the submission name, reviewer role, status and recommendation.
   - **Tabs** – This area displays Correspondence, Notes, IRB, All Issues, Documents, Change Tracking, and History tabs.
4. At My Reviews, click on **Click here to edit review** to open the Staff Reviewer Checklist (Staff Review page).

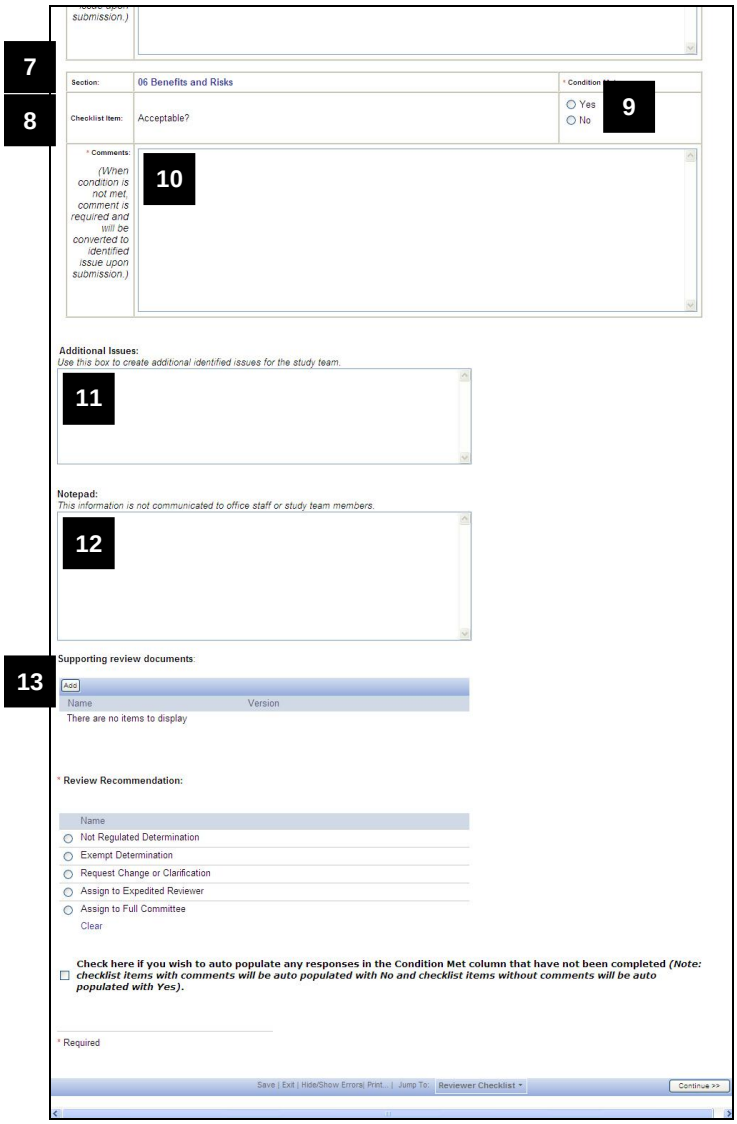
Reviewer Checklist & Printable Version of the Submission



5. If desired, click **Print Version of the Submission** to open the submission.
6. The **Printable Version of the Submission** opens in a separate window which can be referenced when completing the Staff Reviewer Checklist.

   Note: The submission can be moved around and resized within the eResearch window.

Staff Reviewer Checklist



7. Verify the **Section** of the submission that needs to be reviewed.

   Note: You can click on the section number to go directly to that section of the Smartform.

8. Read the **Reviewer Checklist Item** (question and sub-set question needed for review).

9. Click **Yes** if the condition in the Reviewer Checklist item has been met.

   Note: At the end of the checklist, you can auto populate any responses in the Condition Met column that have not been completed.

10. Enter **Comments** for reference at a later date.

    Note: When a condition is not met, a comment is required and will be converted to an identified issue upon <u>submission</u> of the Reviewer Checklist.

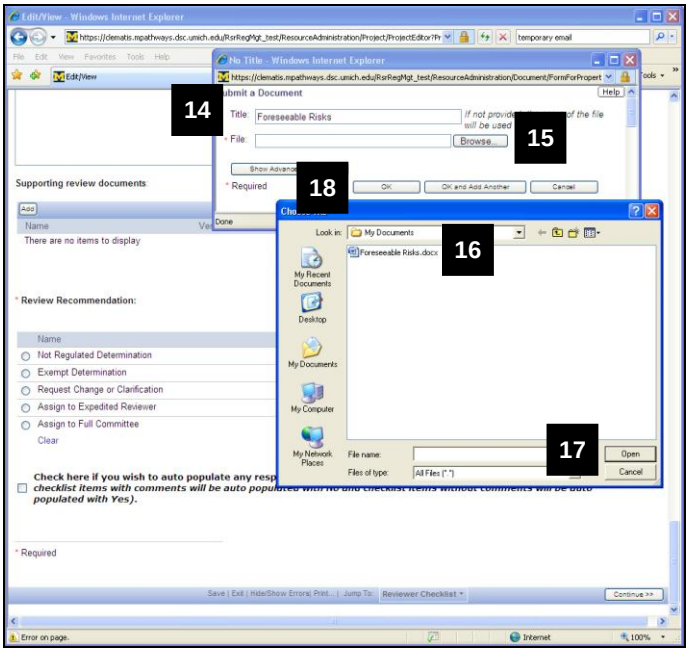
11. Enter additional identified issues for the study team in **Additional Issues**.

12. Enter notes in the **Notepad** for your reference.

    Note: This information is not communicated to office staff or the study team.

13. Click **Add** to include **Supporting Review Documents**, if desired.

Adding Supporting Documents - Optional



14. Enter a title for the uploaded document.

    Note: Entering a title is optional. If you do not enter a title, the filename becomes the title of the document.

15. Click the **Browse** button to locate the document on your computer.
16. Select the file to upload.
17. Click **Open**.
18. Click **OK** to return to the Reviewer Checklist.

Reviewer Checklist (Continued)

19. Select the **Review Recommendation** based how you would like the application reviewed.

    What you select here determines what options appear on the Submit Review page.

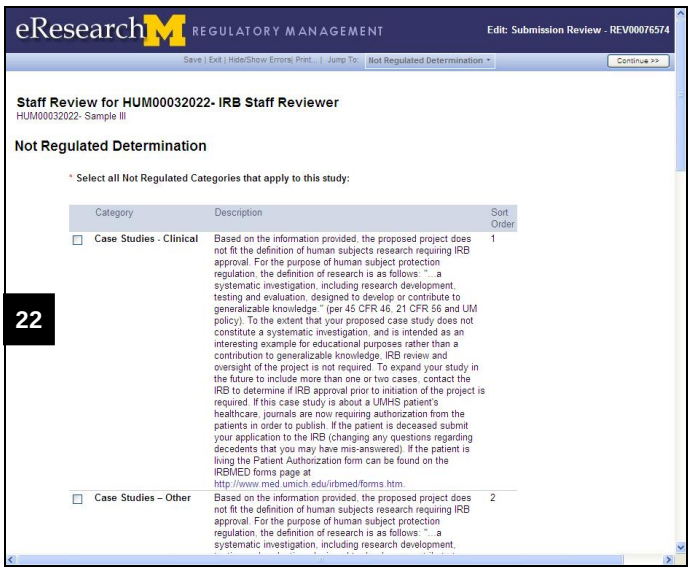
    Review options include:
    - **Not Regulated Determination**
      Refer to steps 22-25.
    - **Exempt Determination**
      Refer to steps 26-27.
    - **Request Change or Clarification**
      Will not send the project team any communication about changes required. If you would like to communicate requested changes with the project team, you need to complete a separate activity. See the *Requesting Changes from the Study Team procedure* for more information.
    - **Assign to Expedited Review**
      Refer to steps 28-30.
    - **Assign to Full Committee**
      Refer to steps 31-33.

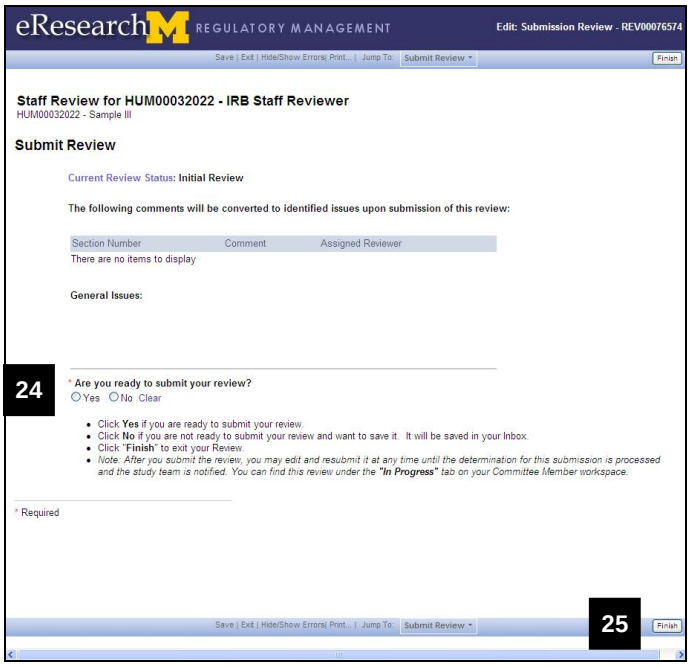
20. Select the **Check here…** box if you would like to auto populate any Condition Met

responses that were not completed. Checklist items with comments will be populated with No and items without comments will be populated with Yes.

21. Click **Continue.**

Submit Review - Not Regulated Determination





STEPS FOR NOT REGULATED REVIEW ONLY

22. Choose the correct **Not Regulated Category**.

    Note: Multiple categories may apply to the study. Select as many that apply.

23. Click **Continue.**

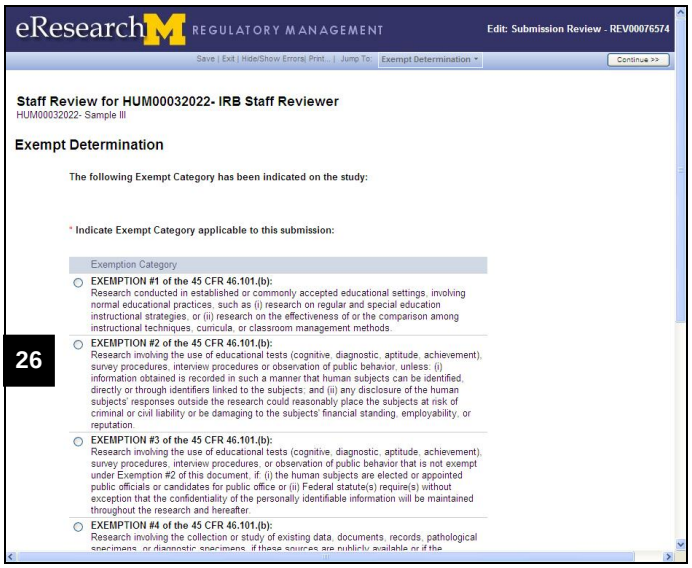
24. Check **Click here if you are ready to submit this review.**

    Note: If you are not ready to submit the review, click on **Save** to save your work and then **Exit**.

25. Click **Finish**.

    Note: Although you have finished the Reviewer Checklist, you must now process your Not Regulate Review decision. See page 26 for the steps required to process your decision.

