Study Start-Up Consultations:
A New Quality Improvement Resource for Study Teams

As a study team member, either new to the job or with years of experience, you will, at some point, have the experience of “shooting yourself in the foot” somewhere along the way. Maybe you’ve inadvertently included a procedure in your protocol that you don’t intend to do. Maybe you didn’t realize you needed a Delegation of Authority Log for your study. Or maybe you forgot to include height as a data collection point on your case report form.

Identifying what regulations/policies apply to your research, complying with those regulations/policies and demonstrating compliance can be a challenge for all researchers as can maintaining those methods for demonstrating compliance.

In addition to routine, directed, and board-requested reviews, OHSP’s Division of Quality Improvement (OHSP-QI) is pleased to announce the addition of Study Start-Up Consultations to available services. The primary goal of this service is to set Investigators and study staff on the road to compliance with applicable regulations/policies and to ensure subjects enrolled in research are adequately protected at the beginning of the trial.

Upon request, prior to initiating a study, the OHSP-QI staff is available to provide guidance on best practices for meeting your responsibilities, as they relate to the conduct of a specific study, and to evaluate study documentation (e.g. regulatory file & case report forms) you’ve prepared for implementation of your study and collection of data.

After the consultation, OHSP-QI will provide a written assessment, educational materials, references, support, and study tools, as appropriate.

Specifically, what can OHSP-QI assist you with during Study Start-Up Consultations?
• Assess your preparedness to achieve compliance with IRB approved protocol/amendment(s), IRB requirements, OHSP and UR Policy, applicable federal regulations, and the University’s Federal Wide Assurance (45 CFR 46)
• Provide tools and resources to support training, mentoring and research staff development
• Identify processes for ensuring protocol adherence
• Establish a forum for frequent communication between OHSP-QI staff and Research Staff
• Focus on outcomes to support clinical management, essential documentation, subject safety, quality of care, and research oversight

Please contact OHSP-QI to schedule a study start-up consultation.
Changing Jobs or Advancing Roles? Let Us Know!

Please be sure to let OHSP/RSRB staff know if you change roles, advance positions or move to a different department (e.g., a graduating fellow entering into a full-time faculty position or a study coordinator changing departments), to ensure your RSRB Online Submission System (ROSS) profile is updated accordingly. This update is essential, not only for facilitating communication, but also for ensuring all new study applications are appropriately funneled to the correct department for scientific review. Profile updates can be facilitated through your RSRB specialist or by emailing James Wanzenried directly.

Similarly, membership profiles in CITI (Collaborative Institutional Training Initiative) should be updated when completing human subjects training refreshers. This will provide OHSP staff updated information to enter into your ROSS profile as re-certifications are processed.

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.

Subject, Not Participant

Please be reminded that OHSP requires that study team members use the term “subject”, not “participant” or “volunteer” when referring to individuals who choose to enroll in research (or potentially enroll). This terminology is consistent with the language used in the Belmont Report and the federal regulations and as such, should be used in all study-related documents (i.e., the study protocol, consent forms, recruitment materials, surveys, etc.).

New Employee? Training Guidance is Available!

Training checklists to facilitate and document study team training are available on the OHSP Division of Research Education & Training website. Four basic training checklists (Investigator-Biomedical; Investigator-Behavioral; Coordinator-Biomedical; Coordinator-Behavioral) are available, each with a basic set of training activities. Within the checklist, University-required training is identified with asterisks, all other required training is dependant on individual research roles. These checklists are meant to act as a guide only and should be modified to suit each individual department’s and/or study team’s needs; activities that do not apply to a trainee should be eliminated from the checklist. Similarly, additional training elements can be inserted to the checklist (additional training resources are identified in OHSP’s “Study Team Member Training & Resource Reference List”). If you would like guidance on developing departmental and/or study team training standards, contact Kelly Unsworth.
Save the Date! Upcoming Educational Opportunities

**OHSP Research Education & Training Sessions**

**“Research Boot Camp”**
Friday, July 31st 8:00am-12:00pm, Location TBD
To register, please email [Kelly Unsworth](mailto:Kelly.Unsworth@vanderbilt.edu)

**“Core Training”**

Core Training Module 5: Recruitment & Retention
Monday, April 27th 12:00-1:30pm, HWH 1W-509

Core Training Module 6: Informed Consent
Monday, May 11th, 8:00-10:00am, HWH 1W-502

Remaining Core Training modules will continue to be implemented, with one training module introduced per month through September 2015. This includes: Investigational Products (June); Subject Safety (July); Essential Documentation (August); and Quality Management & Non-Compliance (September). Core Training Modules will be repeated starting in January 2016.

Specific information regarding all training sessions will be announced through the OHSP listserv. To subscribe to the listserv, please email [Kelly Unsworth](mailto:Kelly.Unsworth@vanderbilt.edu) providing your name, study team role and email address.

****SPECIAL TRAINING SESSION**

OHSP staff will host a specially scheduled training session, “Central IRBs: Where Does the UR Fit into the Picture?”, on Wednesday, April 15th from 9:30-10:30am in Helen Wood Hall Auditorium (1W-304).

**Achieving High Quality Clinical Research Seminar Series**

The Achieving High Quality Clinical Research Seminar Series will resume in September.

**Miss a Previous Seminar?**

Presentation materials and links to videos of previous seminar series presentations are available on the [OHSP](http://ohsp.vanderbilt.edu) and [CTSI](http://www.ctsi.vanderbilt.edu) Websites.

