eResearch Release 1.4

Overview of Changes

This document provides a description of changes to the eResearch system that may impact core staff functions. These changes are effective March 4, 2006.

I. For all submissions in the state Core Staff Contingency Review, the activity Changes Requested by Core Staff has been replaced with the Approved with Contingencies activity. This change allows staff to send an updated Contingency letter each time the study team responds to contingencies.

II. The Exempt Review workflow has been corrected so that submissions that are Approved with Contingencies will now move to the state Exempt Approved – Initial when the final approval letter is posted.

III. The Expedite activity has been added to the state Validate Expedite Decision for all submissions. This allows the staff to reassign the submission to a different expediting reviewer or return the submission to the original expediting reviewer.

IV. On the Record Expedited Decision activity page the motions of Disapproved and Disapproved Final have been removed. These motions have also been removed from the Submit-Edit Expedited Review activity page.

V. Updates have been made to the Administrative Review process, including:

- The Submit Administrative Review activity now moves submissions to the state Validate Administrative Decision.
- The Approve and Change to Exempt activity has been added for amendments and continuing reviews.
- The termination letter template has been added to the Approve activity for continuing reviews.

VI. The following completed activities now display on the Correspondence tab under “For Reviewers & IRB Office”:

- Administrative Review
- Submitted Administrative Review
- Recorded Administrative Decision

VII. The following changes have been made to the Correct Required Core Committee activity page:

- only one IRB can be selected
- PRC and GCRC have been removed as options
- the staff owner is cleared upon completion of the activity allowing the study to display on the Unassigned Applications tab for the new IRB
- the completed activity displays on both the Correspondence and History tabs
- the activity sends a notification to the PI and the study team members
- a comment field has been added

VIII. Users with the role Core Committee Super Admin can now submit all application types on behalf of the PI.

IX. The Inbox Staff Notes can now be edited on the Changes Requested by Core Committee Staff activity

page.

X. The Approve activity page for Emergency Use submissions no longer displays an error message when no expiration date is entered.

XI. Studies that have received approval by the NIH NCI Central IRB can now be processed in eResearch using Facilitated Review, which is included in the Expedited Review workflow. A Facilitated Review option has been added to the list of Expedited categories on both the Expedited and Submit-Edit Expedited Review activity pages.

XII. The Edit Committee Members detail page now allows staff to update Conflict of Interest and Areas of Expertise.

XIII. In the Assign Owner activity page for Adverse Events, the select owner process has been changed to match all other Assign Owner activity pages.

XIV. The following information now auto-populates in the Staff Notes column upon submission:

- New Applications
  - Study Type (Umbrella, Standard, Emergency Use, Humanitarian Use Device, Facilitated Review)
  - Exemption
  - Student Project
  - Waiver
  - Documentation Waiver
- Amendments
  - Study Type (Umbrella, Standard, Emergency Use, Humanitarian Use Device, Facilitated Review)
  - Expiration date at time of submission
  - Review Type of parent submission (Expedited or Full Board)
- Continuing Reviews
  - Study Type (Umbrella, Standard, Emergency Use, Humanitarian Use Device, Facilitated Review)
- Adverse Events
  - Study Type (Umbrella, Standard, Emergency Use, Humanitarian Use Device, Facilitated Review)

XV. The following information now auto-populates in the Staff Notes column when a review is submitted:

- All submissions
  - Primary review submitted
  - Expedited review submitted
  - Contingency review submitted

XVI. The following information now auto-populates in the Staff Notes column when a new application is approved:

  - Expiration date

XVII. The “Agenda Item History” data now displays on the History tab for studies that are Action Deferred.

For additional information please refer to the Release Notes for Release 1.4 on the eResearch website.