Submit Review – Exempt Determination

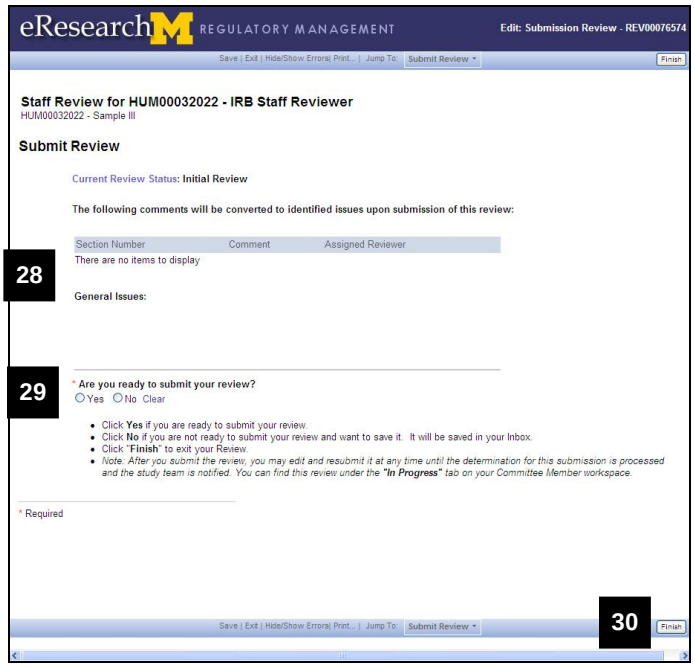


STEPS FOR EXEMPT DETERMINATION ONLY

26. Check on the **Exempt Category** applicable to the submission.
27. Click **Continue**.

    Note: Although you have finished the Reviewer Checklist, you must now process your Exempt Review decision. See page 23 for the steps required to process your decision.

Submit Review – Expedite

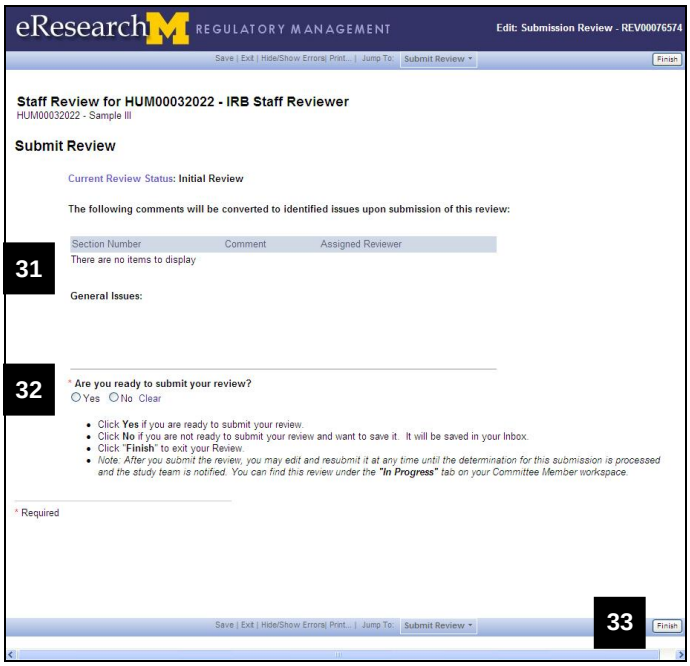


STEPS FOR EXPEDITE REVIEW ONLY

28. When a condition is not met, the associated comment will be converted to an **Identified Issue** upon submission of the review.
29. Check **Click here if you are ready to submit this review.**
30. Click **Finish**.

    Note: Although you have finished the Reviewer Checklist, you must now assign the reviewer.

Submit Review – Full Committee



STEPS FOR FULL COMMITTEE REVIEW ONLY

31. When a condition is not met, the associated comment will be converted to an **Identified Issue** upon submission of the review.
32. Check **Click here if you are ready to submit this review.**
33. Click **Finish**.

    Note: Although you have finished the Reviewer Checklist, you must now process your Full Committee Review decision. See page 29 for the steps required to process your decision.

Expedite Review

Important Information:

Expedite Review requires review by a selected committee member only. The committee is selected and a designated reviewer is assigned. The submission is not scheduled for a review meeting.

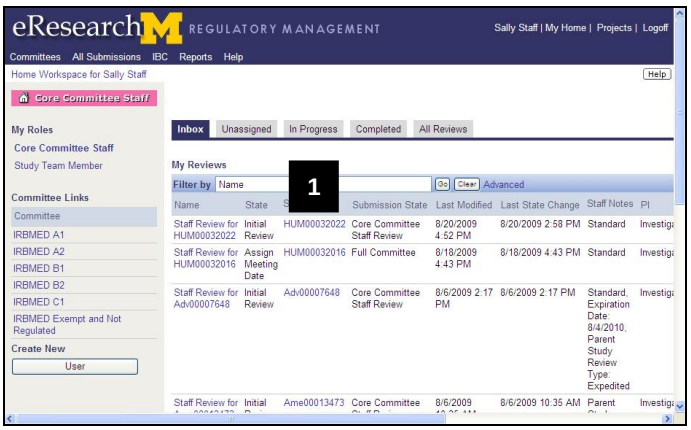
To complete an Expedite Review, you must:

- STEP 1: Select the Submission that needs review.
- STEP 2: Select Committee (IRBMED, PRC, or MCRU only).
- STEP 3: Select Expedite Activity.
- STEP 4: Assign Reviewer.
- STEP 5: Validate the Review (record review decision) which includes:
  - Select Reviewer Determination
  - Process Decision
  - Finalize Documents

⚠ **Prior** to assigning the expedite reviewer; staff should complete the **Staff Reviewer Checklist**.

STEP 1 - Select the Submission

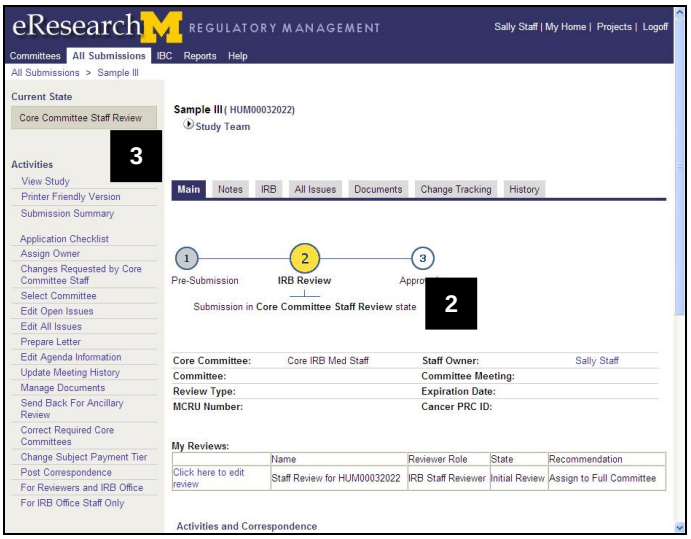
eResearch Home Workspace



1. Select the submission that needs to be reviewed.

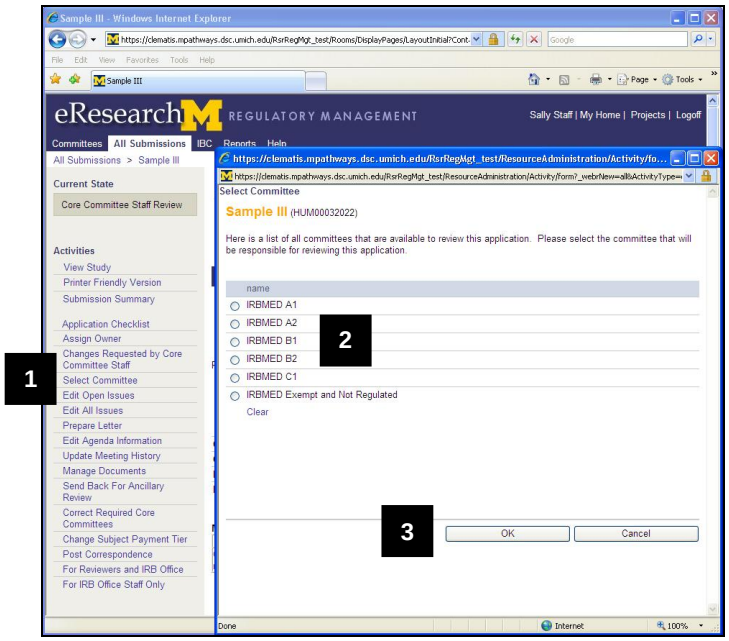
   Note: You must select the application by its submission ID and not its Project Name.

Study Workspace



2. Verify that the current state is **Core Committee Staff Review**.
3. Multiple functions can be performed from **My Activities**. See the **My Activities** section for detailed information.

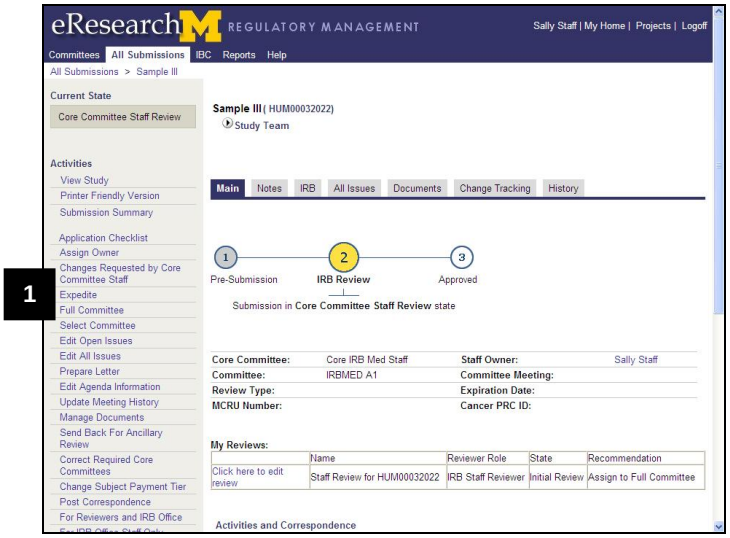
STEP 2 - Select Committee (IRBMED, PRC, or MCRU Only)



1. If you are from IRBMED, PRC, or MCRU click **Select Committee** to assign the submission to a committee.
2. Select the committee that will be responsible for reviewing the application.

   Note: Select the committee on which the expedited reviewer sits.
3. Click **OK** to save your committee selection and return to the Study Workspace.

STEP 3 - Expedite Submission Activity

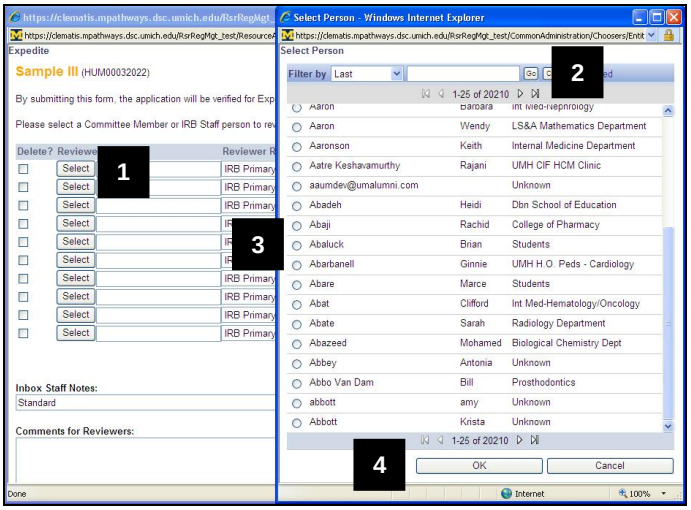


1. Click **Expedite** to assign the reviewer.

   Note: If you are from IRBMED, PRC, or MCRU, Expedite is not an option until you select your committee.

