

Release 1.6 Core Staff Overview of Changes

Overview of Changes

This document provides a description of changes included in release 1.6 of the eResearch system, specifically related to the Core Committee Staff. These changes are scheduled to be implemented August 20, 2007.

Changes for Core Committee Staff

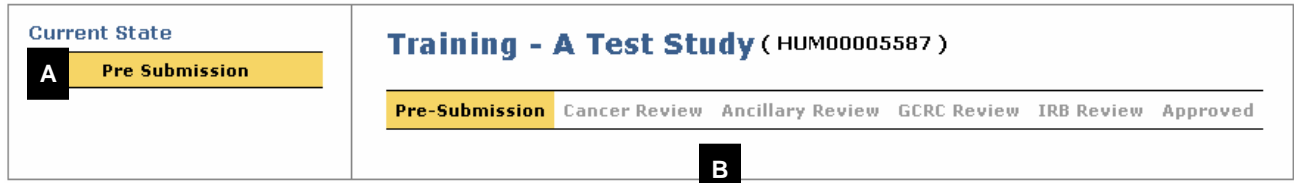
- I. Status Meter Redesign
- II. Unassign Expedited Reviewer
- III. Highlighted Jump-To
- IV. Links in email notifications
- V. 24 Month Approval
- VI. New Exemption Category
- VII. Supporting documentation in approval letters
- VIII. Summary of Fixes
- IX. Form changes

Details

The following pages provide details about the changes listed above.

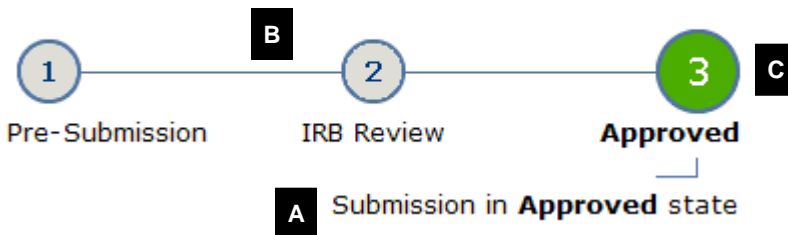
I. Status Meter Redesign

Current Design



New Design

Sample Study III (HUM00014348)



Note the following changes to the status meter display display:

- A The current study state is displayed under the status meter.
- B The status meter is now dynamic and changes based on the routing determined by the submission. If Cancer, Ancillary, or GCRC reviews are not required for the submission, they will not display on the status meter.
- C The current state of submission is colored and the circle is larger. A red circle indicates that the submission requires an action by the study team. A yellow circle indicates the submission is under review and a green circle indicates it is approved.

