New Years Resolutions for the UR Researcher

Looking for a New Year’s resolution? While we know that human error occurs, implementing these resolutions into your everyday practice can help to improve the conduct of your research (additional resolutions were provided in our 2015 Q1 OHSP Newsletter):

- **Be Mindful of Your Resources:** The Office for Human Subject Protection has numerous resources available for the University of Rochester research community. Resolving to take full advantage of these resources will help ensure a smooth IRB review process and increase the likelihood of compliance once the study is underway. Just to name a few…

- **OHSP Policies and Guidelines:** Knowing what’s expected of you is half the battle in conducting compliant research. Be sure to refer to the 70+ different policies and guidelines on the review and conduct of human subject research both during the protocol development process and as questions or concerns arise during the conduct of your research. Only have time to read just 1? Let it be this one: OHSP Policy 901 Investigator Responsibilities!

- **Protocol and Consent Templates:** No need to start from scratch when you’re developing a new IRB submission! The Research Subjects Review Board has six different protocol templates and over 20 different consent templates available on their website. Word to the wise: Make sure you’re selecting the appropriate template(s), based on the nature of your research! This will help you: 1) address all (continued on page 2)

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**2015 OHSP Year in Review**

The Office for Human Subject Protection (OHSP) had a busy year! We’ve…

- Reviewed over 500 new studies (83 Full Board, 282 Expedited & 201 Exempt) and managed over 1800 active study protocols (543 Full Board; 1275 Expedited)
- Conducted approximately 120 Quality Improvement reviews, more than 80 were routine (or “random”) reviews
- Trained over 340 faculty and staff with elements of the OHSP Education & Training Framework, including the newly implemented Core Training
- Successfully received full re-accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP)

For more information and other OHSP updates, please join us for our “Annual Updates from the Office for Human Subject Protection” seminar on Tuesday, January 26, 2015 at 12pm in Helen Wood Hall Auditorium.
New Years Resolutions (Continued) (continued from page 1)

(continued from page 1) relevant information; and 2) avoid including unnecessary information that may complicate the IRB review process. Sample consent document language is also available for drafting consent forms, once you’ve selected the appropriate consent template.

- Study Documentation Templates & Self-Audit Tools: Approximately one-third of the 2015 OHSP Quality Improvement (OHSP0-QI) reviews included findings related to inadequate, inconsistent or missing source documentation, therefore every study team’s mantra should be ‘Document Everything!’ With that in mind, take advantage of the over 40 customizable study documentation templates and self-audit tools available through OHSP’s Division of Quality Improvement. Templates are available in Microsoft Word (or Excel) and should be modified to meet each individual study’s needs.

- Study Start-Up Consultations: Consider some of the other 2015 OHSP-QI stats: 22% of reviews had findings related protocol non-adherence; 12% had findings related to Data and Safety Monitoring Plan non-compliance; and 6% had findings related to inadequate adverse event assessment. Scheduling a Study Start-Up Consultation could help you avoid being included in these stats for 2016. This service, which typically occurs after IRB approval but prior to initiating study conduct, will help to provide you the tools to achieve compliance by evaluating planned study documentation and collaborating with study staff to ensure a full understanding of applicable regulations, policies and guidelines specific to an individual research study.

- Re-Train Your Brain to Stay Engaged: Because of the vast array of research conducted at the University, you’ve likely had the experience of sitting in on a training session or meeting and thinking to yourself ‘this doesn’t apply to me’. While we agree that all regulations and policies do not apply to all types of research, challenge yourself to stay in engaged in the conversation. How can I apply the information to my research? Can part of the information be applied in a useful manner? Can the information be used to approach an issue from a different angle? Learning about other types of research or hearing about other people’s experience informs your perspective and thereby affects how you approach (or fail to approach) the responsibilities related to the conduct of your research.

- Change Your Process & Print Consent Forms Directly from ROSS: Over 50% of 2015 OHSP-QI reviews included findings related to the failure to appropriately document informed consent, a portion of which was the use of outdated versions of the consent form. If you’re not doing so already, resolve to print consent forms directly from the RSRB Online Submission System (or any other applicable IRB review system, as appropriate) at the time of obtaining consent thereby preventing the use of an outdated version of the document.

- Implement a New Checklist: Checklists are a simple, yet effective, solution to ensure a consistent process during the course of a research study, thus decreasing the likelihood of non-compliance. Resolve to implement just 1 new checklist into your everyday process (or, if you’re feeling ambitious, shoot for 1 new checklist each quarter)! Consider a checklist for study staff training, study team meetings, post-IRB approval processes, consent documentation, study visits, event reporting or quality-related spot checks.
Leaving the UR? A PI’s Departing To-Do List

While faculty leaving the University may already have multiple academic and/or clinical tasks on their “Departing To-Do” list, including the appropriate management of a Principal Investigator’s ongoing research activities on that list is a must! At a minimum:

- **Notify the RSRB.** Per OHSP Policy 901 Investigator Responsibilities, Investigators are required to notify the RSRB if they are departing from the University either temporarily or permanently. All other applicable IRBs of record (e.g., Western Institutional Review Board) must be notified as well.

- **Determine whether active research will continue locally or be closed.** If active research will continue at the University, the study must be transferred to another Principal Investigator (a change that must submitted to the IRB of record and approved via amendment). Please note the IRB will need documentation of agreement from the new PI in order to make the change. If research activities will not continue, a final closure report needs to be submitted.

- **Notify ORPA.** Existing grants, contracts and sub-

- **Contracts need to be appropriately managed.** This may include transferring a grant to a new institution or reviewing/modify the terms of a current agreement (e.g., changing the Principal Investigator on a Clinical Trials Agreement).