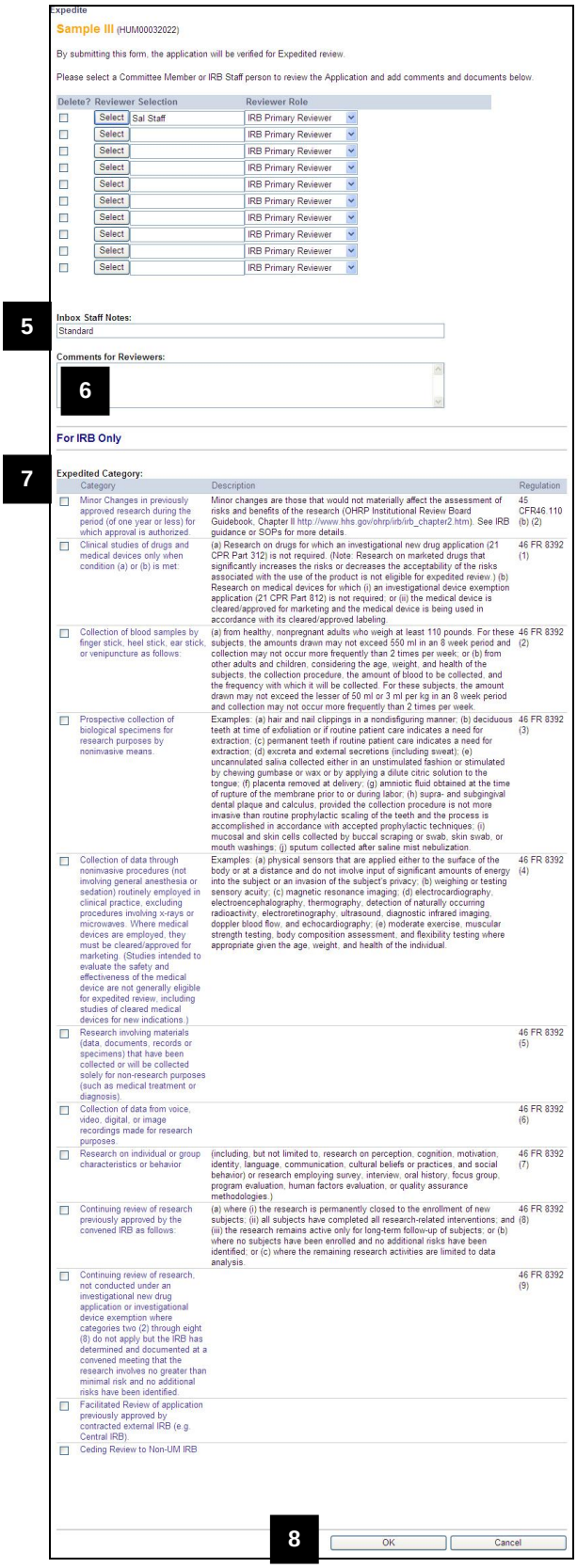
STEP 4 - Assign Reviewer

Select Expedited Staff Primary Reviewer



1. Click **Select** to assign the primary Reviewer.
2. Type the first three letters of the last name and click **Go**.
3. Select the Committee member.
4. Click **OK** to assign the reviewer and return to the Core Staff Expedited Review page.

Core Staff Expedited Review



Expedite

Sample III (HUM00032022)

By submitting this form, the application will be verified for Expedited review.

Please select a Committee Member or IRB Staff person to review the Application and add comments and documents below.

Delete?	Reviewer Selection	Reviewer Role
☐	Select Sal Staff	IRB Primary Reviewer
☐	Select	IRB Primary Reviewer
☐	Select	IRB Primary Reviewer
☐	Select	IRB Primary Reviewer
☐	Select	IRB Primary Reviewer
☐	Select	IRB Primary Reviewer
☐	Select	IRB Primary Reviewer
☐	Select	IRB Primary Reviewer
☐	Select	IRB Primary Reviewer
☐	Select	IRB Primary Reviewer

5

Inbox Staff Notes:
Standard

Comments for Reviewers:

6

For IRB Only

7

Expedited Category:

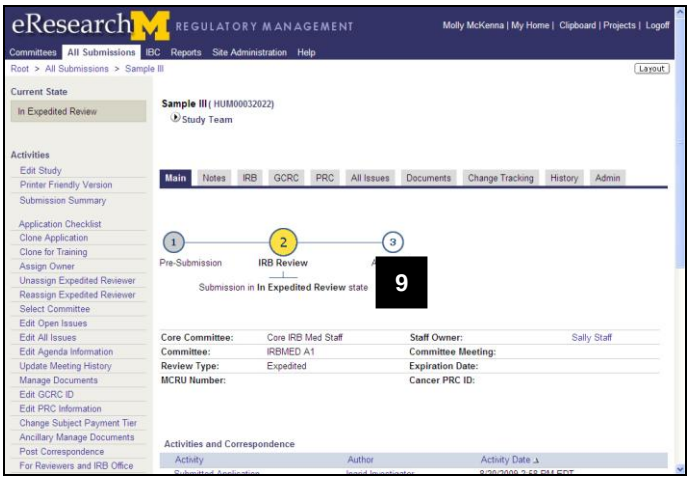
	Category	Description	Regulation
☐	Minor Changes in previously approved research during the period (of one year or less) for which approval is authorized.	Minor changes are those that would not materially affect the assessment of risks and benefits of the research (OHRP Institutional Review Board Guidebook, Chapter II http://www.hhs.gov/ohrp/irb/irb_chapter2.htm). See IRB guidance or SOPs for more details.	45 CFR46.110 (b) (2)
☐	Clinical studies of drugs and medical devices only when condition (a) or (b) is met:	(a) Research on drugs for which an investigational new drug application (21 CPR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CPR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.	46 FR 8392 (1)
☐	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:	(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.	46 FR 8392 (2)
☐	Prospective collection of biological specimens for research purposes by noninvasive means.	Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.	46 FR 8392 (3)
☐	Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)	Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.	46 FR 8392 (4)
☐	Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).		46 FR 8392 (5)
☐	Collection of data from voice, video, digital, or image recordings made for research purposes.		46 FR 8392 (6)
☐	Research on individual or group characteristics or behavior	(including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.)	46 FR 8392 (7)
☐	Continuing review of research previously approved by the convened IRB as follows:	(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.	46 FR 8392 (8)
☐	Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.		46 FR 8392 (9)
☐	Facilitated Review of application previously approved by contracted external IRB (e.g. Central IRB).		
☐	Ceding Review to Non-UM IRB		

8

OK Cancel

5. Enter **Inbox Staff Notes**, if applicable.
6. Enter **Comments for Reviewers**, if applicable.
7. If you are from an IRB, choose an **Expedited Category**.
8. Click **OK** to assign to the reviewer.

Study Workspace



9. Verify that the study state changed to **In Expedited Review** status.

   Note: The Expedite activity no longer appears as an option under my activities.

   If you need to assign a different reviewer, use the **Reassign Expedited Reviewer** button under My Activities.

   Note: If you want to change from Expedite review to a Full Committee review use the Unassign Expedited Reviewer button to remove the reviewer.

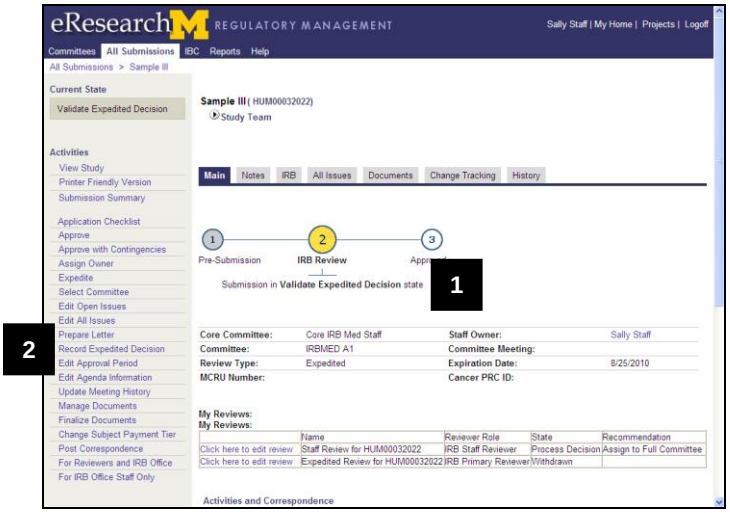
   Note: You cannot validate the review (record your review recommendation) until:

   - Your assigned reviewer completes the Committee Member Reviewer Checklist

     and

   - the study state changes to **Validate Expedited Decision** status.

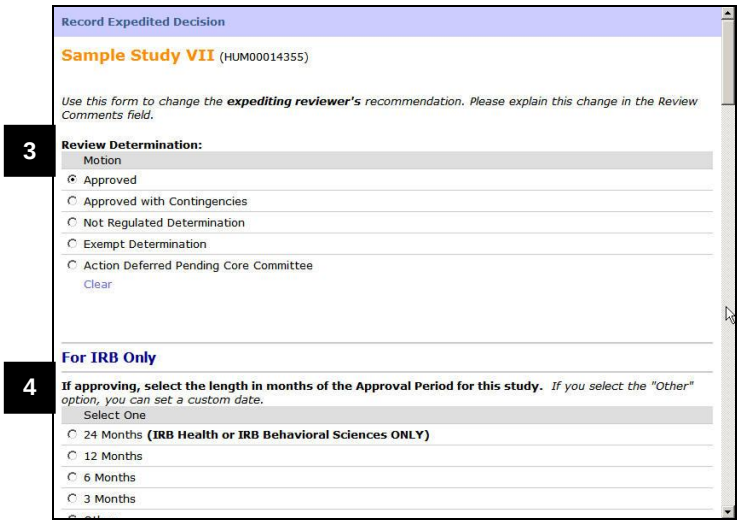
STEP 5 - Validate Review (Record Review Results)



Note: Validate Expedited Decision can <u>only</u> take place after the expediting review has been submitted by the expedited Reviewer (Committee Reviewer checklist complete).

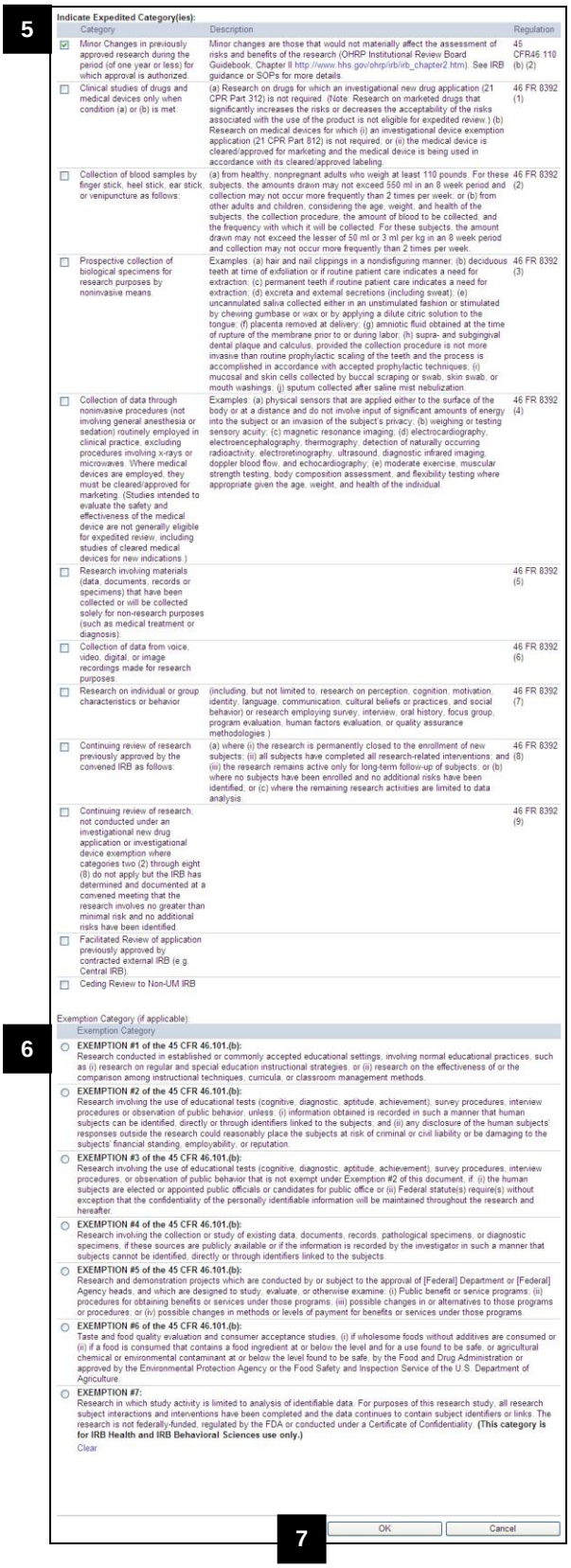
1. Verify the current state is **Validate Expedited Decision**.
2. Click **Record Expedited Decision**.