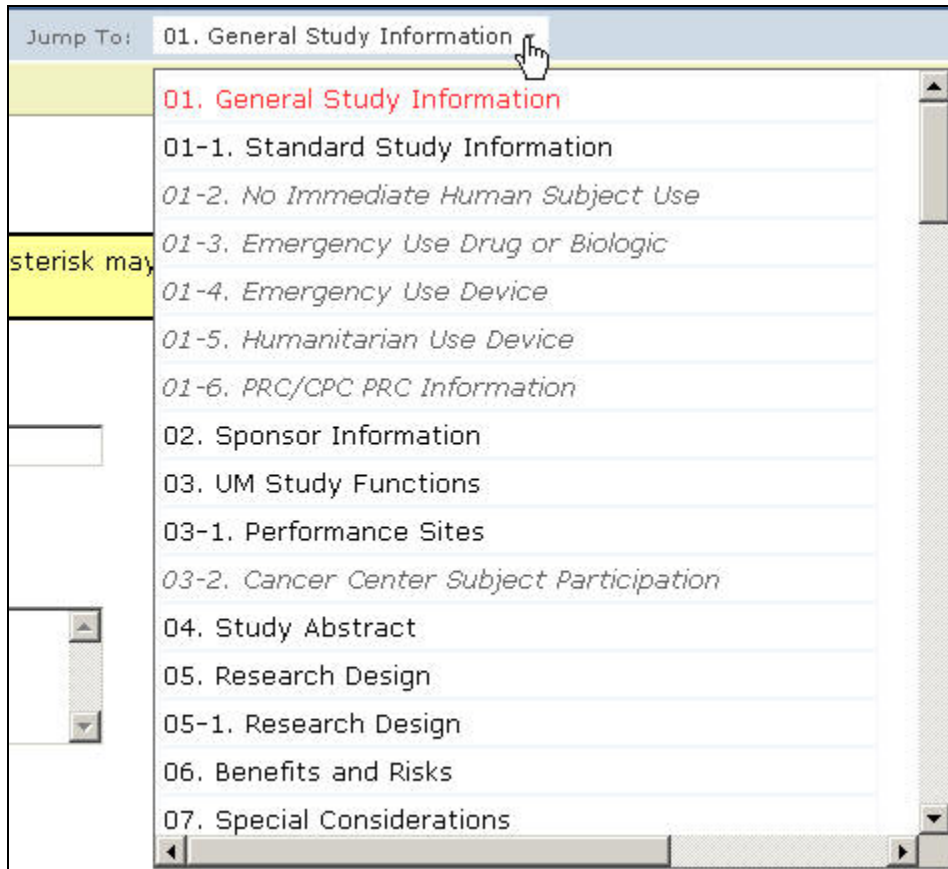
II. Unassigned Expedited Reviewer Activity

A new activity, Unassigned Expedited Reviewer, has been added to the Core Committee Staff workspace for applications, amendments and SCRs. A new activity, Unassign Single Member Reviewer, has been added to the Core Committee Staff workspace for adverse events/ORIOs. Both activities do the following:

- Remove all currently assigned reviewers
- Change the state of their review to withdrawn
- Change the state of the submission to core committee staff review

III. Highlighted Jump-To

The drop down menu in the application now displays the required sections in bold and non-required sections in italics based on what the user has completed thus far in the smartform logic. The current section displays in red.



IV. Links in email notifications

There was a problem with links in notifications for users who view email in plain text mode (vs. HTML). These links will now take users directly to the submission noted in the email.

eResearch still recommends that users set their email client to display email in HTML format. For instructions on doing this refer to the FAQ on the eResearch Web site.

V. 24 Month Approval

For IRB-Behav Sci/Health Sci applications that are not FDA regulated, federally funded, clinical interventions, involve prisoners or were issued a Certificate of Confidentiality, the IRB can issue a 2 year approval. This capability has been added to eResearch via a new approval period option and new approval letter templates.

VI. New Exemption Category

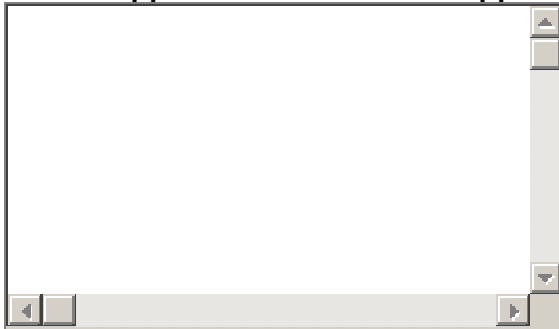
For IRB-Behav Sci/Health Sci applications that are not FDA regulated, federally funded, clinical interventions, involve prisoners or were issued a Certificate of Confidentiality, the IRB can issue a 2 year approval. New exemption category #7 has been added to section 12 of the application and to the list of possible exemption category determinations in the reviewer checklist form. The category reads as follows: "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. Research which is federally funded, FDA regulated or was issued a Certificate of Confidentiality may not select this category. (This category is for IRB Health and IRB Behavioral Sciences use only)."

VII. Supporting documentation in approval letters

Some sponsors for clinical trials require that IRB approval letters contain a list of the supporting documents approved with the application. To support this, new question 44.2 has been added to the application and amendment forms, and new question 14.1 has been added to the adverse event form. Only studies going through IRBMED will see this new question. The new question allows the study team to list the names of the supporting documents as they would like them to appear on the IRBMED approval letter.