**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](mailto:Sue.Flanigan@vanderbilt.edu).

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**Research QI ‘Gold Star’ Award**

The QI division would like to recognize [Christopher Drinkwater, MD](mailto:Christopher.Drinkwater@vanderbilt.edu) and [Amy Battisti](mailto:Amy.Battisti@vanderbilt.edu) for their quality work on the ‘A Prospective, Multi-Centered Study of the Birmingham Hip Resurfacing System’ trial. This dynamic study team is part of the Department of Orthopaedics and is based at Highland Hospital.

They received the OHSP-QI ‘Gold Star’ award for demonstrating attention to regulatory compliance, exceptional subject recruitment/retention practices, and high quality, organized study-related documentation. Their consenting process and inclusion/exclusion criteria documentation was outstanding.

**Congratulations!**
Frequently Asked Questions

What are the RSRB's full board review submission deadlines?
Submissions that require full board review (e.g., a new application involving greater than minimal risk research) are scheduled for review on a first come, first serve basis; standard submission deadlines are not set.

The RSRB works diligently to schedule review items in a timely manner; however several extraneous factors may affect the timing of your board review (e.g., the quality of the submission, the number of other review items already scheduled for any one meeting, and board member time constraints).

If you know in advance you will be submitting a timely review item (e.g., a Just-in-Time application), please notify your RSRB Specialist as early in the process as possible. Notification will help facilitate well-timed submissions and prompt board review.

When can I close my study and how do I submit my final report?
Studies are considered complete when subjects are no longer being recruited, no longer being followed, primary data analysis has been completed according to the protocol and results are available, and identifiers have been removed (not destroyed) from the analysis dataset. In the event, the local study team is not involved in data analysis (i.e., acting as an enrolling site on multi-center research), the study may be closed once subjects are no longer being followed, all data queries have been resolved (i.e., the medical record is no longer being accessed) and the sponsor has provided permission to do so.

Investigators can submit final reports, at any time, by completing a Continuing Review Report in the RSRB Online Submission System. Once a study is closed, all study activity must cease; though data analysis may continue as long as identifiers have been removed by the dataset.

Additional information can be found in OHSP Policy 502 Types of RSRB Submissions.

eRecord & Research Updates

Changes to External Study Monitor eRecord Access
Per a new eRecord policy, external study monitor eRecord accounts will be deactivated between visits. Notification will now need to be provided a few days before the visit so the account can be reactivated. Deactivating study monitor (ePartner) accounts in between visits complies with URMC Information Security access control policies, as noted on the NEW Study Monitor Access Request Forms available on the eRecord site. Please note that:

* With the new form, the Principal Investigator and Program Administrator will need to sign off on the request, consistent with the request.
* To reactivate the external study monitor access, the local study team will need to email eRecordExternalReviewerRequest@URMC.Rochester.edu at least 3 days prior to the visit and include: study name (include CTO#), study monitor name(s) and dates access is needed.
* New request forms must be submitted for new studies and for new study monitors to existing studies.

Find Patient Information Faster with Chart Search
A powerful new search engine lets researchers enter a keyword or key-words to search the patient chart for problems, progress notes, medications, labs, and other orders from one search bar. Users can also find and open Synopsis views, notes and other available Hyperspace activities through this search—without needing to remember the necessary menu paths. Click here for more information on what you can search and how it works.

Questions regarding either of these updates should be directed to Research Help.
Current Events

- Informing the Protocol Building Process with the Patient in Mind (Bookbinder, M. [2014, July15]. Clinical Informatics News.)
- Rethinking the Therapeutic Misconception: Social Justice, Patient Advocacy, and Cancer Clinical Trial Recruitment in the US Safety Net (Burke, N. [2014, September 20]. BMC Medical Ethics, 15 [68].)
- Patient Empowerment Key to Trial Recruitment, Report Finds (McKee, S. [2014, November 28.] PharmaTimes Digital.)
- Fraudulent Clinical Trials Know to FDA ‘Hidden From Journals and Public’ (MacGill, M. [2015, February 10]. Medical News Today.)

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.

Did You Know...

- The CTSI launched the Research Request Dashboard, a one-stop web-based application that manages Research Navigator Program requests, this past November. Users can log in using their NetID to request general or project-specific assistance, access resources, request referrals and communicate directly with the Research Navigator. Questions regarding the application should be directed to researchhelp@urmc.rochester.edu
- TransCelerate Biopharma Inc. recognizes the following professional certifications as evidence of Good Clinical Practice (GCP) training: ACRP’s Certified Clinical Research Coordinator (CCRC), Certified Clinical Research Associate (CCRA) and Certified Principal Investigation (CPI); and SoCRA’s Certified Clinical Research Professionals (CCRP). This means that if you are conducting a study sponsored by a TransCelerate member, you may utilize your certification evidence of current GCP training thereby avoiding having to take redundant training. A complete list of TranCelerate members is available here.

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
Sue Flanigan, Data Manager (585) 275-3050
Nilsa Hernandez, Administrative Asst (585) 275-2398

RSRB Board Specialists
Linda Palm-Montalbano, Board 1 (585) 273-4578
Kathleen Buckwell, Sr. Specialist, Board 2 (585) 275-7446
Igor Milosevic, Board 3 (585) 273-2117
Michelle Giglio, Board 4 (585) 273-4576
James Filingeri, Board 4 (585) 273-4577
Nicole Mason, Board 5 (585) 276-3856
Suzanne Cogliitore, 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