Record Expedited Decision



3. Select **Review Determination**.
4. For IRB only, choose **Approval Period**.

Indicate Expedited Category



Indicate Expedited Category(ies):

	Category	Description	Regulation
☑	Minor Changes in previously approved research during the period (of one year or less) for which approval is authorized.	Minor changes are those that would not materially affect the assessment of risks and benefits of the research (OHRP Institutional Review Board Guidebook, Chapter II http://www.hhs.gov/ohrp/irb/irb_chapter2.htm). See IRB guidance or SOPs for more details.	45 CFR46.110 (b) (2)
☐	Clinical studies of drugs and medical devices only when condition (a) or (b) is met:	(a) Research on drugs for which an investigational new drug application (21 CPR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CPR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.	46 FR 8392 (1)
☐	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:	(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.	46 FR 8392 (2)
☐	Prospective collection of biological specimens for research purposes by noninvasive means.	Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.	46 FR 8392 (3)
☐	Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)	Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.	46 FR 8392 (4)
☐	Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).		46 FR 8392 (5)
☐	Collection of data from voice, video, digital, or image recordings made for research purposes.		46 FR 8392 (6)
☐	Research on individual or group characteristics or behavior.	(including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.)	46 FR 8392 (7)
☐	Continuing review of research previously approved by the convened IRB as follows:	(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.	46 FR 8392 (8)
☐	Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.		46 FR 8392 (9)
☐	Facilitated Review of application previously approved by contracted external IRB (e.g. Central IRB).		
☐	Ceding Review to Non-UM IRB		

Exemption Category (if applicable):

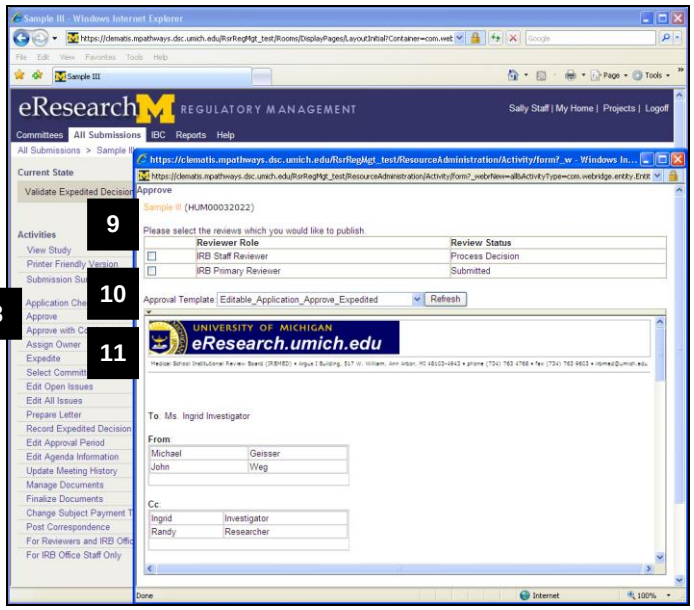
	Exemption Category
○	**EXEMPTION #1 of the 45 CFR 46.101.(b):** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
○	**EXEMPTION #2 of the 45 CFR 46.101.(b):** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
○	**EXEMPTION #3 of the 45 CFR 46.101.(b):** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Exemption #2 of this document, if: (i) the human subjects are elected or appointed public officials or candidates for public office or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and hereafter.
○	**EXEMPTION #4 of the 45 CFR 46.101.(b):** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
○	**EXEMPTION #5 of the 45 CFR 46.101.(b):** Research and demonstration projects which are conducted by or subject to the approval of [Federal] Department or [Federal] Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
○	**EXEMPTION #6 of the 45 CFR 46.101.(b):** Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
○	**EXEMPTION #7:** Research in which study activity is limited to analysis of identifiable data. For purposes of this research study, all research subject interactions and interventions have been completed and the data continues to contain subject identifiers or links. The research is not federally-funded, regulated by the FDA or conducted under a Certificate of Confidentiality. **(This category is for IRB Health and IRB Behavioral Sciences use only.)**

Clear

OK Cancel

5. Verify **Expedited Category**, if needed.
6. If the reviewer has determined this submission is exempt, verify the **Exemption Category**.
7. Click **OK**.

Approve Expedited Decision

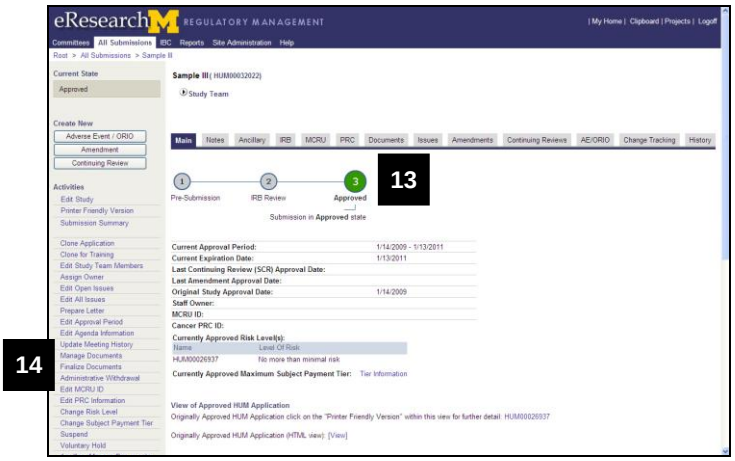


8. If the reviewer has approved, click **Approve**.
9. Optional, select the **Reviews** to be published.
10. Choose the **Approval Template** from the drop-down menu.
11. Review the **Approval Letter**.

    Tip: Verify that the correct committee, correct signature and correct approval date is displayed.

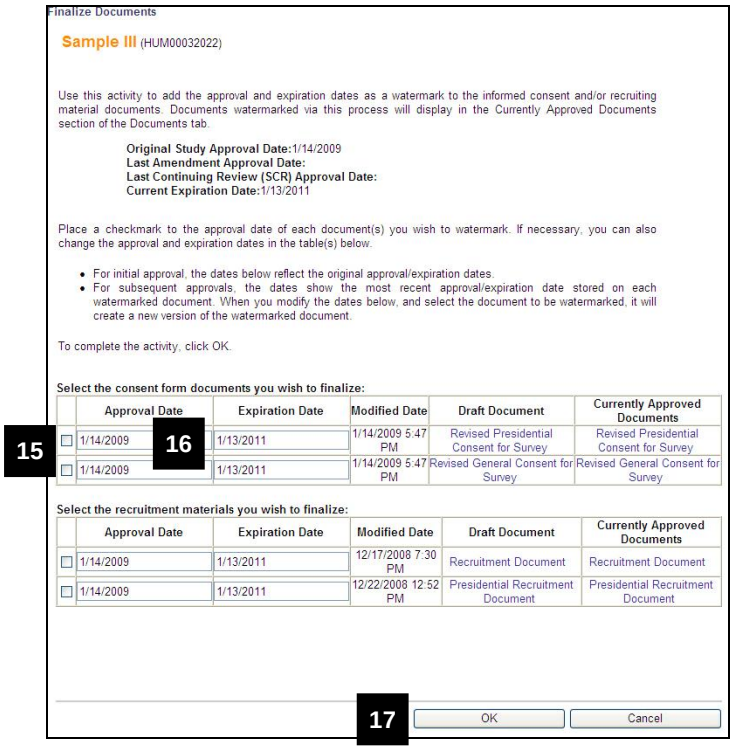
12. Click **OK**.

Study Workspace – Approved Study



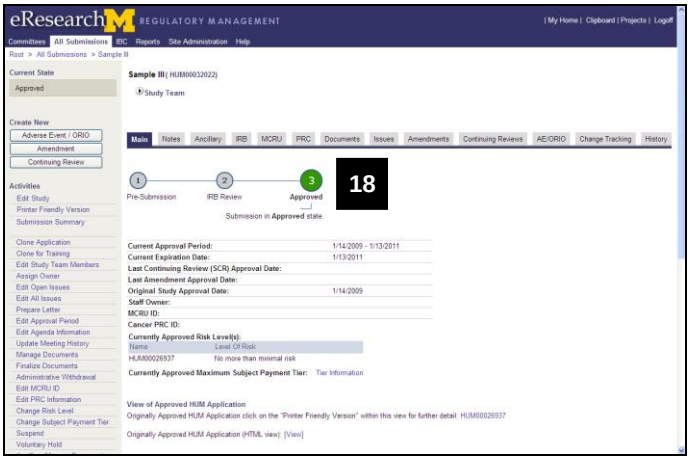
13. Verify the current state is **Approved**.
14. Click **Finalize Documents**.

Finalize Documents



15. Select the **Consent Form** documents and/or **Recruitment** materials to finalize.
16. Verify the dates and edit, if necessary.
17. Click **OK** to watermark the document(s) and move it to the Currently Approved Documents area under the Documents tab in the application workspace.

Submission Approval Complete



18. The Submission has been approved for research.

Exempt Determination

Important Information:

Exempt Determination denotes that the submission is exempt from Federal Regulation. The submission is not scheduled for a review meeting.

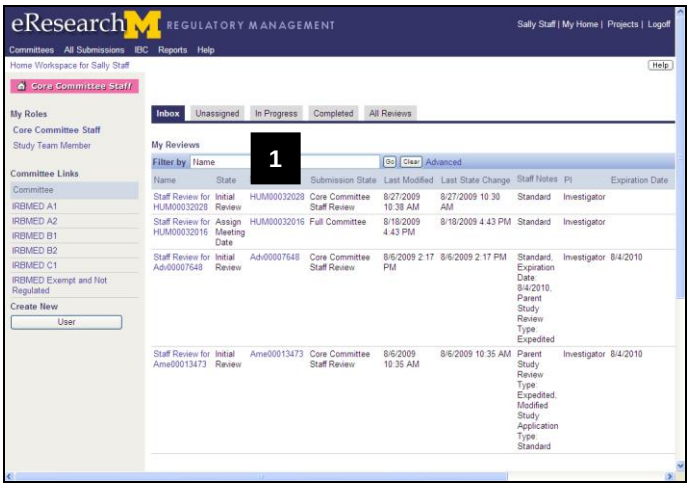
To complete an Exempt Determination, you must:

- STEP 1: Select the Submission that needs review.
- STEP 2: Select Committee (IRBMED only).
- STEP 3: Select Exempt Determination Activity to process the review decision.

⚠ **Prior** to completing the exempt review; staff need to complete the **Staff Reviewer Checklist**.

