2017 OHSP Year in Review

The traditional act of ‘welcoming in the New Year’ carries new meaning, and possibly a heavier weight, this year as faculty and staff conducting and overseeing human subject research face impending regulatory changes. As we prepare to face those challenges, let’s reflect on the Office for Human Subject Protection’s (OHSP) previous year.

Research Subjects Review Board (RSRB)

On par with previous years, the RSRB reviewed 779 new studies in 2017 (82 by a convened board, 402 via the expedited review pathway, and 292 were deemed exempt). In combination with existing research, this totals 2288 active study protocols (note that this total is not inclusive of studies reviewed and approved by external IRBs [e.g. Western IRB]).

RSRB turnaround times were also consistent with years past (see Figure 1). Of note, the median number of calendar days from submission to initial review and submission to approval by the convened board has decreased considerably (by approximately one-third).

And, moreover, RSRB turnaround metrics exceed those of other accredited academic institutions across the board. (Metrics published by the Association for the Accreditation of Human Research Protection Programs on academic institutions report time from submission to approval for convened board reviews, expedited reviews and exemption determinations as follows: 41, 20 and 12 calendar days [respectively].)

In addition to reviewing and approving research, the RSRB has continued to work on improving the efficiency of the review process and existing human subject protection mechanisms. Several policies and guidelines were updated to be consistent with current practice, and the RSRB Online Submission System (ROSS) has been updated (continued on page 2).

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<tr>
<th>Review Level</th>
<th>2017</th>
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<td>Review</td>
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<tr>
<td>Convened (Full) Board</td>
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<td>Exempt</td>
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2017 Major ROSS Updates

ROSS has undergone the following significant revisions this year (see the OHSP Q4 Newsletter for additional information):

- Section 63 (Study Sites) was updated to better delineate non-UR site engagement
- An automated process to withdraw stalled new applications was implemented
- New processes to facilitate Surgical Pathology and Radiation Safety ancillary reviews were implemented
- The submission process for protocols undergoing review by the Western IRB was revised
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(continued from page 1) for improved functionality. These updates will continue as the RSRB implements the revised Common Rule.

Research Education & Training

OHSP Research Education & Training has trained 144 individuals over the course of 2017, with attendees completing anywhere between 1 and 10 components of the OHSP Education & Training Framework (e.g., Orientation to Conducting Human Subject Research, Research Boot Module, Core Training Module 1, etc.).

Total attendance across all existing training components for 2017 was 365, which is considerably less than attendance rates in 2016 but consistent with 2015. The most popular courses, with 40-60+ attendees/course completions, include Orientation to Conducting Human Subject Research, Research Boot Camp, and Core Training Module 9: Essential Documentation (bear in mind that both the Orientation and Research Boot Camp courses are available for completion in MyPath while the Core Training modules are only offered in-person, each at one time point over the course of the previous year). Overall course ratings and feedback were largely positive.

Goals for 2018 include:

- Updating the Orientation and Research Boot Camp courses
- Transitioning all Core Training Modules to an electronic format (e.g., MyPath, Blackboard)
- Enhancing accessibility to training framework components for students
- Hosting an ‘Advanced Training’ day-long workshop

Quality Improvement

The OHSP Quality Improvement (OHSP-QI) team was very busy this year, exceeding their review goal of 60 with 63 reviews conducted in 2017. Eighty-six percent of those reviews were routine and approximately 60% were rated with either an ‘Acceptable’ or ‘Commendable’ rating (for a complete breakdown of OHSP-QI review ratings see Figure 2). The follow-up OHSP-QI feedback survey, indicates over 90% of respondents thought the reviewer’s recommendations were helpful, constructive, relevant and achievable.

Of note, the total number of QI reviews conducted each year continues to trend down as a result of the planned expansion of other services provided by QI (see Study Start-Up information below). In 2015, there were 119 QI reviews conducted, (continued on page 3)
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(continued from page 2) 78 in 2016 and 63 this past year. In addition, the percentage of board-directed reviews has also decreased over the past couple of years from 17% in 2015 to 11% in 2017.

In contrast, the total number of Study Start-Up (SSU) consultations has dramatically increased. OHSP-QI started 2017 with the goal of conducting 40 SSUs over the course of 2017 but far exceeded this goal with 61 consultations conducted. Just over 98% of SSU survey respondents found the consultation feedback helpful, constructive, relevant, and achievable. OHSP-QI also conducted 3 Quality Management Plan consultations, another new OHSP-QI initiative over the past year.

Looking ahead to 2018, OHSP-QI has set goals similar to previous years, with a goal of 60 OHSP-QI reviews and 40 SSU consultations. Routine reviews will continue to be conducted across the University (i.e., River Campus and Medical Center) and are selected using a risk-based approach.

