As of Monday, August 26th, the University of Rochester’s Office for Human Subject Protection will be using the University of Miami’s online Collaborative Institutional Training Initiative (CITI) program for certification in human subject research.

CITI will be used for both initial certification and re-certification. Instructions for Initial Certification and Recertification are available on the OHSP Research Education and Training website.

If you have any questions, please contact Bill Kelvie at bill_kelvie@urmc.rochester.edu or (585) 275-5244.

Achieving High Quality Clinical Research Seminar Series

October 15th, 2013 “Clinical Trials: Changes and Challenges”
Karen E. Woodin, PhD
JKK Consulting, LLC
Kalamazoo, MI

Time: 12:15 p.m.—1:15 p.m.
Place: School of Nursing
Helen Wood Hall Auditorium
1W304

Upcoming Educational Workshops

SAVE THE DATE:

December 4-6, 2013, 2013
“Conducting Clinical Trials” – 3 day workshop

CLICK HERE: For more information and to register.

OHSP List Serve

You can subscribe to the OHSP list serve and receive training and educational announcements by sending a request to: bill_kelvie@urmc.rochester.edu

OHSP Website:
www.rochester.edu/ohsp
Quality Improvement News

The purpose of a Quality Improvement (QI) Review is to evaluate, improve and monitor research studies on a routine basis, assisting in providing a better understanding of compliance by investigators, and to ensure the safety of research subjects.

If your review results in findings, what should you do?

During the Exit Interview:

- Take notes and ask questions
- Ensure you understand the comments from the reviewers
- Acknowledge errors and think about possible measurable solutions for correction

Tips for Decreasing Findings:

- Read carefully communication from RSRB, including initial approval, amendment approval, and continuing review letters.
- Have a staff member not involved in the study review the study files for completeness on a monthly or quarterly basis.
- Address issues within the conduct of the study immediately with the Principal Investigator and study team.
- Review the study with a ‘reviewer’s eye’: Is there adequate documentation for a reviewer unfamiliar with the study to understand the course of events, and what occurred with each subject?

Research QI ‘Gold Star’ Award

The QI division would like to recognize Anton Porsteinsson, MD & AD-CARE for their quality work on the ‘Alzheimer's Disease Neuroimaging Initiative 2 (ADNI-2)’ trial. This dynamic study team also includes Bonnie Goldstein, Kim Martin, and Russ Kurvach, and is located at Monroe Community Hospital.

They received the ‘Gold Star’ award for demonstrating attention to regulatory compliance, exceptional subject recruitment/retention practices, teamwork amongst site staff, and high quality, organized study-related documentation.

CONGRATULATIONS!!

If you have any questions, please contact Kathleen Wessman at Kathleen.wessman@urmc.rochester.edu or (585) 273-2118.
Research Subjects Review Board News

Using a Short Form to Obtain Consent—When a Principal Investigator anticipates enrolling even one subject who does not speak English, the RSRB requires that the consent form be translated into the subject’s primary language. There are times, however, when an investigator may need to unexpectedly enroll a non-English speaking subject.

If a subject unexpectedly presents at the research site, the use of the short form is acceptable for obtaining consent the first time, after that the consent must be translated into the subject’s primary language. Here are the steps to take to use a short form:

1. Submit an amendment request to the RSRB (expedited review is permitted)
   - The amendment must include a short-form written consent document in the subject’s primary language, that includes the following:
     - Title of the study
     - The study’s consent was presented orally to the subject/subject’s authorized representative
     - The presentation included the purpose, risks, benefits and alternatives (if any) of participation
     - Participation is voluntary. The subject does not have to take part and can withdraw at any time
     - The subject was given a copy of the standard (English) consent form and of the short form. And name, signature line and date for the subject
     - Attestation, signature line and date for the witness

   An English version of the short form is included with the RSRB consent templates. Use this version to translate into the subject’s language. The RSRB has Spanish, Russian, and Mandarin translated short forms under “Consent Form Templates” on the RSRB website.

2. When using the short form, ensure the following:
   - The English-version of the written consent states the elements of disclosure required by regulations have been presented orally to the subject or the subject’s authorized representative.
   - The written summary or the English-version of the written consent embodies the basic and required additional elements of disclosure.
   - There is an adult witness to the oral presentation of the short form who is conversant in both English and the subject’s primary language. The witness must be unaffiliated with the research and it is best if the witness is a fluent professional. It is best if the witness is not a family member.
   - The translator should not be the same person as the witness.
   - The subject or the subject’s authorized representative will sign and date the translated short form.
   - The witness will sign both the translated short form and the English-version of the written consent.
   - The person obtaining consent from the study team will sign the English-version of the written consent.
   - Copies of the translated short-form and the English-version of the consent will be given to the subject or the subject’s authorized representative.
   - Both the original signed translated short-form and the signed full English version are to be kept in the research records with other signed consent forms.

3. If the subject enrolls into the study using the short form, the English consent form and other relevant study documents (e.g. surveys, questionnaires, etc.) are required to be translated into the subject’s language as soon as possible. Once the documents have been translated, an amendment should be submitted to provide the RSRB with the translated documents (including a completed translator’s declaration and the CV of the translator). Once approved the translated documents should be provided to the subject.