STEP 1 - Select the Submission

eResearch Home Workspace



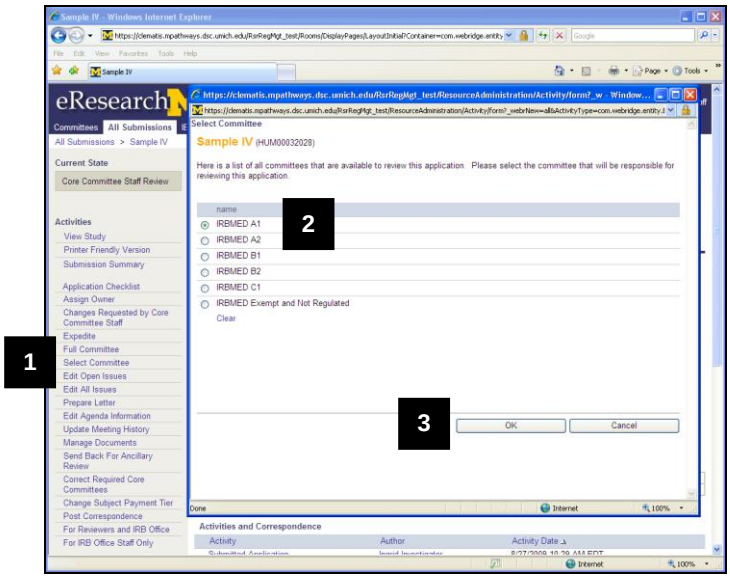
1. Select the submission that needs to be reviewed.

   Note: You must select the application by its submission ID and not its Project Name.

Study Workspace

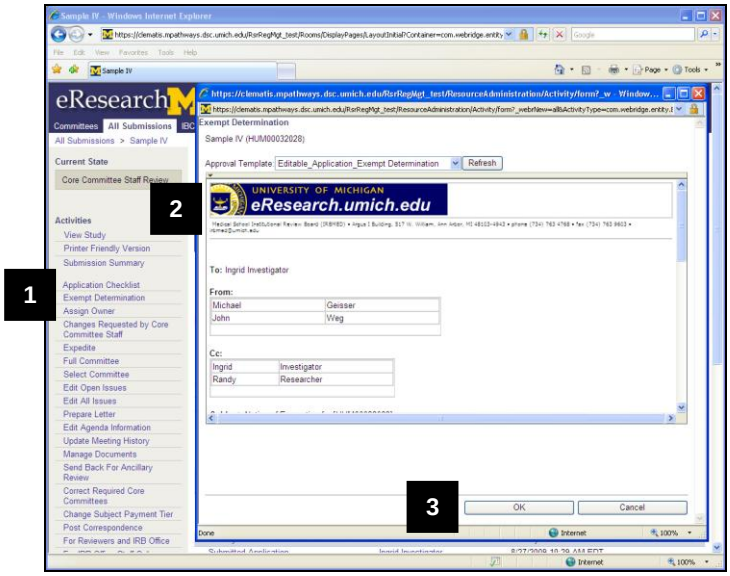
2. Verify the current state is **Core Committee Staff Review.**
3. Multiple functions can be performed from **My Activities**. See the **Review Activities** section for detailed information

STEP 2 - Select Committee (IRBMED)



1. If you are from IRBMED, click **Select Committee** to assign the submission to a committee.
2. Select the committee that will be responsible for reviewing the application.
3. Click **OK** to save your committee selection and return to the Study Workspace.

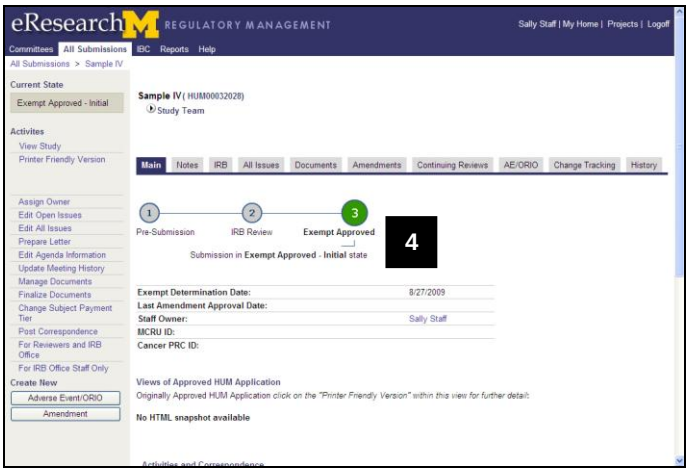
STEP 3 – Exempt Determination Activity



1. Click **Exempt Determination**.
2. View the **Approval Letter**.
3. Click **OK**.

Note: If the submission needs to be reviewed, follow expedite or full committee step-by-step instructions.

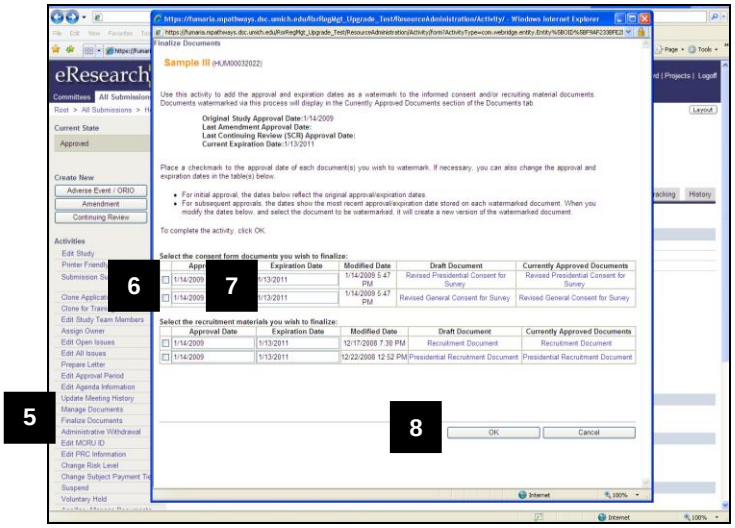
Exempt Approved - Initial



4. Verify the current state is **Exempt Approved – Initial**.

   Note: The submission is now approved.

Finalize Documents



5. Click **Finalize Documents**.
6. Select the documents to finalize.
7. Verify the dates and edit, if necessary.
8. Click **OK** to watermark the document(s) and move it to the Currently Approved Documents area under the Documents tab in the application workspace.

Not Regulated

Important Information:

A Not Regulated submission does not require IRB approval. A letter is prepared and sent to the study team, and the submission is stored in the Exempt & Not Regulated section of eResearch.

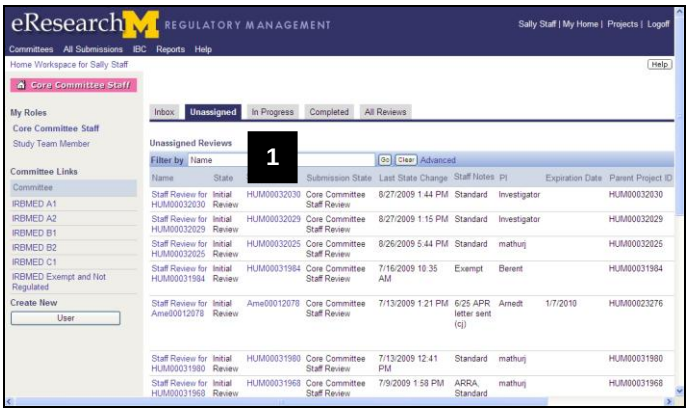
To complete a Not Regulated Review, you must:

- STEP 1: Select the Submission that needs review.
- STEP 2: Select Committee (IRBMED only).
- STEP 3: Select Not Regulated Determination Review Activity to process the review decision.

⚠ **Prior** to completing the Not Regulated review; staff need to complete the **Staff Reviewer Checklist**.

STEP 1 - Select the Submission

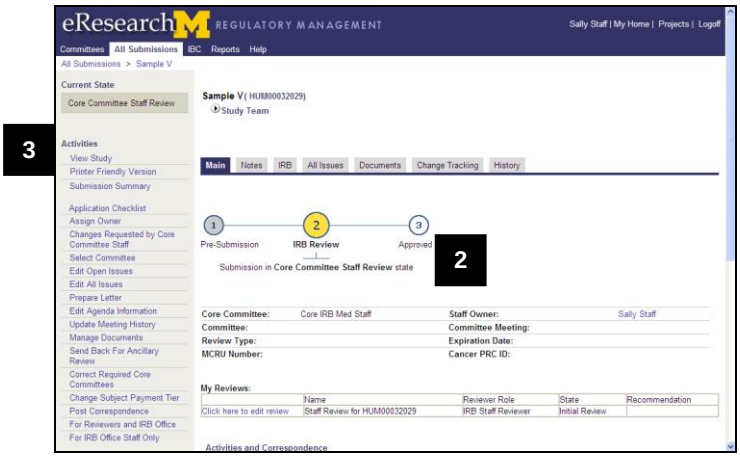
eResearch Home Workspace



1. Select the submission that needs to be reviewed.

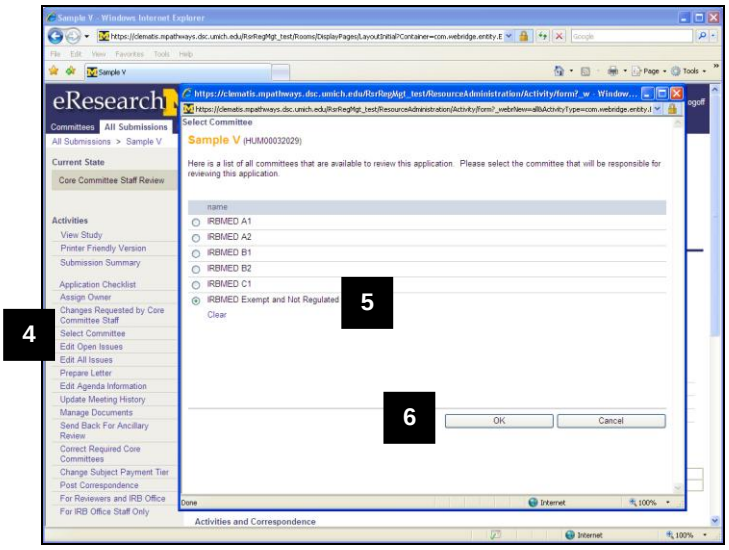
   Note: You must select the application by its submission ID and not its Project Name.

Study Workspace



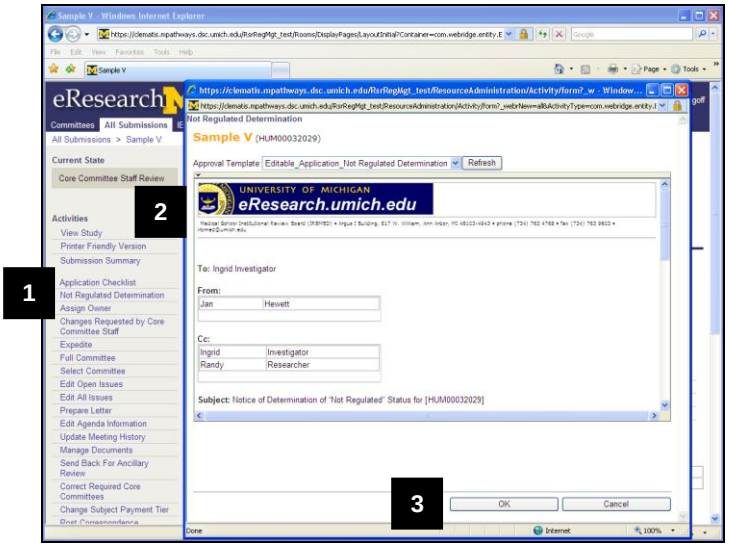
2. Verify the current state is **Core Committee Staff Review.**
3. Multiple functions can be performed from **My Activities**. See the **Review Activities** section for detailed information

STEP 2 - Select Committee (IRBMED)



4. If you are from IRBMED, click **Select Committee** to assign the submission to a committee.
5. Select the committee that will be responsible for reviewing the application.
6. Click **OK** to save your committee selection and return to the Study Workspace.

