The Office for Human Subject Projection (OHSP) has been diligently working over the past several months with University IT, Huron Consulting and the Research Administration Modernization Advisory Committee to prepare and implement a new online Institutional Review Board (IRB) submission and review platform. The new review platform is set to go-live Monday, November 5th. An email, sent via OHSP’s email distribution list, will notify the University’s research community once the new review platform is accessible.

This issue of the OHSP Newsletter is dedicated to providing information and support to study team members during this transition.

Click® IRB: A Primer

Click® IRB, is the product through which all human subject research will be reviewed after ‘go-live’ (Huron Consulting is the vendor of this product). The Click® product is a large suite of modules that facilitates and integrates research administration. As part of the Research Administration Modernization Project (see additional information in the OHSP Q2 Newsletter), once the IRB review module has stabilized, the project will shift focus to the grants module (e.g., pre- and post-award grant management).

What about the name?
As the Click® product will include more modules than the IRB alone, a new name has not yet been determined for the platform. Please bear in mind going forward, this may change. For now, references to the ‘new’ RSRB Online Submission System (ROSS), an online IRB review system, and Click® IRB all refer to the same platform.

How do I access the new system?
After ‘go-live’, the new submission system (Click® IRB) will be available to access from the OHSP homepage (www.rochester.edu/ohsp). All University of Rochester (UR) faculty, staff and students with current human subjects training will be able to log into the new system following go-live with their Active Directory credentials (i.e., the credentials used to log in into your computer/UR email); users will not need to request accounts. In the event you are unable to log in, please contact OHSP. (See additional article in this newsletter for information on access for new users.)

What will happen to ROSS?
The original RSRB Online Submission System will remain available for read-only access. Current users can continue to use their existing username and passwords to log into ROSS. However, submissions and review activities will not be available; all new review activities must be completed in the new online review system (Click® IRB).
New System, New Lingo & Functionality

With the new IRB review system, there is new lingo, activities, and functions. Below is a list of some basic functions that all users will want to familiarize themselves with:

- **Modification (MOD)** = Referred to as an amendment in ROSS, this is the process by which study teams will submit revisions/changes to the RSRB for review and approval.

- **Modification/Continuing Review (MOD/CR)** = The new review system allows for a modification and a continuing review to be submitted at the same time, as one review item; this allows a study team to submit revisions to the research while reporting updates/progress report information.

- **Report New Information (RNI)** = Referred to as a reportable event in ROSS, this is the process by which study teams will submit events/incidents, per OHSP Policy 801 Reporting Research Events, for review.

- **Follow-On Submissions** = A collection term for any type of submission that follows the initial approval of the research (i.e., a MOD, CR, MOD/CR or RNI). All follow-on submissions can be accessed from the study workspace by selecting the ‘Follow-on Submission’ tab.

- **IRB Coordinator** = Referred to as RSRB Specialist in ROSS, is the individual who will facilitate IRB review of submissions.

- **PI Proxy** = A study team member (or members) that can perform activities on behalf of the Principal Investigator (PI) in the IRB online review system. These activities include submitting items for review and receiving notifications/clarifications sent by the IRB. Note: Only the PI can assign the PI Proxy role to study team members. The PI Proxy can be assigned at any time and does not require review and approval by the IRB. Furthermore, assigning this role does not alleviate the PI from their responsibilities of being the PI, as defined by OHSP Policy 901 Investigator Responsibilities.

- **Primary Contact** = A study’s main point of contact. This individual will receive all notifications sent by the IRB and can be any user that has access to the review system (meaning, it does not need to be a study team member). The role can be assigned at any time and does not require review and approval by the IRB.

Research QI ‘Gold Star’ Award

The QI division is recognizing **Marc Lande, MD** and **Erika Little** for their quality work on the **‘SHIP AHoy: Study of High Blood Pressure in Pediatrics: Adult Hypertension Onset in Youth’** study. This energetic study team works in the Medical Center in the Department of Pediatric Nephrology.

The study site received the OHSP-QI ‘Gold Star’ award for their commendable work in serving a challenging subject base, demonstrating attention to regulatory compliance/protocol adherence, and conducting excellent research (following the guidelines), with high quality, organized study-related documentation. The Investigator oversight, consenting processes, and inclusion/exclusion criteria documentation was also outstanding.

**Congratulations!**
New! Remote Access Requirements

For security purposes, two-factor authentication is now required when users log into the new IRB review system remotely. This means that users attempting to log into the review system outside of the University’s network will be asked to verify their identity via an alternate physical device (i.e., via your mobile phone, tablet or a landline phone). To facilitate this, OHSP recommends that users who anticipate accessing the review system remotely on a regular basis, enroll in Duo (instructions for doing so are available [here](#)). Additional information on two-factor authentication is available through University IT.

