

## **Regulatory Management Upgrade – Overview of Changes**

### **Overview**

The eResearch Regulatory Management system is scheduled for a software upgrade on April 30, 2017. This document provides a description of changes included in the upgrade.

### **Major Changes**

- I. Look and feel changes including:
  - New banner
  - Menu breadcrumbs
  - Updated button look
  - Updated icon images
- II. Document management:
  - New drag and drop functionality when adding documents
  - Upload revision
  - View revision history and delete document
- III. New workspace layout:
  - Similar layout throughout all project types

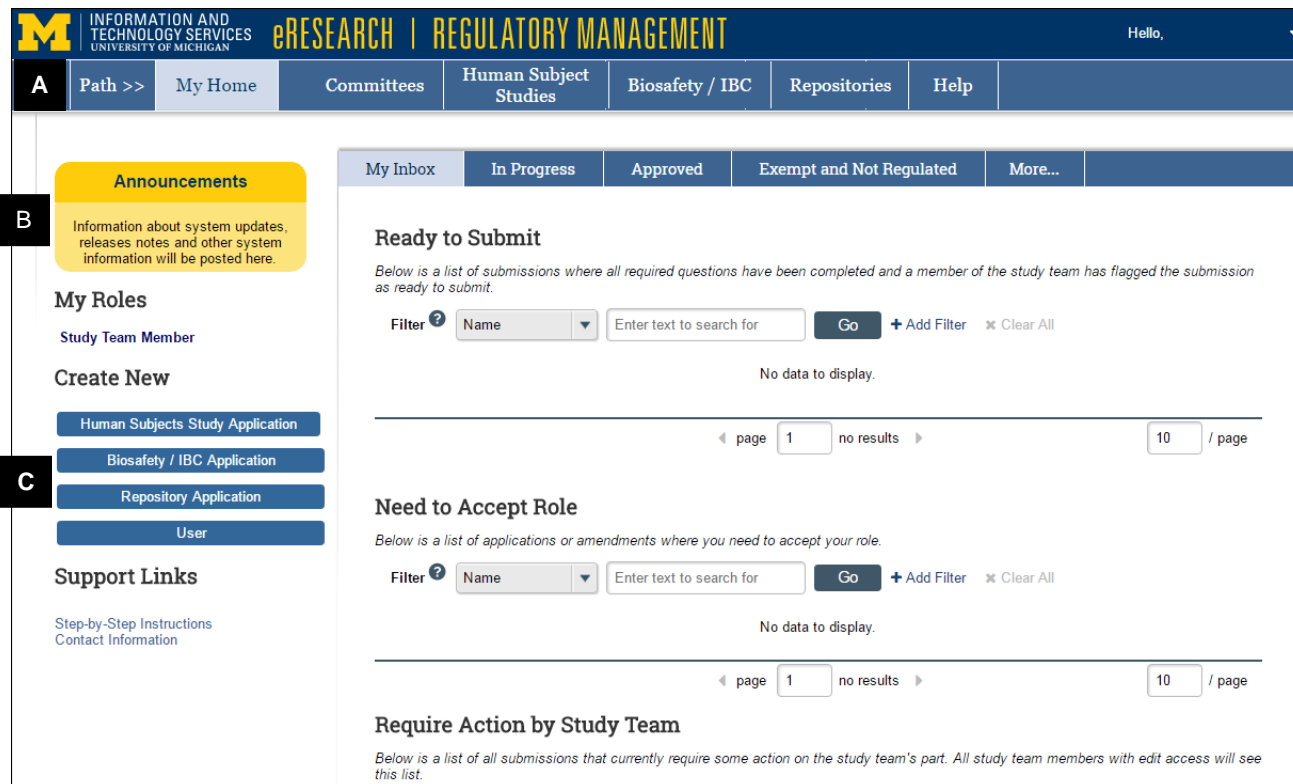
### **Details**

The following pages provide details about the changes listed above.

## I. Look and Feel Changes

From the home workspace, you will experience an updated look and feel along with a new banner. Menu options have also changed and are listed below.

### Home Workspace





A	<p>Menu options have slightly changed but perform the same functions. Changes include:</p> <ul style="list-style-type: none"> <li>• <b>Path</b> – New! Click to display breadcrumbs.</li> <li>• <b>My Home</b> – New location! Click to return to the home workspace.</li> <li>• <b>Committees</b> – No changes. Visible only to users that work with or on Committees.</li> <li>• <b>Human Subject Studies</b> – previously All Submissions</li> <li>• <b>Biosafety/IBC</b> – previously IBC</li> <li>• <b>Repositories</b> – previously Repository Applications</li> <li>• <b>Help</b></li> </ul>
B	<p><b>Announcements</b> about system updates or outages is now prominently displayed.</p>
C	<p>Updated button wording and look.</p>

## II. Document Management

New drag and drop functionality easily allows you to add documents. When using drag and drop, the document name will default with the file name. To rename the document, click **Upload Revision** and enter a new **Title**.

When uploading a revision to an existing document, **do not** use drag and drop. Instead, click **Upload Revision** and choose the revised file. The drag and drop functionality only works for adding new documents (the first file in a document stack). If you use drag and drop for a revision, it will result in a new document stack.

To **View revision history**  or **Delete**  a document, hover over the document line and the buttons will display.

### Additional Supporting Documents

#### 44. Additional Supporting Documents


44.1 Please upload any additional supporting documents related to your study that have not already been uploaded. Examples include, but are not limited to, data collection sheets, newsletters, subject brochures, and instructional brochures.

 **Add** Drag and drop files to upload

Name		Version
  Upload Revision	Test.docx	0.01 

44.2 Enter any information that should show in a "Supporting Documents" list on the current submission's approval notice, such as document names and version numbers or version dates. Text entered here will AUTOMATICALLY appear word-for-word on the approval letter.