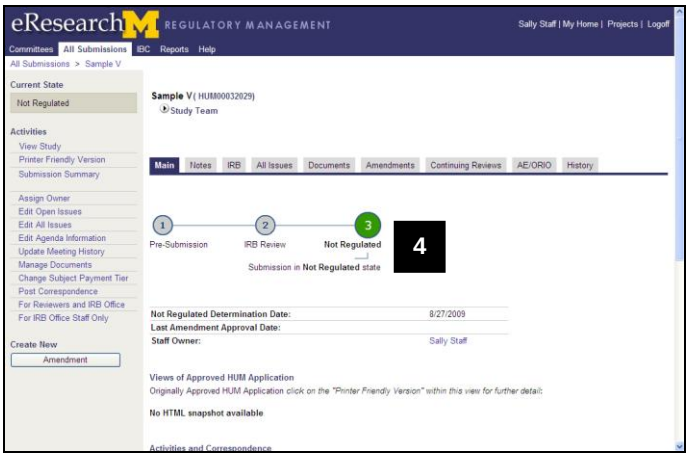
STEP 3 – Not Regulated Determination Activity



1. Click **Not Regulated Determination**.
2. Review the approval letter.
3. Click **OK**.

   Note: If the submission needs to be reviewed, follow expedite or full committee step-by-step instructions.

Not Regulated



4. Verify the current state is **Not Regulated**.

Full Committee Review & Adverse Event Review

Full Committee– The submission requires review by the full IRB committee. A committee is selected and primary and secondary reviewers, if needed, are assigned. You can also assign additional reviewers as needed. The submission is scheduled for review at an IRB meeting. Meeting decisions are recorded in eResearch by the Core Staff.

To complete a Full Committee Review, you must:

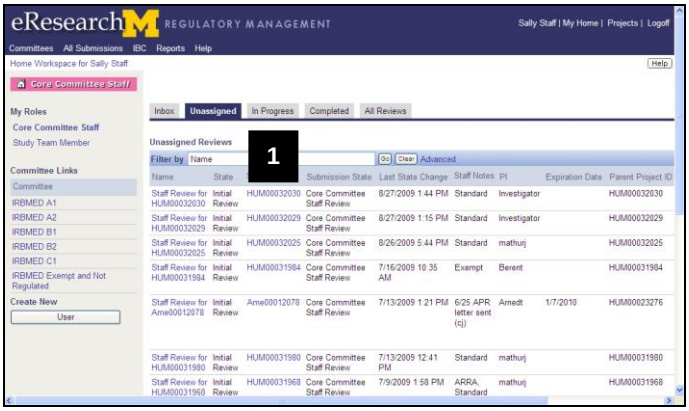
- STEP 1: Select the Submission that needs review.
- STEP 2: Select Committee (IRBMED, PRC, or MCRU only).
- STEP 3: Select Full Committee Activity to process the review decision.
- STEP 4: Assign Reviewer.
- STEP 5: Validate the Review (record review decision) which includes:
    - Record Discussion Elements
    - Record Committee Decision
    - Validate Committee Decision
    - Approval Letter
    - Finalize Documents

Note: The steps for a Full Committee Adverse Event & Full Committee review only differ in that Adverse Event/ORIO is the Agenda Item Type for a Full Committee Adverse Event.

⚠ **Prior** to completing the full committee review or adverse event review, staff should complete the **Staff Reviewer Checklist**.

STEP 1 – Select the Submission

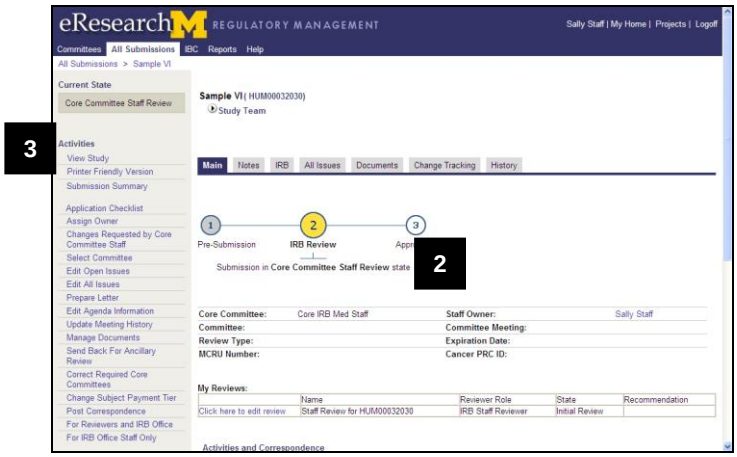
eResearch Home Workspace



1. Select the submission or adverse event that needs a full committee review.

   Note: You must select the application by its submission ID or adverse event ID and not its Name.

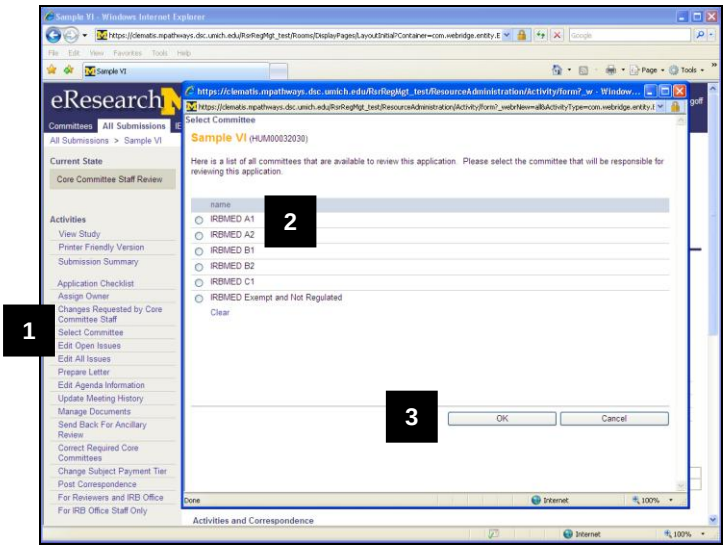
Core Committee Staff Review



2. Verify the current state is **Core Committee Staff Review.**
3. Multiple functions can be performed from **My Activities**. See the **My Activities** section for detailed information.

STEP 2 – Select Committee (IRBMED, PRC, or MCRU Only)

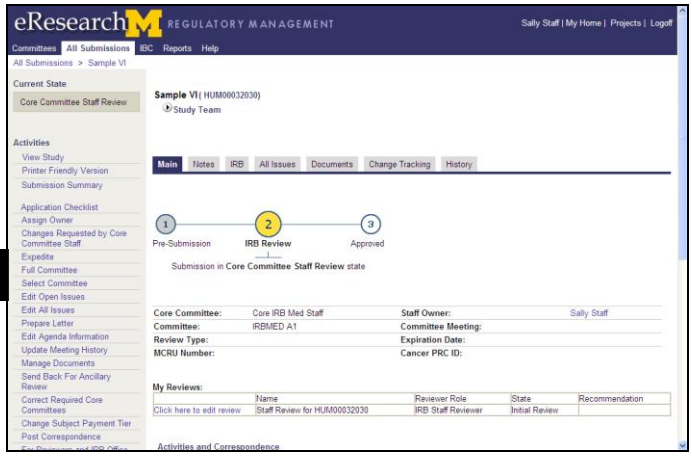
Select Committee



1. If you are from IRBMED, PRC, or MCRU, click **Select Committee** to assign the submission to a committee.
2. Select the committee that will be responsible for reviewing the application.
3. Click **OK** to save your committee selection and return to the Study Workspace.

STEP 3 – Full Committee Activity

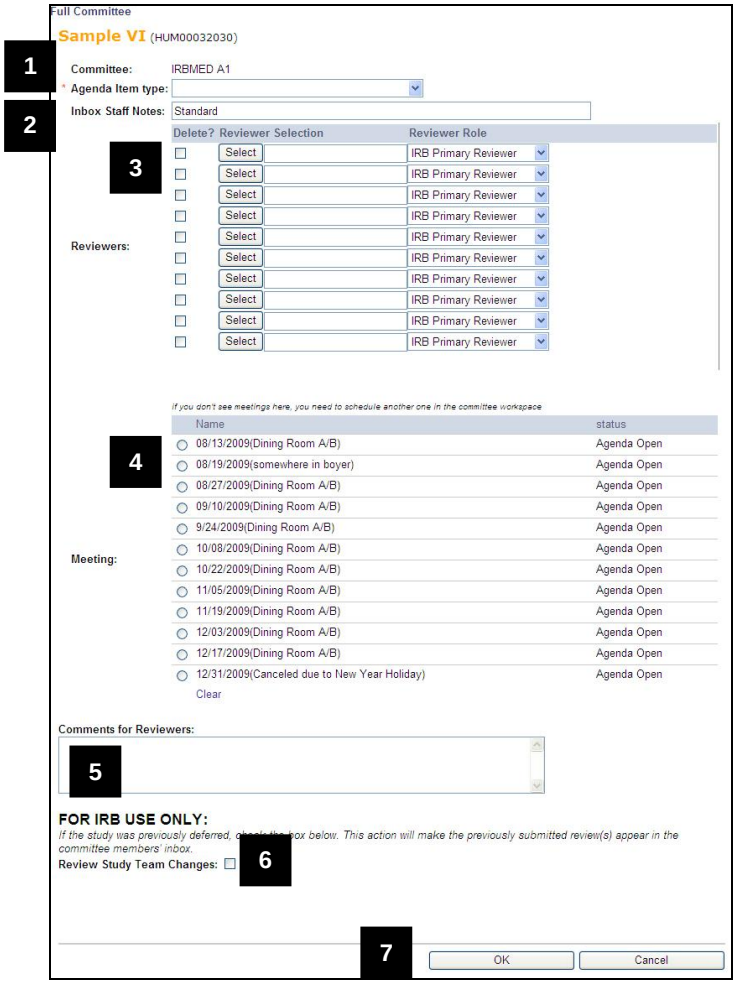
1



1. Click **Full Committee** to process the review decision.

   Note: If you are from IRBMED, PRC, or MCRU, Full Committee is not an option until you select your committee.

STEP 4 – Assign Reviewer – Assign to Full Committee



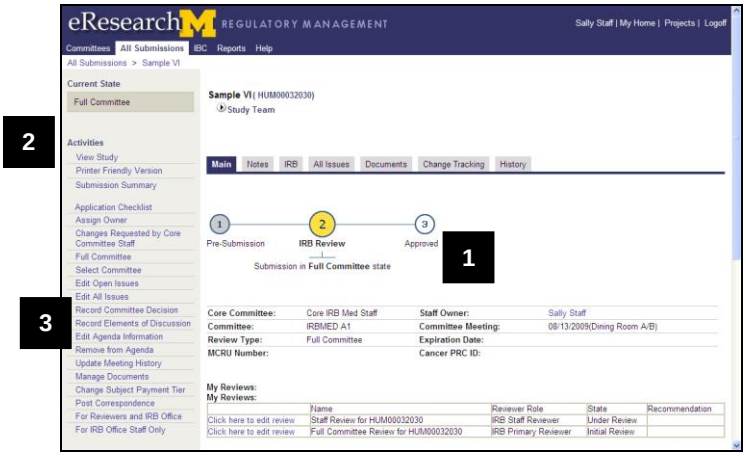
1. Select the **Agenda Item Type.** Options include:
   - New Study
   - Deferred Study
   - Deferred – Pending Clarification
   - Continuing Issues
   - Amendment
   - Adverse Event / ORIO
     Note: selected for adverse events
   - Reactivation Request
   - Scheduled Continuing Review
   - Final Reports
   - HIPPA Requirement
   - Discussion Items
   - Resubmission
   - Previous Meeting
   - IBC Registration
   - Unanticipated Problem Review
2. Add **Inbox Staff Notes**, if applicable.
3. Use **Reviewer Selection** to select Primary, Secondary, Regulatory, Scientific, and Other Reviewers, if applicable.

   Note: If desired, Staff can assign Reviewers and not assign a meeting, or assign a meeting and not assign Reviewers.
4. Choose the **Meeting Date**.
5. Enter **Comments for Reviewers**, if applicable.
6. If you are from IRB, select **Review Study Team Changes** if the study was previously deferred.