If the study sponsor requires that the IRBMED approval letter contain a list of supporting documents, list the names of the documents in the box below as they should appear on the IRBMED approval letter:



VIII. Summary of Fixes

Activities

- Auto-generated contingencies will no longer be created for items that were responded to with "no electronic documentation available" prior to Release 1.5.
- The created by field for auto-generated contingencies (issues) will display as a blank field. Currently, the field displays IRB Reviewer.
- The Changes Requested by Core Committee activity referenced the Edit Identified Issues activity, which as of Release 1.5.4., is no longer in use. The activity form has been updated to reference the Edit Open Issues activity.
- Staff must select a reviewer when executing the Refer to Designated Reviewer activity to review contingencies. An error message will appear if a reviewer is not selected.

Inbox

- The staff notes for SCRs were often incorrectly displaying the parent original review type. This has been corrected.

Meetings

- When the reviewer is changed on a submission, the original reviewer's, along with the new reviewer's name, was displaying on the printer friendly agendas. Now only the current reviewer's name will display.

- The Submission Summary for Adverse Events will now display the current risk level and expiration date.

Notifications

- The date of approval on the amendment approval letter for Expedited and Full Committee Review was displaying incorrectly. This has been corrected.
- The Continuing Report Approve with Contingencies and Action Deferred Pending Study team notifications incorrectly referenced an obsolete activity, Create Related Amendment. This has been corrected.
- In the Withdrawn and Changes requested by Core Committee activities for Adverse Event, the notification setting has been updated so they will be sent to all study team members that are authorized to receive notifications.
- When a change to the study team has occurred while a Continuing review is in progress, the updated list of study team members was not displaying correctly in the Continuing Review final outcome letters. This has been corrected.
- The approval letter for Exempt Continuing Reviews was truncating the exemption category. This has been corrected.

Review

- The printer friendly version for SCR Terminations was incorrectly displaying the original study instead of the current submission. This has been corrected.
- A printer friendly version of the reviewer checklist has been added.
- If the SCR submission type is changed from renewal to termination, the related reviews submission type will now change to correspond with the new SCR submission type.

Workspace

- Under the documents tab, the link to the documents in form section 1-1.4 is now active.
- eResearch will only track and display PEERRS data for human subject research modules.
- PEERRS data will no longer truncate on the study team member detail window for Amendments, Continuing Reviews and Adverse Events/ORIOs.
- The expiration date column has been removed from under the documents tab in submission workspaces.
- The parent study's last SCR approval date is updated when the SCR is approved.
- PI is now searchable across project types.
- For emergency use device studies, the Submission Summary and Documents tab are now active.
- The reviewer field in the submission summary page was removed. Application, AE, Continuing report and Amendment all had this field which was not being populated and was blank. The field was removed in all the 4 areas only in the submission summary page
- The All Issues tab in the amendment, continuing review and adverse event/orio workspaces is now displays the same information as All Issues tab in Applications.

Other

- An instruction page has been added to the Internal Server Error -1 error page that reads: "The system is currently not able to process your request. Please try again later.

If the problem persists, please contact the MAIS Help Desk at 734-936-7000 or maishelpdesk@umich.edu"

IX. Form Changes

Study teams can now submit applications, amendments, adverse events/ORIOS, and continuing review from within the form. Previously, this activity had to be completed on the submission workspace.

The activities included section 45 of the application are:

Notify Study Team Members to Accept Roles	Sends an email notification to selected study team members requesting them to accept their role.
Error Check	System check to see if all required sections of the application are complete.
Move to Ready to Submit Inbox	Sends an email to the selected study team members that the application is ready to submit and moves the application into the Ready to Submit section of the Inbox for all who have access to submit.
Submit	Submits the application.

For a complete list of form changes refer to the [form changes for Release 1.6 spreadsheet](#).