So, What’s the “The Plan”??
An Update from the OHSP Division of Research Education & Training

If you’ve attended any of the recent OHSP seminars, SCORE meetings or the CTSI Town Hall meeting you’ve probably heard reference to the new Research Education & Training Framework that OHSP has been developing with other key players in the University of Rochester’s Human Subject Protection Program (UR-HRPP). So, what is the plan?

While a few details of the revised framework are still being worked out (and will continue to be a work-in-progress for the next year), OHSP intends to start rolling out initial components of the new training framework within the next month. In addition to the required basic human subjects training completed through the Collaborative Institutional Training Initiative (CITI), the new framework will consist of:

- **Orientation**: This 1-2 hour seminar will introduce basic UR policies and required reviewed processes concerning human subject research. The seminar will also highlight resources available at the UR for designing and implementing study protocols.
- **Boot Camp**: This 1/2 day workshop will apply the basic human subjects protections introduced via CITI and the policies/procedures reviewed in Orientation to conducting research at the UR. The workshop will address basic protocol development elements, RSRB/WIRB review processes, informed consent and post-approval considerations.
- **Core Training**: Core Training will consist of approximately 8-10 modules aimed at cultivating an advanced understanding of all aspects of human subject research (e.g., federal regulations and Good Clinical Practices, study documentation, study drug & device regulations and accountability, event reporting, etc.). Modules will be conducted throughout the academic year and in collaboration with other key players within the UR-HRPP.
- **Advanced Training**: This 1 day workshop will aim to augment the regulatory and project management topics covered in Core Training. The course will likely also include a team management and leadership training component.

**Supplemental Materials**: In addition to the previously described courses, supplemental training materials and resources will be developed and available through the OHSP website. This will include material such as quick reference guides.

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guides, short training videos and training checklists. These courses are intended to meet the needs of the entire UR research community—biomedical researchers as well as social-behavioral researchers; investigators as well as study coordinators and all roles in between. As such, courses will be open to all study team members and enrollment will not be restricted based on study team roles.

Courses will initially be held in-person by OHSP and other UR-HRPP staff with a long-term goal of converting courses, or pieces of each course, to an electronic format, as appropriate. It is also important to note that these new courses (those provided beyond CITI training) are meant to provide a training framework for the UR community and, while OHSP may provide training recommendations, the courses are not required institutionally. Requirements that fall within this framework may however be set forth by department chairs, center directors, administrators or other senior UR leadership.

An informational session will be held regarding the revised framework on Wednesday, April 9th at 12pm in Helen Wood Hall Auditorium. Please bring any question regarding the framework to this session. Consultation with OHSP staff is also available for department chairs, division chiefs, center directors and administrators wishing to institute departmental/division/center training requirements. Please contact Kelly Unsworth, should you have questions or wish to set up a meeting to further discuss how the framework can be utilized within your department/division/center.

Save the Date! Upcoming Educational Opportunities

OHSP Research Education & Training Sessions
(as described above in “So, What’s the Plan?”)
“Orientation to Conducting Human Subject Research at the University of Rochester”
Presented by: Kelly Unsworth, Mike Ritz, Diane Healy & Eric Rubinstein
April 17, 2014, 12:00-1:30pm
Helen Wood Hall Classroom 1W509

“Research Boot Camp”
Presented by: Kelley O’Donoghue, Tiffany Gommel & Kelly Unsworth
May 5, 2014, 8:00am-12:00pm
Helen Wood Hall Auditorium

Achieving High Quality Clinical Research Seminar Series
“Understanding RSRB Review Processes to Improve Submissions”
Presented by: Tiffany Gommel, RSRB Director
April 29, 2014, 12:15pm-1:15pm
Helen Wood Hall Auditorium

Miss a Previous Seminar?
Presentation materials and links to videos of previous seminar series presentations are available on the OHSP and CTSI Websites.

ROSS Training
The RSRB Office provides training for the RSRB Online Submission System (ROSS) the 3rd Monday of every month from 2-3pm. Upcoming dates include April 21st, May 19th & June 16th. To sign-up for this training, please email Sue Flanigan.
Amendment Requests:
Methods for Facilitating RSRB Review

Obtaining amendment approvals can sometimes turn into an unexpectedly challenging process for both the study team and RSRB staff. Consider the following when preparing your next amendment submission:

- When preparing an amendment, ensure that the document you are modifying (e.g., the study protocol) is the currently approved version of the document. In some cases, revisions are made to an old version, thereby unintentionally removing modifications that were previously approved.
- When modifying consent or recruitment materials, provide tracked changes on a Microsoft Word version of the document, as opposed to a PDF version of the file. Using a PDF, watermarked version of documents to make tracked changes requires additional changes by the study team during the review of the amendment. Providing changes in Microsoft Word enables the RSRB to appropriately watermark the document upon approval as well as, facilitate the request for changes process, between the study team and the RSRB.
- Modifying the currently approved application occurs through 2 mechanisms within an amendment:

  1. **Amendment Form:** Complete the amendment form, *in its entirety*, first, uploading revised versions of the protocol, consent and recruitment material within the form itself. This includes uploading tracked materials as indicated. Tracked versions of the consent and recruitment material should be uploaded in the amendment form only (tracked versions uploaded elsewhere may necessitate changes by the study team). Note that a “clean” version of the protocol is not required with most amendments, only tracked versions.