   Note: This will make the review appear in the committee members' inbox.
7. Click **OK** to submit the review to the full committee.

STEP 5 – Validate the Review (Record Review Decision)

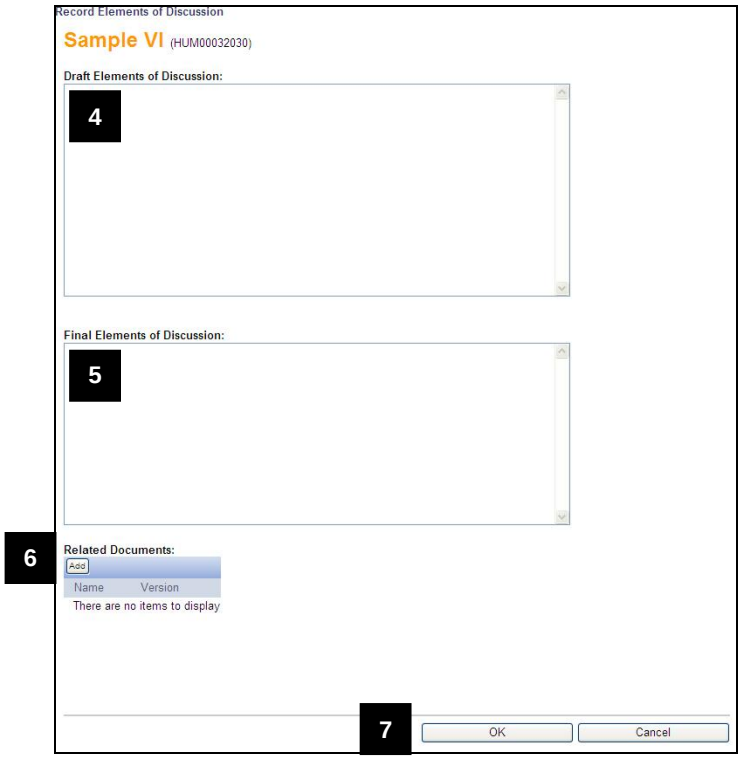
Full Committee Review



1. Verify the current state is **Full Committee**.
2. The following new actions can be performed from **My Activities**:
   - **Full Committee**: Used to add, delete, and/or modify agenda item type, inbox staff notes, reviewers, meeting date and conflicted committee members.
   - **Record Committee Decision**: Used to record the results of the meeting (does not send the PI any correspondence).
   - **Record Elements of Discussion**: Used to record both the draft and final elements of discussion and to add any related documents.
   - **Remove from Agenda**: Removes the submission from the meeting agenda it is currently assigned to.

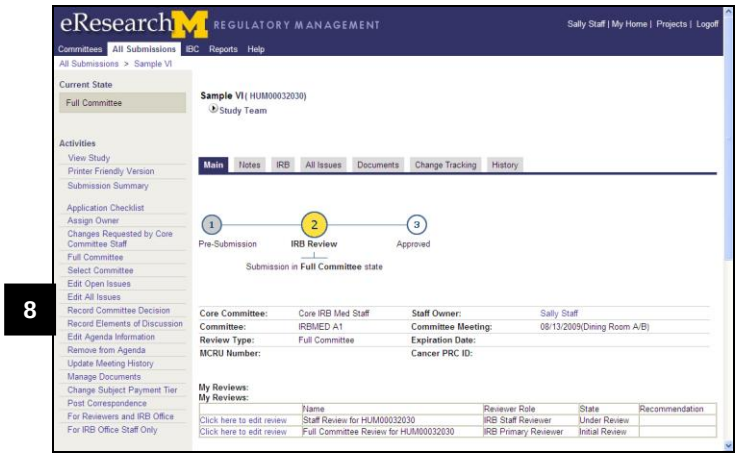
     Note: The Reviewer Checklist will remain with the currently assigned Reviewer(s) unless you delete the Reviewer in the Full Committee or Expedite activity.
3. Click **Record Elements of Discussion**.

Record Elements of Discussion



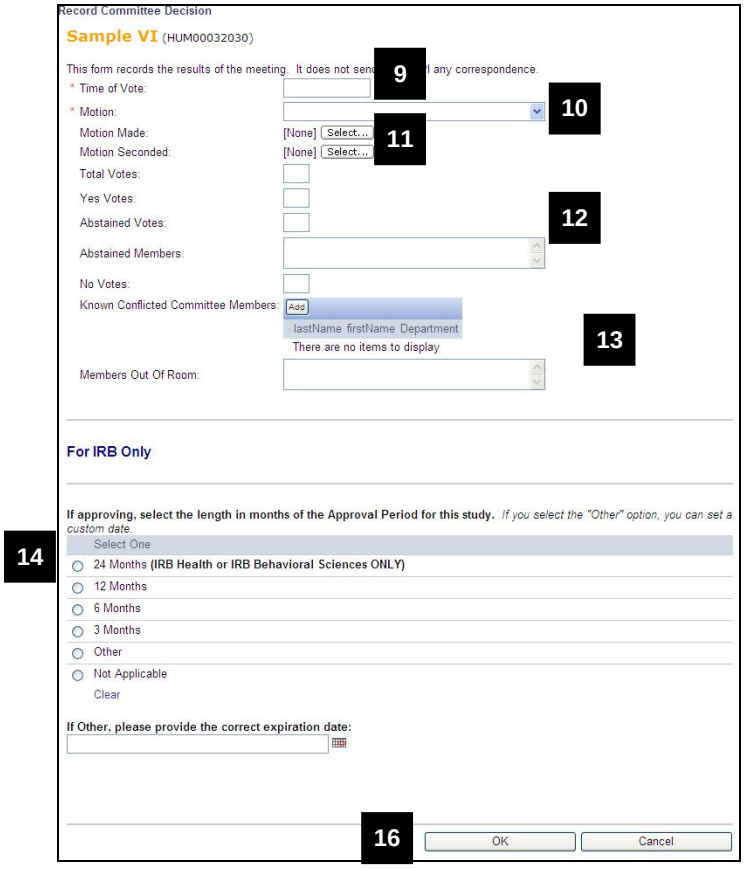
4. Enter **Draft Elements of Discussion**.
5. Optional – enter **Final Elements of Discussion**.
6. Add **Related Documents**, if applicable.
7. Click **OK**.

Study Workspace



8. Click **Record Committee Decision**.

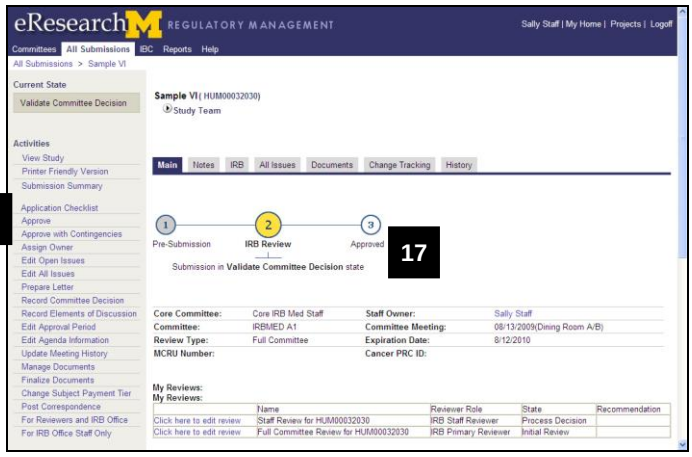
Record Committee Decision



9. Enter **Time of Vote**.
10. Choose **Motion**.
    - Approved
    - Approved with Contingencies
    - Action Deferred Pending Study Team
    - Exempt Determination
    - Action Deferred Pending Core Committee
    - Not Regulated Determination
    - Disapproved
    - Disapproved Final
    - Tabled

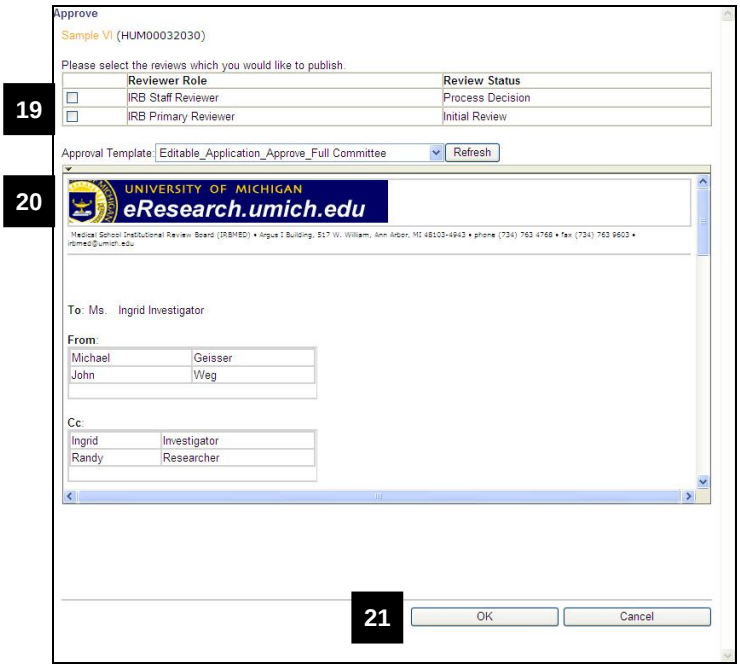
    Note: This example assumes the motion is approved. For more information about the various motion types, see *Module 6: Validating Decisions*.
11. If applicable, select the **Committee Member** for **Motion Made** and **Motion Seconded**.
12. Enter **Total Votes**, **Yes Votes**, **Abstained Votes**, **Abstained Members** and **No Votes**.
13. Add **Known Conflicted Committee Members** and **Members Out of Room**, if applicable.
14. IRB Only: Select the length in months of the **Approval Period** for the study.
15. Adverse Event full committee review only, answer if the board considered this submission for an unanticipated problem.
16. Click **OK**.

Validate Committee Decision



17. Verify the current state is **Validate Committee Decision**.
18. If the motion was approved, click **Approve**.

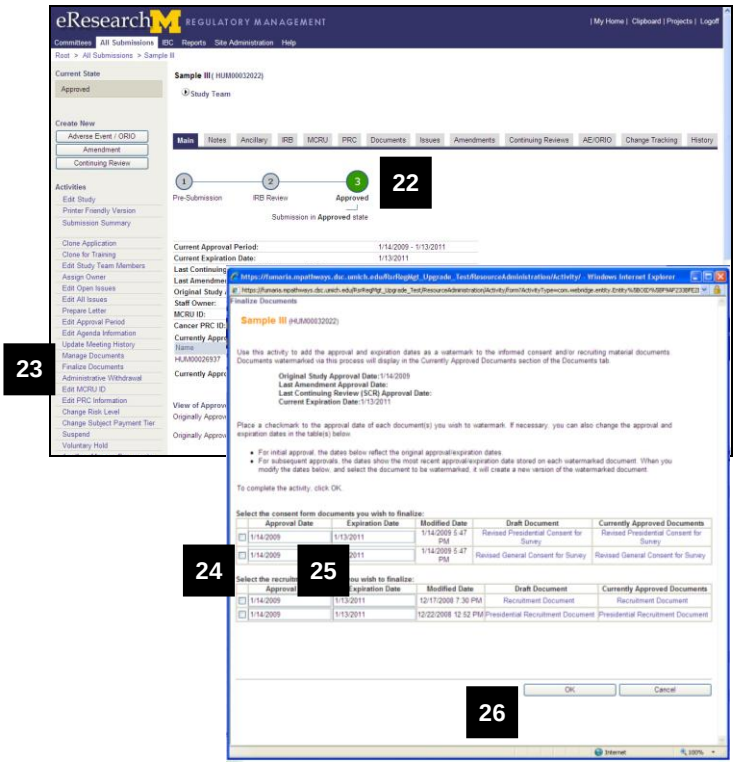
Approval Letter



19. If desired, select the **Reviews** to be published.
20. Verify **Approval Letter** contents.

    Tip: Verify that the correct committee, correct signature and correct approval date is displayed.
21. Click **OK**.