- **If research data, samples or equipment will be transferred to the new institution, determine the appropriate method for doing so.** Research material collected, developed or used during the course of a study may be shared with your new institution, as long as it’s done so appropriately. Typically, this can be accomplished under a Material Transfer Agreement (MTA). However, if the Principal Investigator is part of the URMC and Affiliates covered entity, additional steps may need to be taken to comply with the Health Insurance Portability and Accountability Act (HIPAA). Options for data/specimen sharing that comply with HIPAA may include: obtaining HIPAA authorization from subjects indicating agreement to release information to the new institution; sharing only a Limited Data Set under a Data Use Agreement with the new institution; or sharing only de-identified data/samples.

- **Manage your study documentation.** Essential documentation, including signed consent forms and source documentation (e.g., questionnaires & assessments) must be maintained for a minimum of 3 years after the study is closed or 6 years after the study is closed if the study involved the collection of PHI (protected health information) under the URMC and Affiliates covered entity. *This documentation is property of the University of Rochester and should not be transferred elsewhere.*

Additional information is available via the OHSP Guideline for Investigators Leaving the Institution and HIPAA Policy 0P-25 Use or Disclosure of PHI for Research Activities. Also note that information on a similar standard for clinical staff, titled “Managing the Protected Health Information Requirements Associated with Incoming and Department Employees, including Faculty”, is available through the HIPAA intranet site.

Not a PI? Stay tuned for next quarter’s OHSP Newsletter which will include information for other departing research staff.
Communicating with Research Subjects via Email

If you are conducting research under the URMC and Affiliates covered entity (or have study team members who are part of the covered entity) and plan to transmit protected health information (PHI) via email, subjects must provide written consent prior to doing so. A Research Subject Email Consent Form is available on the RSRB website for this purpose. RSRB review and approval of this e-mail consent form is not required, but your protocol should indicate that you plan to use this form.

Please be reminded that, once written consent is obtained, email communications containing PHI still need to be transmitted in a secure manner. All email communications should include “!secure” in the subject line of the message as this automatically encrypts the message. Additional information is available in HIPAA Policy OP-29 Electronic Communication of Protected Health Information via Facsimile, Electronic Medical Records and Email, as well as on the URMC Information Systems Division’s Secure Email Service website.

Subject, Not Participant

When referring to an individual enrolled (or potentially enrolled) in a research study, OHSP requires that study team members use the term “subject”, as opposed to “participant” or “volunteer”. This terminology is consistent with the language used in the Belmont Report and the federal regulations employed by the Department of Health and Human Services (45 CFR 46) and the Food and Drug Administration (21 CFR 50). As such, the term “subject” should be used in all study-related documents (i.e., the study protocol, consent forms, recruitment materials, surveys, etc.)

Achieving High Quality Clinical Research Seminar Series

January 26th: Annual Updates from OHSP
March 8th & April 5th: To Be Determined

Seminars are held at 12:00-1:00pm in Helen Wood Hall Auditorium (1W-304). Continuing Medical Education credit is typically available for each seminar. Lunch is provided. Please bring your own beverage.

Not Able to Attend?

Live streaming of seminars is typically available through the CTSI. Presentation materials and links to videos of previous seminar series presentations are available on the OHSP and CTSI Websites.

Reminders
Frequently Asked Questions

I completed human subjects training through CITI at my previous institution. What do I need to do to meet the University’s training requirements?

Training can vary from one institution to another as courses within the Collaborative Institutional Training Initiative (CITI) are customizable. Each institution determines which modules they require for their own training purposes. As such, we require all personnel to complete the University of Rochester’s version of the training through CITI. Fortunately, credit for modules completed previously will transfer. Trainees only need to complete the required modules not previously completed.

Note that while individuals may have previously completed human subjects training through CITI, those completing the training for the University of Rochester for the first time must complete one of the initial certification programs (as opposed to a recertification course). Questions regarding this process can be referred to Kelly Unsworth.

Food for Thought


- **Trends in National Institutes of Health Funding for Clinical Trials Registered in ClinicalTrials.gov** (Ehrhardt, S., Appel IJ, Meinert CL. [2015, December 15]. Journal of the American Medical Association.)

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.

Contact Information

**Department Administration**
Kelley O’Donoghue, Director OHSP (585) 273-4631
Tiffany Gommel, Director RSRB (585) 273-4574

**Research Education & Training**
Kelly Unsworth, Director (585) 275-5244

**Clinical & Regulatory Systems**
Thai Nguyen, Director (585) 273-4583
James Wanzenried, Sr. Programmer (585) 273-4579

**Quality Improvement**
Kathleen Wessman, Director (585) 273-2118
Jennifer Dolan, QI Associate (585) 276-5709

**Administrative Staff**
Janice Taylor, Administrative Asst (585) 273-4127

**RSRB Board Specialists**
Randall Buermann, Board 1 (585) 273-2117
Kathleen Buckwell, Sr. Specialist, Board 2 (585) 275-7446
Linda Palm-Montalbano, Board 3 (585) 273-4578
Michelle Giglio, Board 4 (585) 273-4576
James Filingeri, Board 4 (585) 273-4577
Nicole Mason, Board 5 (585) 276-3856
Suzanne Coglitore, Exempt/WIRB (585) 276-5544
Emily Flagg, Senior Specialist (585) 276-5537

**Main Office**
Phone: (585) 273-4127
Fax: (585) 273-1174

**Website**
[www.rochester.edu/ohsp](http://www.rochester.edu/ohsp)