# What’s new in the eIRB System Upgrade?

**Login URL:** New System: [http://eirb.ohsu.edu](http://eirb.ohsu.edu); Old System: [http://irb.ohsu.edu](http://irb.ohsu.edu)

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<tr>
<th>Item/Activity</th>
<th>What’s different in the new eIRB system?</th>
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| **System Changes and Differences** | • IRB Analysts (IRB Coordinators) will no longer be able to make changes in the Smart Forms (the IRQ, Mod, CR, RNI, etc.) on the behalf of study team members.  
  o Please be extra careful to answer the eIRB questions completely and accurately.  
  o The IRB Coordinator must return the submission to you (Request Clarification) for corrections.  

  • To contact the PI, Study Team Members or the IRB Coordinator (Analyst), choose ‘Add Comment’ and select who should receive email notification.

  • All help text is now accessed via the blue question mark bubbles. Please refer to these for helpful explanations and tips.

  • Question 3 of the IRQ called “Brief Description” will capture the Brief Project Description (formerly called the Lay Summary). This is no longer an uploaded stand-alone document.

  • You now upload key documents (protocol, consent, etc.) throughout the system rather than at the end. However, there is still a Supporting Documents Section at the end of the IRQ. **NOTE:** do not upload every document in each section.

  • There are no longer separate pathways for Request Waiver of Oversight to Another IRB, Future Human Subjects, Request a Determination or Repository Only (data/biological specimen registries, repositories, data banks or libraries).

    o To request a waiver of IRB oversight, answer “yes” to question 7 on the first (Basic Information) page of the IRQ. Provide additional information in the section called “External IRB”. If the external IRB you are proposing is not in the drop down list, please email David Holmgren, IRB Manager or call him at 503-346-3528.

    o For Future Human Subjects Research or to Request a Determination, upload the appropriate form in addition to, or in lieu of, a protocol on the first (Basic Information) page of the IRQ and complete the rest of the IRQ as applicable and submit for IRB review. You can also access these documents directly on the IRB Policies and Forms Website.

    o Repository Only studies are processed the same as any other study submission. These are not treated differently in the new system.

  • Study Documents (especially protocol, local context supplement) will need to provide all of the pertinent study details (e.g., # subjects, NEW Decisionally impaired information, data safety monitoring plan (DSMP), etc.) as the IRQ is significantly shortened.

  • Unanticipated Problems (UPs) and Protocol Deviations (PDs) will be submitted in the new system under an activity called Reportable New Information (RNI)

    o See RNI Policy and RNI Quick Guide on the IRB Policies and Forms website

  • Read/Edit rights along with custom email notifications are no longer an option. If you have a person who is not part of
the research that you would like to be able to view the study/study documents, you can add them to the guest list.

- The new system log in page will have a section where you can provide your feedback and suggestions.

**Navigation Note:** Required questions are denoted with red asterisks. If any required/asterisked item is not answered, the system prevents you from moving on to the next page. We know you may want to continue to work on other parts of your submission while you wait for key information; so you can circumvent this by clicking on the drop down arrow in the center right at the top of the page and selecting another section. This allows you to skip to that page and in order to input additional information. Make sure you save your work – and remember to eventually complete all required fields before submitting (or before notifying your PI) your study for IRB review.

**Terminology Changes**

- IRB Analysts are now referred to as IRB Coordinators in the new system.
- The study status “Closed to Enrollment” does not exist in the new system.
  - Do NOT submit a modification if your study has ‘closed to enrollment’ per the protocol (e.g., enrollment target met).
  - Submit a modification or RNI (as applicable) if your study closes to enrollment due to reasons outside of your protocol (e.g., toxicity, futility, etc.)
- Terminating a study is now referred to as ‘closing’ a study. Once ‘Closed’, it will be in the ‘Archived’ list.
- Status/State Terminology Changes:

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<tr>
<th>Old Terminology (Status)</th>
<th>New Terminology (State)</th>
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<tbody>
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<td>Pre-Submission</td>
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<tr>
<td>CI Review</td>
<td>Cancer Institute Review</td>
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<tr>
<td>Researcher Revision</td>
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<tr>
<td>Analyst Review</td>
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<td>Pre-Board Revisions</td>
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<td>Pre-Review Completed</td>
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<td>Chair Screening</td>
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<td>Board Review</td>
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<td>Researcher Revision</td>
<td>Modifications Required</td>
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<td>Analyst Review</td>
<td>Modifications Submitted</td>
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<td></td>
<td>Post-Review</td>
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- **Other:**

<table>
<thead>
<tr>
<th>Old Terminology</th>
<th>New Terminology</th>
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<tbody>
<tr>
<td>UP/PD/some Mods</td>
<td>New Information Reports</td>
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### Locating Studies

To find a study:

- Click on ‘My Inbox’ in upper right corner.
- Select ‘Study Team Inbox’ in lower left.
- In the middle of the page on the grey tabs, your Inbox should display options:
  - ‘Action Required’
    - Studies that you are in the process of creating.
    - Studies you need to submit.
    - Studies that have been returned by the IRB for your attention/Action.
  - ‘All My Studies’.
    - All approved studies on which you are listed as a study team member.

In the upper left of the page, there is also an ‘IRB’ link. Here you will see all studies you are listed as a PI or study team member including those items that are:

- In-Review
- Active - it is from here you would select a study already IRB approved if you need to submit a:
  - Continuing Review (with no changes).
  - Modification.
  - Modification-Continuing Review –
    - The new system allows you to do a combinations modification and continuing review under a single submission.
  - Reportable New Information (RNI)
- Archived (previously known as terminated)
- New Information Reports
- All Submissions

### Follow-on Submissions

### Additional Guidance

Please refer to the new eIRB Library Study Team User Guide

If you need additional assistance or have any questions, please contact the following persons:

- Navigation and Technical Issues: [Andrew Perluss](mailto:andrew.perluss@ohsu.edu) or [David Holmgren](mailto:david.holmgren@ohsu.edu)
- Study-specific information: Contact an IRB Specialist (Analyst) or the IRB Manager, [David Holmgren](mailto:david.holmgren@ohsu.edu)
- You may also contact the IRB Help Desk at: 503-494-7887, option 1 or email [irb@ohsu.edu](mailto:irb@ohsu.edu)