Changes to the RSRB Watermark

On April 2nd 2018, the RSRB will be revising the format of the watermark. For research undergoing EXPEDITED or CONVENED BOARD review, the sample watermark in Image 1 will be used. This watermark will no longer contain the RSRB number, as this should already be contained in the document footer, nor the initials of the individual approving the research. The watermark will now clearly state the approval date and expiration date of the document. As documents are amended throughout the year, the “approved” date may change, but the expiration date will remain the same. Expiration dates will only change at the time of continuing review when a study is re-approved.

For research confirmed to be EXEMPT, the watermark applied to approved documents will remain unchanged; the watermark will only include the date the document was deemed exempt (see sample watermark in Image 2).

Did You Know...

- The University of Rochester’s Finance Department has recently updated their F-4 Payment Request form. All study teams utilizing this method to pay research subjects must use the updated form. As of February 1, 2018, failing to do so will result in the return and/or denial of payment requests. A copy of the revised F-4 form, as well as F-4 payment request instructions and F-4 payment request training are available on the Finance Department’s website. For further reference, a copy of the Finance Department’s policy on payments to research subjects is available here.

- The RSRB’s Guideline for Coordinating Center Studies is a great resource to use not (continued on page 4)
Did You Know...
(continued from page 3) only for coordinating center studies, but also multi-site studies. With the National Institute of Health (NIH) requirement for single Institutional Review Board (IRB) review of multi-site research, the role of a coordinating center may need to be applied to a wider variety of studies than ever before. The guideline provides detailed information on different types of coordinating center studies, roles and responsibilities, and RSRB review of coordinating center activities.

- The University of Rochester is part of the Clinical Trials Transformation Initiative (CTTI), a public-private partnership aimed at driving the adoption of practices designed to increase the quality and efficiency of clinical trials. The organization includes more than 80 organizations that span clinical trial activities including government agencies, industry sponsors, academic institutions, professional organizations, patient advocacy groups and other interested parties. Initiatives have included projects related to informed consent, investigator qualifications, site metrics, recruitment, central IRBs, and several others. Faculty and staff can sign up for CTTI updates and notifications via their website.

- The National Institutes of Health (NIH) updated their policy on the inclusion of women and minorities in clinical research on November 28, 2017. The amended policy requires submission of valid analyses by sex/gender, race and/or ethnicity to ClinicalTrials.gov for NIH-funded Phase III clinical trials. This requirement applies to all new, competing grants and cooperative agreements awarded on or after December 13, 2017. Additional information concerning this policy is available on the NIH’s website. Also note, that assistance with reporting in ClinicalTrials.gov is available through the University’s Clinical and Translational Science Institute.

Hold that Thought!

Common Rule Revision Delayed

The Department of Health and Human Service (HHS) released revisions to the Common Rule (the ‘Federal Policy for the Protection of Human Subjects’) in January 2017, with an initial effective date of Friday, January 19th 2018. An announcement was released to the research community on Wednesday, January 17th at 4:52 pm indicating that the effective and general compliance date originally published with the final rule has been delayed to July 19, 2018.

What Does This Mean For You?

- Until July 19, 2018, all new and ongoing research must comply with the pre-2018 Common Rule (i.e., business as usual, complying with the Common Rule regulations last revised in 1991). Updates concerning exemption categories, continuing review, subject screening, clinical trial consent posting, etc. will not be implemented until July 19, 2018.

- Continue to use the new consent form templates. Although the new consent form templates available on the RSRB website include additional elements of consent and the presentation of ‘key information’ as required in the new regulations, the UR research community is instructed to continue to use these templates as they remain consistent with the regulations in the pre-2018 Common Rule. While the additional elements and presentation of ‘key information’ are not required under the current rule, they do not conflict with current regulations.

For your information, there are summaries of the revised regulations available in the Office for Human Subject Protection’s Q4 Newsletter and in the seminar on Common Rule Changes presented on 09/27/17. Additional information concerning the timeframe for implementation of the new regulations will be provided as it becomes available. Further training concerning the revised regulations will resume in the future.
Research QI ‘Gold Star’ Award

The QI division is recognizing Lauren O’Donoghue and Nicole Murray for their implementation of a site-level, program-wide Quality Management Plan (QMP). This team is based in the Cancer Control Research Program. The QMP involves, in part, utilizing the Study Start-Up Consultation service for each newly approved study and a yearly review of regulatory binders for all open studies.

They received the 1st Quarter, 2018 OHSP-QI ‘Gold Star’ award for their commendable work in assessing research by quality measures and creating a detailed strategy to enhance continuous quality improvement which further protects the health, safety, and welfare of subjects.

Congratulations!

A Year End Review from OHSP-QI

Sonny Spot reflects on the past year working as a Study Coordinator on a research study:

- He has learned lessons from Quality Improvement reviews past, including maintaining a regulatory file, using the watermarked consent form, and to initial and date corrections for errors.
- Presently, the most pressing items of the day are demonstrating protocol adherence, documenting the data and safety monitoring plan, and assessing adverse events.
- And, yet to come, in his research study future is developing a quality management plan, using RedCap for data entry, and submitting a Central IRB application.

Past, Present, and Future leads to protecting human subjects and ensuring data integrity.

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