The Office for Human Subject Protection (OHSP) had a busy year! We’ve...
- Written/Revised approximately 55 policies and supporting guidelines
- Reviewed over 700 new studies (98 Full Board, 319 Expedited & 309 Exempt) and managed over 1700 active study protocols (508 Full Board; 1201 Expedited)
- Conducted approximately 122 Quality Improvement reviews, 90 of which were routine (random) reviews (see page 4 for additional information regarding review ratings and common findings).
- Designed a new study team training framework, of which 2 courses were implemented with over 166 faculty/staff in attendance

2015 will continue to be a busy year with our upcoming AAHRPP (Association for the Accreditation of Human Research Protection Programs) re-accreditation. For more information about AAHRPP and other OHSP updates, please join us for our “Annual OHSP Updates and Quiz Show” Seminar on Tuesday, January 13, 2015 at 12pm in Helen Wood Hall Auditorium.

2014 OHSP Year in Review

Looking for a 2015 New Year’s resolution? There’s always room for improving the conduct of our research! Consider working the following resolutions into your everyday practice in 2015:

- **Maintain Your Regulatory File:** Resolve to update your regulatory file within one week of each RSRB approval notification. Your regulatory file should be systematically organized and include all RSRB-approved study documents, including all approved versions of the study protocol and all watermarked versions of consent forms and recruitment materials, as well as all RSRB approval letters. Cueing yourself to update your regulatory file after each RSRB approval is key! HINT: Don’t delete or move your RSRB approval notification email out of your inbox until you’ve updated your regulatory file (and don’t rely on the RSRB Online Submission System as a mechanism to maintain your documents)!
  Additional resources on documentation maintenance and organization can be found in the OHSP Study Documentation Toolbox.

- **Submit Your Progress Reports at least 60 Days Prior to Study Expiration:** The key to obtaining timely study re-approval is early progress report submission. Sixty days may seem like a lot of time but review of a progress report may require an extended period of time once you factor in RSRB review time and requests for clarification to the study team (a cycle which may repeat multiple times). Progress reports requiring review by the full board require an even longer review period, given that (continued on page 2)
(continued from page 1) the report must be: 1) reviewed by the RSRB specialist in preparation for the meeting, which may require clarification from the study team; 2) scheduled for the board review at least 1 week prior to the board meeting to provide reviewers enough time to complete their review (keep in mind, some boards only meet once or twice per month); and 3) potentially re-reviewed by either the RSRB chair if approval stipulations were required or the full board if the progress report was tabled. Failing to submit a progress report in a timely manner can result in an unnecessary study expiration.

- **Strive for 5:** No, we’re not referring to servings of fruits and vegetables! Strive for the 5 steps to a “healthy” informed consent process:
  1. Obtain consent in a manner consistent with your RSRB-approved protocol
  2. Use only the watermarked version of the consent form to obtain consent
  3. Use only the most current version of the consent document to obtain consent
  4. Ensure that the first page of the document is printed on letterhead
  5. Only allow IRB-approved study team members to obtain consent

- **Utilize a “Second Set of Eyes” Prior to IRB Submissions:** Consider having an independent colleague review your protocol and any supporting documents prior to RSRB submission. Having a “second set of eyes” (with appropriate background knowledge) review your submissions may help to identify protocol elements that could potentially result in future non-compliance (e.g., Is the protocol written in a manner that leaves certain critical elements open to interpretation? Is the safety monitoring plan do-able? Is the information provided within the protocol and in supporting documents consistent?)

- **Commit to Participating in a Research-Related Professional Development Activity at Least Twice a Year:** Everyone has busy schedules but it’s increasingly important to stay current on salient research topics. Take some time out of your schedule to attend an OHSP or CTSI seminar, read through the OHSP newsletter, or complete online training activities. This may save you time in the long-run by preventing non-compliance. Information regarding OHSP and CTSI events are most easily accessed through their respective email distribution lists (see [OHSP](#) and [CTSI](#) to sign-up).

- **Kick Your Oversight Up a Notch:** Whether 2014 sailed by seamlessly or you encountered issue after issue, consider modifying just one process to improve your oversight of the research you conduct. This could be something simple, such as modifying your subject eligibility documentation to include a signature line and date for the Principal Investigator to demonstrate agreement that the subject meets eligibility, or it could be more far-reaching, such as implementing a quality assurance process within your study. Other options might include:
  * Instituting a pre-study documentation review process whereby key study team members meet prior to initiating a study, to review all study case report forms or data collections sheets and ensure that study documentation will thoroughly (and appropriately) demonstrate compliance with all protocol-defined study activities
  * Implementing an annual review process to ensure adherence to the protocol-defined data and safety monitoring plan
  * Committing to meeting with the study team on a regular basis (versus on an as needed basis)
Mistakes Happen – Make Sure You’re Correcting them Appropriately!

When making corrections, it’s important to remember you need to maintain an audit trail of your study documentation. To appropriately make corrections, place one line through the error, write the correct entry above or next to the cross out, and initial and date the error. Corrections should not obscure the original entry. As such do not write over, blacken out, or use white-out to make corrections!