Legacy Study To-Do List

As part of the implementation of the new review system, all active and approved studies previously approved by an expedited or full board review in ROSS were transferred into the new review system. Based upon the requirements set forth, only basic information (i.e., a ‘shell’) of these approved studies were populated.

Following ‘go-live’, the ‘shell’ of these existing studies will need to be populated at the time of the first modification (amendment) or continuing review. The list of activities that follow provides guidance for: a) verifying the information imported into the new system is accurate; b) accessing read-only ‘legacy studies’ in ROSS; and c) completing the study shell at the time of the first modification or continuing review in the new online review system.

What if I Submitted a Review Item Prior to the ROSS Freeze & it Wasn’t Approved Before ‘Go-Live’?

Study teams will need to re-initiate any submissions that were submitted in ROSS but did not obtain approval prior to ‘go-live’. This means:

- If a new study was initiated and not approved, a new application will need to be created in the new review system.

  ⇒ Reference the RSRB number in the ‘Brief Description’ section of the new study application, so RSRB staff can access the review history.

- If a modification or continuing review was initiated and not approved, a new modification or continuing review will need to be created in the new review system.

What about Existing Exempt Determinations & Central IRB Studies?

Proposals previously submitted and determined to be exempt will not be migrated into the new review system, nor will administrative reviews of studies submitted to external or central IRBs. The reviews and determinations originally made for these proposals still stand; study teams DO NOT need to submit anything in the new review system to continue conducting these projects. Submissions are only required when/if an existing exemption determination or institutional review of an existing central IRB application require modification. When/if a modification is required, study teams will need to submit these changes as a new application in the new review system. Note: As no legacy link will be available in the new review system for these submissions, study teams should reference the existing RSRB number in the ‘Brief Description’ section of the new study application.
Legacy Study To-Do List (Continued)

(Continued from page 3)

Finding Your Study

- Log in to the new online review system (a link is available on the OHSP homepage).
- Click ‘IRB’ on the blue horizontal navigation bar (see Image 1).
- Go to the Active tab (see Image 1).
- Find the title of the study (see Image 1). Note: all currently approved studies have been assigned new study IDs that begin with STUDY000… If you cannot find a study, contact your RSRB Specialist.
- Click on the name of the study to open the study workspace (See Image 2).
  ⇒ Check the legacy link in the header information (RSRB number).

⇒ Verify the RSB number is correct.
⇒ Click the legacy link to ensure it takes you to the correct study workspace in the RSB Online Submission System (ROSS).
⇒ You will need to log in to ROSS using your ROSS username and password.

- Once you confirm the legacy link is correct, review the information in the study workspace (the study workspace will include the study number in the heading; if you see a ‘MOD’, ‘MODCR’ or ‘CR’ heading you are in modification, modification/continuing review, or continuing review workspace). The following information is populated into the study shell (see Image 2):
  ⇒ Principal Investigator (continued on page 5)

Image 1. Finding Your Studies

Image 2. Study Workspace
Legacy Study To-Do List (Continued)

⇒ (continued from page 4) Study Team Members (Contacts Tab)
⇒ Date of initial approval
⇒ Date of current expiration
• All other information will need to be added by the study team through a modification or modification/continuing review.

Prepare to Fill the Shell
• Log into ROSS and download required approved documents to ensure the most current versions of all documents are uploaded into the new system.
• Under the ‘Documents’ tab in ROSS, access the following, as applicable:
  ⇒ Clean protocol
  ⇒ COI management documentation
  ⇒ Pathology or HURC Ancillary Committee review forms
  ⇒ Letters of Support
• In approved ROSS Application Form, access the following documents, as applicable:
  ⇒ Drug and device documentation: Page 50 in the ROSS Application
  ⇒ Consent documents - being used: Page 83, Question 83.1 in the ROSS Application
  ⇒ Recruitment documents - being used: Page 66, Question 66.1 in the ROSS Application

