Navigating the RSRB Online Submission System (ROSS) can be a challenging process when you’re new to the system or use it infrequently. When utilizing ROSS, keep the following pointers in mind:

**DO:**

- Navigate from page to page within each form using the ‘Continue’ button. Doing so allows the submission system’s branching logic or the ‘smart form’ to function appropriately, thereby ensuring users are directed to applicable pages within each form.
- Carefully read the questions and any corresponding instructions provided in the ‘grey box’ to the left of the question. Following the instructions provided with each question is an important step for ensuring that the questions are answered correctly.
- Ensure each response is consistent with the information provided in the study protocol, any supporting documentation (e.g., consent forms, recruitment materials, and study measures) and all remaining responses within the ROSS form. Inconsistencies will result in the form being returned to the study team for clarifications.
- Upload new and modified documents correctly within ROSS. The ‘Add’ button should only be used to upload new documents. The ‘Upload Revision’ button next to the file name should be used to replace revised versions of previously uploaded documents. Do not delete any documents (continued on page 2)

**DON’T:**

- Leave questions blank; answer all questions. Skipping questions can affect the branching logic within each form. This will leave the RSRB not knowing whether the unanswered questions do not apply or whether the questions were skipped. When appropriate, answer ‘N/A’ to open-ended questions.
- Forget to submit the form within ROSS! Without the submission/re-submission of forms within ROSS, the RSRB is unable to review and/or act upon them. The ‘ball can only be in one court’. All forms must be submitted to the RSRB at the time of initial submission and re-submitted subsequent to making any requested modifications.
- Ignore automated ROSS e-mail notifications. Automated notifications typically indicate that some response is needed on the part of the study team. This could include updating your human subjects training, responding to clarifications or submitting a progress report. Failing to respond appropriately to these notifications will ultimately delay RSRB review or result in a lapse in approval.
- Request RSRB Specialists to make changes on your behalf. This is not permitted. All revisions, including (continued on page 2)
Dos & Don’ts for Navigating ROSS

**DO (CONTINUED):**

(continued from page 1) that were previously approved, even if they are no longer being used. Documents that are no longer in use can be archived at the time of continuing review.

- Refer to applicable sections of your study protocol or other supporting documentation when completing ROSS forms instead of repeating information unnecessarily. For example, sections 66.2 and 78.0 of the new application form request open-ended responses regarding subject recruitment and data and safety monitoring. Rather than paraphrasing or copying this information from the study protocol, simply reference the applicable sections of the study protocol.

**DON’T (CONTINUED):**

(continued from page 1) modifications to study documents and forms within ROSS, must be completed by study team members.

- Include revisions in continuing review forms; all revisions must be submitted via amendment. Amendments and continuing reviews may be submitted and reviewed simultaneously, though it’s recommended that you notify your RSRB Specialist if you do so.

Note that a [ROSS Step-by-Step Training Guide](#) is available online through the Office for Human Subject Protection’s website. It includes instructions for creating new applications, adding study personnel, uploading new and revised documents, submitting amendments and continuing reviews, responding to stipulations and locating approved study documents. Questions regarding the system can also be directed to your RSRB Specialist.

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**Recipe for (Research) Success**

From the Quality Improvement Team

**You Will Need:**

- All IRB-approved documents (regulatory file)
- Signed, original consent forms
- Eligibility assessment
- Adverse event assessment
- Data and safety monitoring
- Quality management plan
- Trained study team

**Method:** Combine all ingredients with teamwork and hard work. **Serves:** Everyone

Enjoy a successful research study!
Drafting Study Documents for Study Subjects? Remember to Use Lay Terms!

Are you working on compiling a new IRB submission or drafting materials for an upcoming amendment? Remember, study documents (consent forms, recruitment materials, questionnaires, subject diaries and interventional instructions) need to be written in a clear and understandable manner. This includes using lay terminology. For example, as the general public may not be familiar with the term ‘principal investigator,’ study documents provided to subjects should refer to Principal Investigators as ‘study doctors,’ ‘investigators’ or ‘researchers,’ as appropriate. It’s also important to use consistent terminology – such as using ‘researcher’ each time within a document rather than varying between ‘investigator’ and ‘researcher.’ Additional considerations for improving the readability of study documents are available in the Office for Human Subject Protections’ Guideline on Informed Consent.

Submitting Site-Specific Protocol Addendums

If you’re acting as an enrolling site on a multi-site study, you may be asked to submit a site-specific protocol addendum to supplement the study protocol provided by the study sponsor and/or coordinating center. The purpose of these addendums is typically to clarify the University of Rochester’s role in the research or how study procedures will be conducted locally. When drafting these addendums, ensure the addendum only provides the additional information requested. Repeating information already provided in the original study protocol is unnecessary and can potentially lead to incidents of non-compliance, if future revisions that apply to both documents are only made in one document.

Uploading Information Sheets into Exempt Applications

Information Sheets uploaded into ROSS exemption requests should be uploaded into Section 66.1 (Recruitment Materials), not Section 83.1 (Informed Consent). Based on the nature of the application, exemption requests do not branch to Section 83. Documents manually uploaded into this section are not considered part of the exemption application and therefore are not reviewed and approved by the RSRB.

Food for Thought

Please note that the articles included in this feature by no means represent OHSP’s current viewpoints; they are merely meant to provoke thought and conversation on issues concerning human

- Cut-Throat Academia Leads to ‘Natural Selection of Bad Science’, Claims Study (Devlin, H. [2016, September 20]. The Guardian.)
- Risk-Based Monitoring: What Does it Mean for Clinical Study Sites? (Bois, B. [2016, October 14]. Applied Clinical Trials.)
- Uber, Lyft Gear Up to Help Get Patients to Clinical Trial Site (Comstock, J. [2016, September 20]. MobiHealthNews.)
Based on the language in the policy ("GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization"), the Office for Human Subject Protection (OHSP) anticipates the requirement may be fulfilled via one of the mutually recognized GCP training platforms identified through TransCelerate BioPharma, Inc. The ‘Mutual Recognition Program’ includes GCP training available through the Collaborative Institutional Training Initiative (CITI), which is available for free to all University of Rochester study personnel. Directions for accessing this training are available on the OHSP website.

If you have questions regarding GCP training, please contact Kelly Unsworth.

“All growth depends upon activity. There is no development physically or intellectually without effort, and effort means work.”

- Calvin Coolidge
Upcoming Educational Opportunities

Achieving High Quality Clinical Research Seminar Series:

Save the date for the following upcoming seminars:

- **November 29th, 12:00-1:00pm** (Location: Whipple Auditorium): Kelley O'Donoghue, Associate Vice President for Human Subject Protection and Kelly Unsworth, Director of Research Education and Training in the Office for Human Subject Protection will present on continuing non-compliance. (Note that the seminar on day-to-day study management tools originally advertised for this session will be re-scheduled in the Spring.)

- **December 20th, 12:00-1:00pm** (Location: Lower Adolph Auditorium): Tiffany Gommel, Director of the Research Subjects Review Board in the Office for Human Subject Protection will present on upcoming amendment processes changes in the RSRB Online Submission System.

**Miss the Last Seminar on 'Using a Single IRB Model'? Not Able to Attend an Upcoming Seminar?**

Presentation materials and videos of previously recorded seminars are available on the OHSP and CTSI websites. Live streaming of seminars is also typically available through the CTSI.

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