** A NEW series of training sessions will begin in 2015. More information will be provided at the 1/13 seminar and through the OHSP listserv. **

ROSS Training

The RSRB Office provides training for the RSRB Online Submission System (ROSS) the 3rd Monday of every month from 2-3pm. To sign-up for this training, please email Sue Flanigan.

Study Documentation & Self Audit Tools

Study documentation templates and self audit tools are available on the OHSP Quality Improvement (QI) website. Questions regarding the use of these templates/tools can be directed to the QI team.

Additional Review Required for Research Conducted at Highland Hospital Facilities

All research conducted within Highland Hospital facilities must be reviewed and approved by the Highland Hospital Administrative Research Review Committee (ARRC) prior to subject enrollment. Studies should be submitted to the ARRC once RSRB/WIRB provide approval. Also note that once the ARRC has approved the study, it is expected that the Principal Investigator will provide annual progress reports and share study findings with the ARRC. Additional information regarding this process can found in Highland Hospital Policy 4.20 (Participation of Human Subjects in Research and Research Approval Process) or by contacting the ARRC Research Coordinator (laurie_ernest@urmc.rochester.edu).

Save the Date! Upcoming Educational Opportunities

OHSP Research Education & Training Sessions

“Research Boot Camp”

January 16, 2015 8:00am-12:00pm; HWH Rm 1W-501

To register, please email Kelly Unsworth

Achieving High Quality Clinical Research Seminar Series

January 13th: Annual OHSP Update & Quiz Show
February 17th: Exempt Research
March 24th: To Be Determined

Seminars are held at 12:00-1:00pm in Helen Wood Hall Auditorium (1W-304).

Miss a Previous Seminar?

Presentation materials and links to videos of previous seminar series presentations are available on the OHSP and CTSI Websites.

Reminders

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2014 Quality Improvement Findings

In further consideration of your New Years resolutions (see page 1) - or if you’re curious how your Quality Improvement (QI) reviews stand up to the rest - we’ve compiled a few 2014 metrics for your review:

- Of the reviews completed over the previous year approximately 4% received a ‘Commendable’ rating, 59% received an ‘Acceptable’ rating, 26% received an ‘Acceptable with Follow Up’ rating, and 11% received an ‘Unacceptable’ rating. Ratings are determined by the OHSP QI team based upon the quality and severity of review findings, as defined by OHSP Policy 1001 Quality Improvement Program. For example, findings that typically push a review into an ‘Unacceptable’ rating involve major deficiencies that may affect subject safety (e.g., not obtaining consent or missing consent documentation, enrolling ineligible subjects, failing to comply with protocol-defined adverse event assessment and/or safety monitoring, and errors related to investigational product assignment or distribution).
- Across all types of QI reviews conducted over the previous year, the most common findings include issues related to:
  1. Regulatory file documentation
  2. Informed consent
  3. Protocol adherence
  4. Subject eligibility
  5. Source documentation

Research QI ‘Gold Star’ Award

The QI division would like to recognize Robert Block MD, MPH, Geoffrey Williams, MD, PhD, Amir Abdolahi, PhD, and Avi Dressler for their quality research work on the ‘Interactive Cholesterol Advisory Tool (ICAT)’ trial. This dynamic study team is a part of the Department of Public Health Sciences and is located at the Healthy Living Center on Prince St.

This study team received the 4th Quarter, 2014 ‘Gold Star’ award for demonstrating attention to regulatory compliance, exceptional subject recruitment/retention practices, and high quality, organized study-related documentation. Investigator oversight, consenting process and inclusion/exclusion criteria documentation was outstanding.

CONGRATULATIONS!!

Current Events

- Filling Information Gaps for Women in Medical Device Clinical Trials (Strauss, D. [2014, June 23]. FDA Voice.)

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 subject research.
Frequently Asked Questions

What is an ‘Institutional Official’?
An Institutional Official, commonly referred to as an “IO”, is responsible for signing off on an institution’s Federalwide Assurance (FWA) with the Department of Health and Human Service (HHS). This assurance is required in order for the institution to receive HHS support and certifies the institution will comply with HHS regulations for the protection of human subjects. As such, an IO is also responsible for implementing and maintaining an institution’s human research protection program (HRPP).

At the University of Rochester, the Senior Vice President for Research (currently Dr. Robert Clark) serves as the IO, with the day-to-day administration of the HRPP falling to the Office for Human Subject Protection.

I haven’t been able to keep up with all of the OHSP policy updates. Are there policies that can be prioritized for my review?
While OHSP hopes that study team members will review policies as they are revised (notifications regarding updates are routinely included in listserv emails), we realize this may not be realistic. As such, we suggest that you prioritize review of the following 3 policies:

- Policy 701 Informed Consent
- Policy 801 Reporting Research Events
- Policy 901 Investigator Responsibilities

Have a FAQ for a future newsletter?
Email Kelly Unsworth with questions and we’ll do our best to include those questions in future newsletters.

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