Filling the ‘Shell’
• From the study workspace in the new review system, click ‘Create Modification/CR’ (See Image 3).
• Select modification (if you are filling in the study shell and providing additional changes) or modification and continuing review (if you are filling in the study shell and a progress report is due). Note that filling the shelling only applies to the modification portion of this form so the remainder of this guidance will only focus on the modification aspect of completing the shell.
• For the modification scope, select both ‘study team member information’ and ‘other parts of the study’ (both must be selected to fill in the shell).
• Reference Table 1 (on the following pages) to complete the remainder of the application.
• Once the form has been completed, select ‘Submit’ to submit the form to the RSRB for review.
• As part of this process, you may wish to assign a primary contact and/or PI proxy, as described earlier in a separate newsletter article (also see Image 3).
<table>
<thead>
<tr>
<th>Modification Form Section in New Review System</th>
<th>Guidance for Filling the Shell</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modification Information: Q1 – Study Enrollment Status</td>
<td>Indicate current study enrollment status.</td>
</tr>
<tr>
<td>Modification Information: Q2 – Notification of subjects</td>
<td>Select the appropriate form of notification. If no notification is necessary, the question may be left blank (e.g., only filling the shell).</td>
</tr>
</tbody>
</table>
| Modification Information: Q3 – Summary of Modifications | • CR / Shell Only: If this submission is for continuing review and to fill the shell (i.e., no changes requested), document there are no changes, this mod will only fill the shell.  
• MOD & Shell: If this submission is for a modification to previously approved materials and to fill the shell, document the requested changes and note this submission will also fill the shell.  
• CR / MOD / Shell: If this submission is for continuing review, a modification, and to fill the shell, document the requested changes and note this submission will also fill the shell. |
| Modification Information: Q4 – Attach Files | If this submission is for a modification (requested changes) and to fill the shell, the ‘Attach Files’ should be used to upload any tracked documents to demonstrate the changes requested in this submission (e.g., protocol, consent, recruitment materials). A summary of changes may also be uploaded, as applicable. **THIS IS THE ONLY TIME REVISED STUDY DOCUMENTS NEED TO UPLOADED IN THIS SECTION.**  
In the future, ‘Attach Files’ will only be used to upload a memo/letter/document that explains the changes. Clean documents will be uploaded into the study application and the ‘Compare’ function used to demonstrate changes.  
• Upload any tracked documents that represent the changes proposed with this submission.  
• If there are no changes requested with this submission, no documents need to be uploaded in this section. |

| Basic Information: Q3 – Brief Description | Enter a brief description of the study. |
| Basic Information: Q8 – Attach the Protocol | Upload a CLEAN version of the protocol (and any additional protocol addendums/supplements/site-specific protocols) |
| Funding Sources | Enter as appropriate:  
• If no funding, leave blank.  
• If department funded, enter the department name (all HR departments are included in the drop down list).  
• If grant funded, enter the funding source. If applicable, enter the grant number. (Note that Fields 2, 3, and 4 are not required.) |
| Study Team Members | All RSRB approved study team members should already be listed on this page; however, roles are not identified. Please review and update:  
• Click into each person’s profile (click ‘Update’) and enter their role on the study (e.g., sub-investigator, study coordinator) and whether or not they have a conflict of interest (refer to page 2 of ROSS application).  
• If an approved study team member is not listed, click ‘Add’ to add them to the page. Note: If a new, not yet approved, study team member is being added during this process, be sure to identify the change on the modification form, Q3 (see above). **(Continued on page 7)** |
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<tr>
<td><strong>STUDY APPLICATION FORM</strong></td>
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<tr>
<td><strong>Study Scope</strong></td>
<td><em>(Continued from page 6.)</em></td>
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<tr>
<td></td>
<td>Answer each question, as appropriate.</td>
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<td></td>
<td>• Answering yes to Q1, 2, or 3 will add additional pages (Research Locations, Drugs and Devices) to the application.</td>
</tr>
<tr>
<td></td>
<td>• Q4 – Conflicts of Interest: Answer yes, if the ROSS application (question 2.2) indicates an <em>institutional</em> conflict of interest and upload copy of conflict management plan in Local Site Documents (see below).</td>
</tr>
<tr>
<td></td>
<td>• Q5 – ClinicalTrials.Gov Registration: Answer yes, if applicable and enter NCT number (question 3.2 in ROSS)</td>
</tr>
<tr>
<td><strong>Research Locations</strong></td>
<td>Click ‘Add’ to add locations commensurate with what is identified in the current ROSS application (questions 63.1.1, 63.2, 63.3, and Highland Hospital, if research is conducted at Highland).</td>
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<tr>
<td></td>
<td>• Some locations are preloaded into review system. Please search for applicable locations in the database first. If your research location is not there, add as appropriate.</td>
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<td></td>
<td>• Please note if you have a letter of support from a non-UR location (e.g. Rochester City School District, Teresa House), it should be uploaded into Q3 on the Local Site Documents page.</td>
</tr>
<tr>
<td><strong>Drugs</strong></td>
<td>Click ‘Add’ to add drugs commensurate with what is identified in the current ROSS application (question 50.1)</td>
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<td>• Drugs are preloaded into the review system. Please search for applicable drugs in the database first. If your drug is not there, add as appropriate.</td>
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<tr>
<td><strong>Devices</strong></td>
<td>Click ‘Add’ to add devices commensurate with what is identified in the current ROSS application (question 50.1)</td>
</tr>
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<td></td>
<td>• Some devices are preloaded into the review system. Please search for applicable devices in the database first. If your device is not there, add as appropriate.</td>
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<tr>
<td><strong>Local Site Documents</strong></td>
<td>Upload CLEAN versions of all consent documents, recruitment documents, and other study documents that are currently being used. Note: If any of these documents are no longer in use, they do not need to be uploaded (please indicate as such in the list of summary modifications in Q3 on the ‘Modification Information’ page).</td>
</tr>
<tr>
<td></td>
<td>• Study measures that are already uploaded in ROSS, do not need to be uploaded to complete the shell.</td>
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<tr>
<td></td>
<td>• Note: Each document must be categorized by type when uploaded.</td>
</tr>
<tr>
<td><strong>Ancillary Committees</strong></td>
<td>If your study did not require Ancillary Committee review, answer NO to this question.</td>
</tr>
<tr>
<td></td>
<td>• If your study required Ancillary Committee approval (documented on page 63 of the ROSS Application), you must answer YES and then respond to each question to indicate the relevant Ancillary Committee approval.</td>
</tr>
<tr>
<td></td>
<td>• Q13 - Documentation required by Surgical Pathology and Human Use of Radiation Committee (HURC), currently uploaded on page 63 in the RSRB application, will need to be included here.</td>
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</table>
|                                               | • Note: Highland Hospital Administrative Research Review Committee (ARRC) is now documented through Research Locations. If Highland ARRC is checked in ROSS, go to the Study Scope page and answer yes to Q1 (Research Locations). Click continue to access the Research Locations page and add Highland Hospital.
Accessing & Utilizing Watermarked Documents