Post Approval – Finalize Documents



22. Verify the current state is **Approved**.
23. Click **Finalize Documents**.
24. Select the **Consent Form** documents and/or **Recruitment** materials to finalize.
25. Verify the dates and edit, if necessary.
26. Click **OK** to watermark the document(s) and move it to the Currently Approved Documents area under the Documents tab in the application workspace.

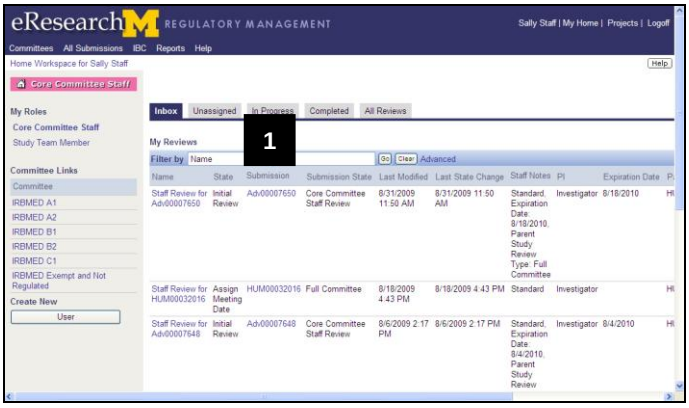
Adverse Event – Single Member Review

To complete an Adverse Event – Single Member Review, you must:

- STEP 1: Select the Submission that needs review.
- STEP 2: Select Single Member Review Activity and Assign Reviewer.
- STEP 3: Validate the Review (record review decision) which includes:
  - Record Decision
  - Approve Decision

STEP 1 - Select the Submission

eResearch Home Workspace



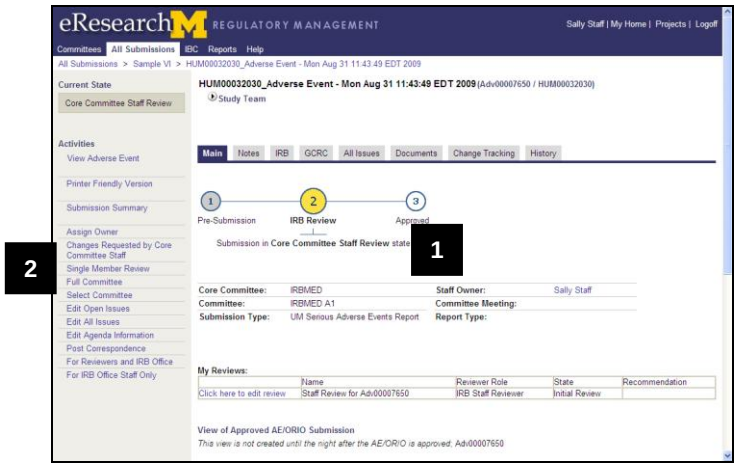
1. Select the adverse event that needs a single member review.

   Note: You must select the application by its submission ID and not its Name.

   Note: If your adverse event needs a full committee review, follow the Full Committee Review & Adverse Event procedure.

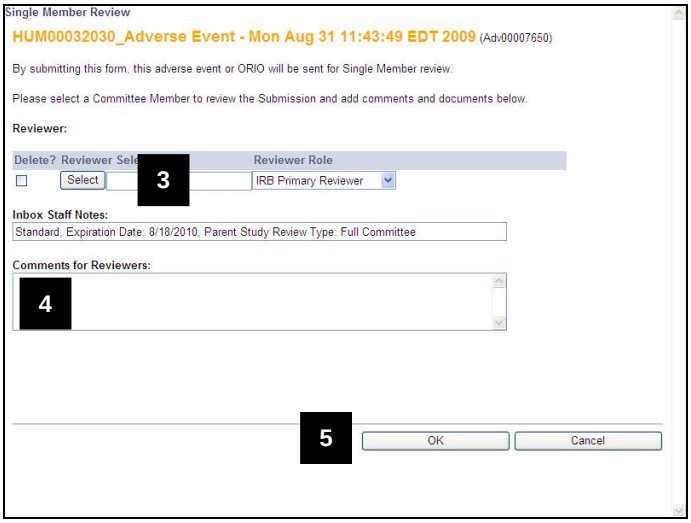
STEP 2 - Select the Single Member Review Activity & Assign Reviewer

Study Workspace



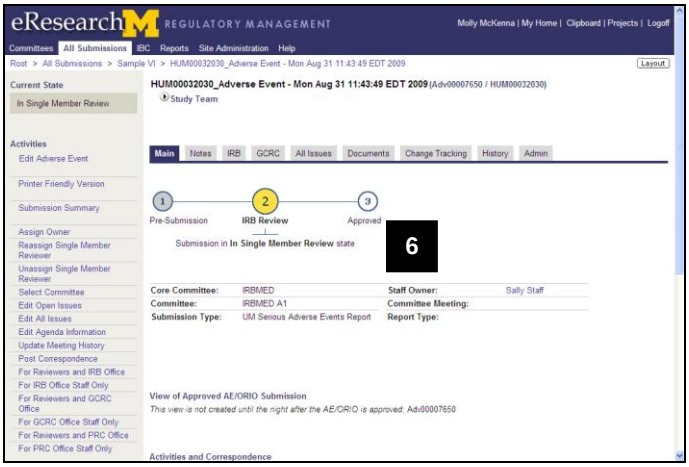
1. Verify that the current state is **Core Committee Staff Review.**
2. Click on **Single Member Review**

Select Single Member Review



3. Select the Primary Reviewer.
4. Enter Inbox Staff Notes and Comments for Reviewers, if applicable.
5. Click **OK**.

Study Workspace



6. Verify that the current state changed to **In Single Member Review.**

   Note: The Single Member Review activity no longer appears as an option under my activities.

   If you need to assign a different reviewer, use the **Unassign Expedited Reviewer** or **Reassign Expedited Reviewer** buttons under My Activities.

   Note: You cannot validate the review (record your review recommendation) until:

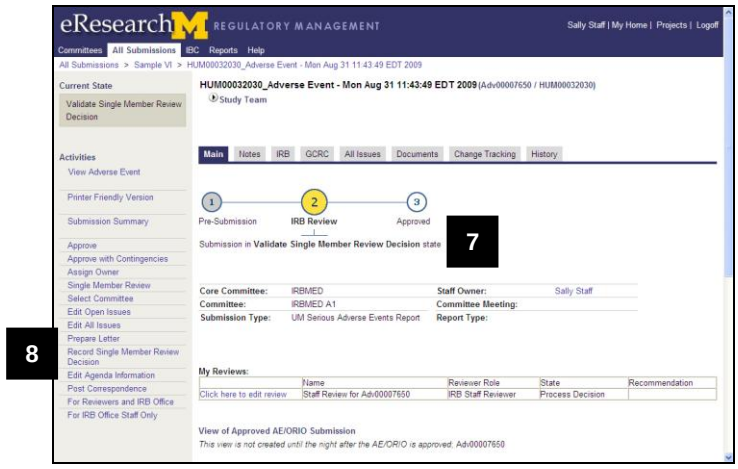
   - Your assigned reviewer completes the Committee Member Reviewer Checklist

     and

   - the study state changes to **Validate Single Member Review Decision**.

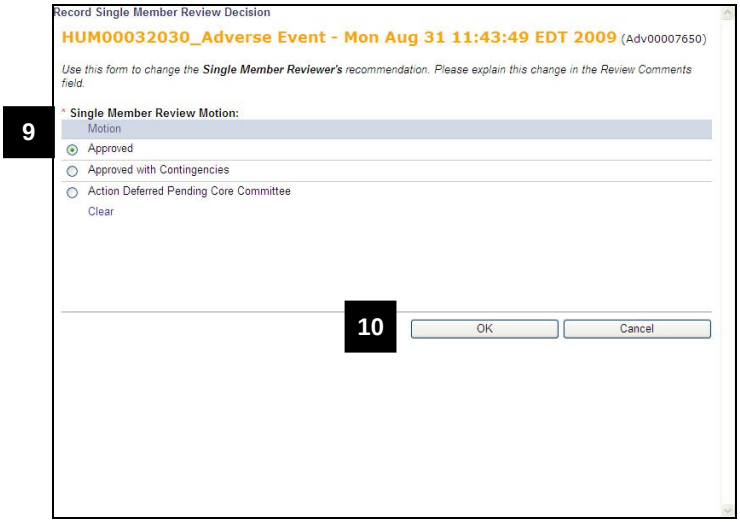
STEP 3 - Validate

Record Single Member Review Decision



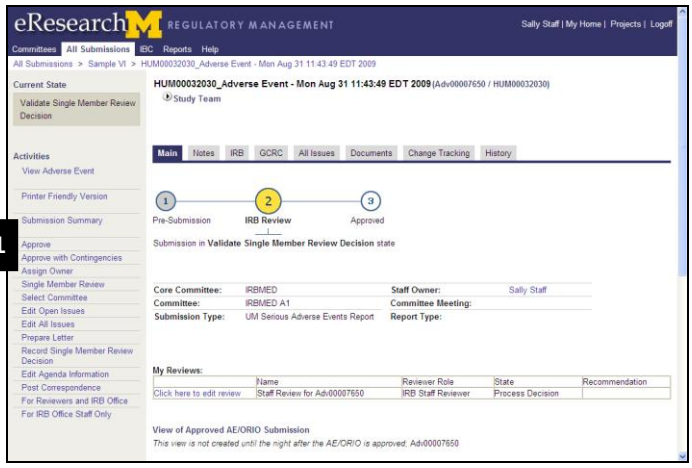
7. Verify that the current state is **Validate Single Member Review Decision**.
8. Click **Record Single Member Review Decision.**

Single Member Review Motion



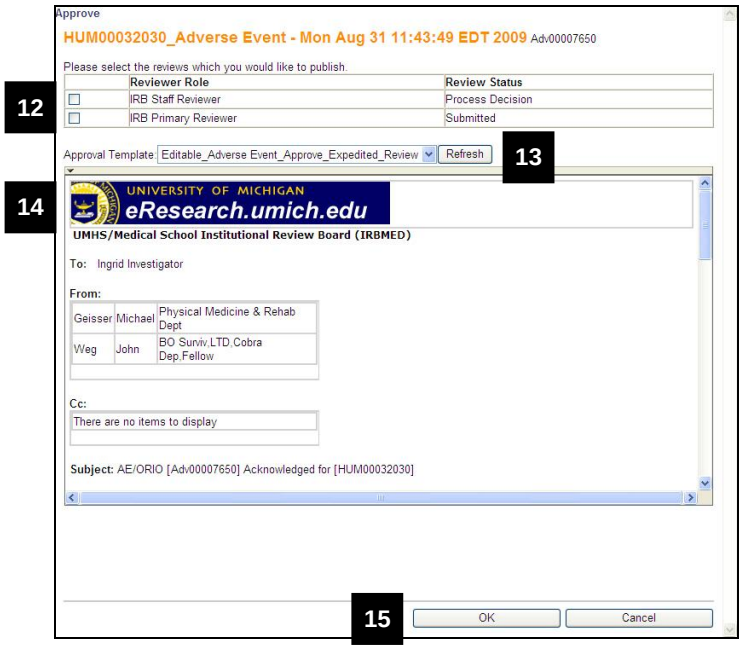
9. Choose the appropriate **Single Member Review Motion**.
10. Click **OK.**

Approve Single Member Review Decision



11. Click **Approve**.

Approve



12. Optional, select the **Reviews** to be published.
13. Choose the **Approval Template**.
14. Review the **Approval Letter.**

    Tip: Verify that the correct committee, correct signature and correct approval date are displayed
15. Click **OK.**