Research Education News

Upcoming Educational Opportunities

Achieving High Quality Clinical Research Seminar Series

October 30th “Clinical Trials: Changes and Challenges”

Presented by: Karen E. Woodin, Ph.D (JKK Consulting, LLC)

Date: Tuesday, October 30th 2012
Time: 12:15-1:15 pm
Place: Helen Wood Hall Auditorium, 1W304

December 11th “Preparation for an FDA Audit”

Presented by: Lorrie D. Divers, CCRP, RQAP-GCP
Executive Director, Global Quality Assurance & Compliance
ACM Medical Laboratory

Date: Tuesday, December 11th 2012
Time: 12:15-1:15 pm
Place: Helen Wood Hall Auditorium, 1W304

January 16-18, 2013 “Conducting Clinical Trials – 3 day workshop”

Time: 8:30 am – 5:00 pm each day
Place: School of Medicine and Dentistry
Place: Northeastern Conference Room 1-9525 & 1-9535

Information regarding the workshop and the registration form can be found at:
http://www.rochester.edu/ohsp/education/coordinators/threeDayWorkshop.html

Remember to check out the NEW OHSP website:

www.rochester.edu/ohsp

To make it easier for our research community to find the services provided by OHSP, we have included them all on one website. The new OHSP website is divided into three sections:

- RSRB
- Education & Training
- Quality Improvement
Quality Improvement News

Did you know the OHSP Quality Improvement Division has Study Self Audit Tools?

These audit tools were created for study sites interested in performing self-audits of their research projects. The objective is to provide easy to use audit checklists that follow the basic principles and procedures of a quality improvement audit as one would expect from an internal or external auditor. There are two main components of any Good Clinical Practice (GCP) study audit, review of the regulatory documents (study documentation) and review of compliance to the protocol (individual subject data accuracy). Checklists for these two components are provided along with instructions and examples of how a completed checklist may look. Information and the Study Self Audit Tools can be found at: http://www.rochester.edu/ohsp/education/coordinators/studySelfAuditTools.html

RSRB News

Activities that routinely do not require review by the RSRB

Case Report:
A summary of clinical data, including medical history and other relevant information, that was collected initially for the purposes of analyzing and diagnosing the individual's condition and/or for instructional purposes, is considered by the RSRB to be a ‘case report’ or ‘case study’. Because this information was not collected with any intent to test hypotheses or otherwise produce ‘generalizable’ knowledge, the activity does not meet the criteria for ‘research’ (45 CFR 46.102 (d)), and ordinarily does not require RSRB oversight.

Program Evaluation:
Program Evaluation involves the systematic collection and analysis of information about the effectiveness of the program in order to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development. The intent of these projects is to inform particular programs about that program’s effectiveness and needs rather than to contribute to generalizable knowledge, they are not considered research.

Quality Assurance and Quality Improvement (QA/QI) Projects:
QA/QI projects do not require RSRB review and approval except when they involve a “research” component as defined by the federal regulations. Precise definitions to permit the distinction between research studies and QA/QI projects have not been established but, in general, the intent of a QA/QI project is focused primarily on improving patient care within a given patient care environment (e.g., hospital or health care organization) and, as such, the results may not contribute to generalizable knowledge because the outcome may not be generalizable to other patient care environments. Publication of a QA/QI project does not, per se, render that project “research” because the intent was not for generalizable knowledge; however, if the QA/QI project is published, the terms “research” and “investigation” should not be used in the publication.

Research Methods Classes:
Universities and colleges offer courses that require students to undertake projects in which other people are interviewed, observed, or otherwise serve as participants. The purpose of these courses is to train students and provide them with a closer view of social, educational, or psychological processes, and an opportunity to practice various research methods. Provided the data obtained will not contribute to generalizable knowledge or be published outside of the classroom they are not considered human subject research that require RSRB oversight.

Research On or Involving Deceased Individuals:
Research performed on individuals who have been declared legally dead and/or research involving the collection of tissues from deceased individuals is not subject to prior review and approval by the University of Rochester RSRB. (Note that the federal regulations governing human research subject protections defines a “Human Subject” as “a living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information.)