Until the ‘shell’ of a legacy study has been updated (as described previously in this newsletter), study teams are expected to continue using the watermarked documents available in ROSS. Watermarked documents will not be available in the new IRB review system until:

- The shell of an existing study has been ‘filled’ (as described in this newsletter) via the modification or continuing review process; OR
- A new study has been approved in the new system; OR
- An exemption has been confirmed in the new system.

Once available, watermarked documents can be found by selecting the ‘Documents’ tab in the study workspace. Within the ‘Documents’ tab, watermarks are applied (when applicable) to the version of the document listed under the ‘Final’ heading (See Image 4).

Note:
- Consistent with the current process, only certain documents will be watermarked during the approval process. As identified in your study approval letter, only the most recently approved version of consent forms and recruitment materials bearing an RSRB watermark may be used when obtaining consent and recruiting subjects.
- The watermarking process in the new IRB review system is automated. Documents required to be watermarked are watermarked in the lower right-hand corner of the document (see Image 5). To ensure adequate watermarking, leave the lower right-hand footer of all consent and recruitment documents blank (do not include page numbers or version dates in this area of the document).

Whenever feasible, it is best practice to utilize the consent templates provided by the RSRB to ensure the spacing in this area is adequate. In the event, the watermarking does not appear correct on a watermarked document, please contact your RSRB Specialist.
Access for New Users

Following ‘go-live’, the process for new users to gain access to the new IRB review system has changed. Going forward, all UR faculty/staff/students will automatically receive access to the review system approximately 1-2 business days following completion of the required [human subject protection training](#) (via the Collaborative Institutional Training Initiative [CITI]). New users will receive a notification from Huron (the Click® IRB vendor) via email once a user account has been created for them. Until that email is received, new users will not show up in any search boxes in the review system. Note:

- To facilitate this process, please encourage all new users to utilize their institutional email when creating a CITI account (this supports the automated process through which course completion data drives account creation).

- The RSRB will no longer be able to create ‘on-the-fly’, urgent user accounts. All accounts will be created through Huron. Please plan for the 1-2 business day turnaround accordingly.

- External study team members will not be permitted access to the new review system, though they can still be added as study team members by the process outlined in the submission process.

Click® IRB: Support & Training Materials

Visit the [OHSP Division of Education & Training](#) website to find:

- Click® IRB Manuals
- Video vignettes of Click® IRB Activities
- Information on open office hours

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