  2. **Amended Application:** Once the amendment form is complete, make any additional necessary changes (e.g., the number of subjects or identification of additional sites) in the amended application.

- If several changes are included in the amendment, consider providing a summary of changes, in table format (uploaded into section 2.1 of the amendment form). This summary will help facilitate review of the amendment by the RSRB.

- Be sure to include rationale for modifications with all amendments. Justification for changes is particularly important for modifications that involve changes in risk.

Reminders:

**Conducting Research at Non-UR Sites**

When research is conducted at sites outside of the University of Rochester, a copy of the site’s IRB approval letter must be included in the RSRB application. Alternately, if the site does not have an IRB, a ‘letter of cooperation’ from the site director should be submitted. Additional documentation (e.g., a Federalwide Assurance) may be required: 1) when the study involves multi-site research and the University of Rochester is acting as a coordinating center; or 2) if the study has federal funding.

Please consult directly with your RSRB specialist with questions concerning non-UR site approvals.

**Study Documentation Toolbox**

OHS’s Quality Improvement Division is pleased to provide customizable research study forms and templates (e.g., delegation of authority logs, enrollment logs, eligibility screening forms, notes to file, etc.) on our [website](#). Not able to find what you’re looking for in the toolbox? Please email the QI team with suggestions—most likely, others need the form too!
Tips from the QI Team

Conducting clinical research is an ongoing process of continual improvement. Here are some helpful tips:

- Conduct the study in accordance with the protocol. Before any changes are implemented to the protocol, RSRB-approval must be obtained.

- Subjects must meet inclusion/exclusion criteria in the protocol before being enrolled in the study. Having the Principal Investigator sign, date, and concur that the subject meets eligibility criteria demonstrates Good Documentation Practice.

- Ensure the subject expresses agreement to participate and signs the consent form prior to any study procedures being conducted. Double-check the consent for all needed signatures, dates, and check-box options. Make certain that the consent form used to obtain consent is the most current RSRB-approved version and that the first page of the document is printed on letterhead.

- All research procedures should be conducted within required timeframes as defined in the protocol.

- Adverse Events should be identified, documented, and reported as defined by the study protocol and/or RSRB requirements.

- Data Safety Monitoring Plan should be conducted (as defined by the RSRB submission, including the application & protocol) and documented to demonstrate meeting the protocol-defined requirements.

- Drug Accountability Logs must be completed with the following information: subject assignment, storage of drug, documentation of the return and/or destruction of drug, and documentation of inventory.

- When making corrections, place one line through the error, write the correct entry above or next to the cross out, and initial and date the error. (Never use white-out!) It is also good practice to document why the change is being made (e.g., error, etc.).

- Document everything! Document incomplete or missing data, and the reason why it is not present using a Note to File and Good Documentation Practices; sign and date each entry.

- Consider implementing a quality assurance/improvement plan at your site to review study files and documentation on a regular basis (e.g. quarterly, annually, after every fifth subject, etc.).

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Research QI ‘Gold Star’ Award

The QI division would like to recognize Sarah Betstadt, MD, MPH for her quality work on the ‘Malpositioned Levonorgestrel IUD: Factors Influencing Post-Procedural Position and Surveillance Outcomes’ trial. This dynamic study team also includes Alexis Pilato, and is located in the Department of Obstetrics and Gynecology.

This clinical research team received the ‘Gold Star’ award for demonstrating attention to regulatory compliance and documentation, exceptional consenting practices, teamwork amongst staff, and overall high quality, organized research.

Congratulations!
How do I obtain a report of my CME activities?

The Center for Experiential Learning (CEL) has a NEW credit management system, called “UR CME”, that allows individuals to access and manage CME activities through the internet, at their convenience. Through this system you will be able to print credit transcripts directly. Instructions for accessing the system are available on the CEL’s UR CME webpage.

When accessing CME transcripts, please keep the following points in mind:

- Credits are only provided to those requesting credit at the time of a seminar (e.g., for OHSP seminars, you must complete and turn in the Participant Evaluation and Information Sheet at the end of each seminar)
- Credits are reported to the CEL office from OHSP on a quarterly basis. As such, recent activities may not appear on credit transcripts.
- Initial and re-approval letters
- The watermark on approved consent and recruitment documents

Where can I find the expiration date of a study?

Expiration dates can be found in a couple of places. This date is identified in:

- The heading on the study homepage in the RSRB Online Submission System
- Initial and re-approval letters
- The watermark on approved consent and recruitment documents

What should the ‘Number of Subjects’ in the study protocol include?

The ‘Number of Subjects’ should include the number of evaluable subjects (i.e., those who meet eligibility criteria), as well as the number of anticipated screen failures necessary to obtain the enrollment goal (i.e., subjects who consent to participate but do not continue in the study as an evaluable subject). A subject is considered in the total count once informed consent is obtained. In the case of multi-site protocols (performance sites in addition to those for which the RSRB has jurisdiction), also include the overall total. Remember...if enrollment will exceed the number for which your study is approved, an amendment must be submitted.

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