

eResearch Release 1.4.1

Overview of Changes

This document provides a description of changes to the eResearch system that may impact core staff functions. These changes are effective April 9, 2006.

New Application

- I. The Record Expedited Decision activity record now appears under the Correspondence tab in the For Reviewers and IRB Office section when the study is in the state Exempt Approved - Initial.
- II. The Submit-Edit Expedited Review activity record now appears under the History tab for studies in the state Exempt Approved - Initial.
- III. The 30-, 60-, and 90-day renewal notices and renewal deadline reminder activities now display in the Correspondence tab on the approved study.

Amendment

- IV. To improve system performance, amendment creation is now a background task. The person who creates the amendment can select which study team member should receive notification that the amendment has been created and is available for editing.
- V. For Amendments, the Record Expedited Decision activity record now appears under the Correspondence tab in the For Reviewers and IRB Office section when the Amendment is in the state Approved.

Amendment and Continuing Review

- VI. The Approve and Change to Exempt activity is now available in the state Core Staff Contingency Review for Amendments and Continuing Reviews.

All Submission Types

- VII. The Changes Requested by Core Committee Staff activity is now available in the state Core Committee Staff Contingency Review. When this activity is performed, the submission is transitioned to the state Contingencies Pending.
- VIII. The Select Committee activity is now available in the state Validate Expedited Decision.
- IX. The Reassign Expedited Reviewer activity has been removed from the state Validate Expedited Decision.
- X. The activity Record Elements of Discussion has been removed from the state Approved.
- XI. Records of completed activities for the following notifications are now listed under the Correspondence and History tabs:
 - o The 14- and 28-day notifications for submissions in states Changes Required by Core Staff and Contingencies Pending.
 - o The 30- and 60-day notifications for new applications in states Pre Submission and Complete Application.

Home Workspace

- XII. A new version of the All Studies tab has been created and moved to be the default tab. The tab does not list studies in the states Original Version, Modification Open and Modification Closed.
- XIII. Upon submission, the current expiration date populates the inbox staff notes for amendments and continuing reviews.

Adverse Event/ ORIO Workspace and Forms

- XIV. Pending contingencies for Adverse Events are now listed under the Pending Contingencies tab in the Adverse Event workspace.
- XV. The following changes were made to the Adverse Event/ORIO form:
 - o Section 0.2 - The "Report(s) to or from oversight entity" option now includes the text "(including reports of study activity conducted during lapse of IRB approval)."
 - o Section 7.1 - The "Internal UM office (University Internal Audits, IRB, ORCR, OVPR)" option now includes the text "(or reports of study activity conducted during lapse of IRB approval)."
 - o Section 7.5 - The text "Investigators' Response: Briefly discuss how the report information will be addressed, rectified or resolved." now includes the text "(If reporting a study lapse, briefly describe any study activity conducted during lapse of IRB approval)."

Committee Information

- XVI. In the Full Committee activity form, the previous two weeks of meetings are now displayed in addition to the future meetings.
- XVII. Confirmed non-member attendees now display on printable meeting minutes.
- XVIII. In the Committee workspace, past meetings now display in descending order based on meeting ID.
- XIX. The Recommended Motions from the Submit-Edit Primary Review and Submit-Edit Secondary Review activity forms do not appear on meeting minutes.
- XX. For Continuing Reviews, the View Agenda by reviewer, and View Agenda by submission type now displays the current expiration date of the study.

For additional information, including the updated step-by-step procedures for Creating an Amendment, please refer to the [Release Notes](#) for Release 1.4.1 on the eResearch website.