### Upload Revision

**Submit a Document**  **Help**


Title:

If not provided, the name of the file will be used


\* File:


 **Choose File**


[View](#)

 **Show Advanced Options**

\* Required

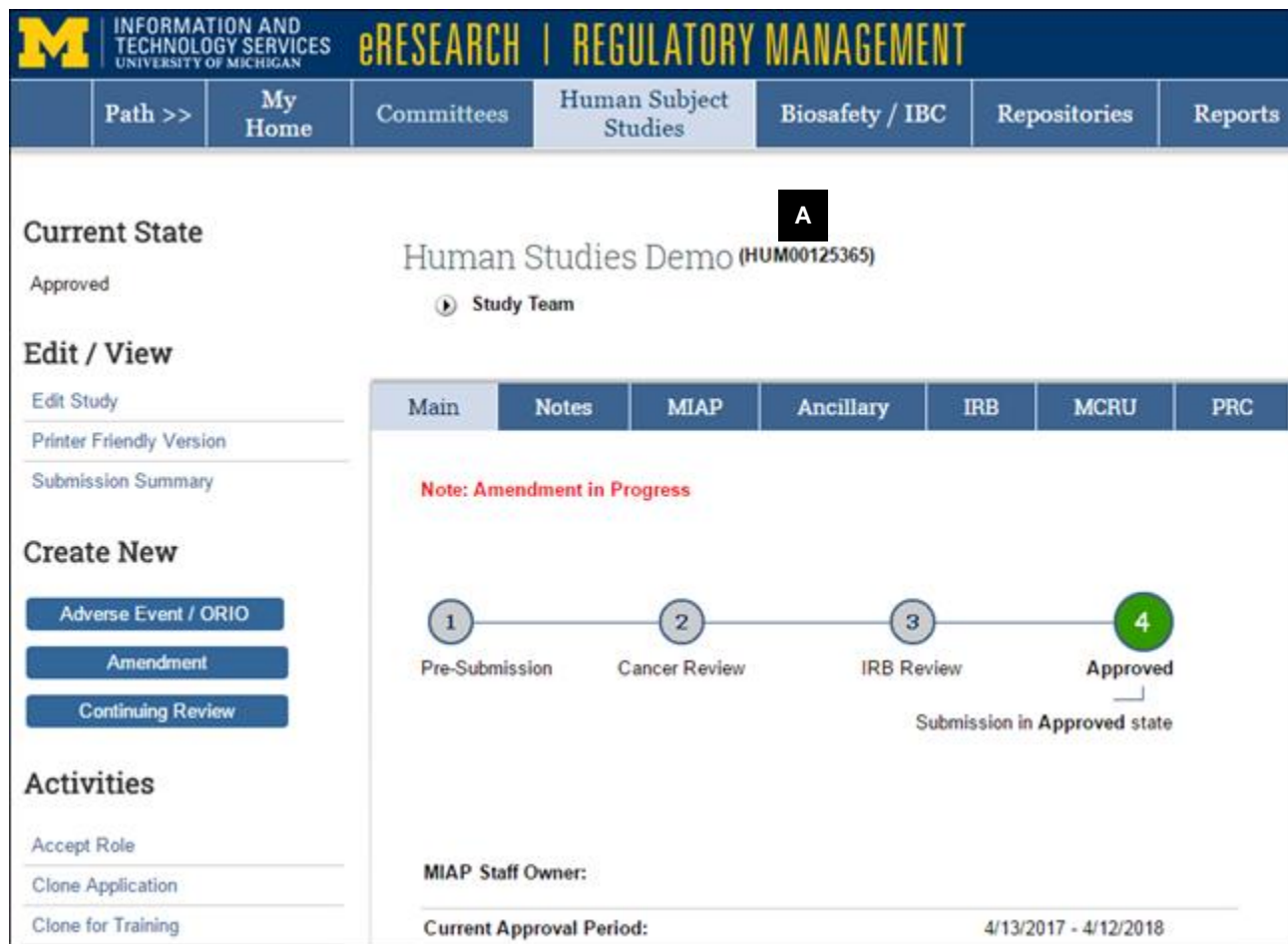
 **OK**

 **OK and Add Another**

 **Cancel**

### III. New Workspace Layout

Unified project workspace layouts throughout all project types. Common elements include Current State, Edit/View, Create New, Activities, Submission Title.



The screenshot displays the eResearch Regulatory Management interface. At the top is a navigation bar with the University of Michigan logo and the text 'eRESEARCH | REGULATORY MANAGEMENT'. Below this is a secondary navigation bar with tabs: Path >>, My Home, Committees, Human Subject Studies (selected), Biosafety / IBC, Repositories, and Reports. The main content area is titled 'Human Studies Demo (HUM00125365)' and includes a 'Study Team' link. On the left, there are three sections: 'Current State' (Approved), 'Edit / View' (with links for Edit Study, Printer Friendly Version, and Submission Summary), and 'Create New' (with buttons for Adverse Event / ORIO, Amendment, and Continuing Review). Below these is an 'Activities' section with links for Accept Role, Clone Application, and Clone for Training. The central workspace shows a 'Main' tab selected, displaying a 'Note: Amendment in Progress' and a workflow diagram with four steps: 1. Pre-Submission, 2. Cancer Review, 3. IRB Review, and 4. Approved (highlighted in green). Below the diagram, it states 'Submission in Approved state'. At the bottom, there are fields for 'MIAP Staff Owner:' and 'Current Approval Period: 4/13/2017 - 4/12/2018'.

- |          |  |
|----------|--|
| <b>A</b> | If you are viewing an amendment, continuing review, or adverse event, click the ID number following the application title to return to the main application workspace. |
|----------|--|