

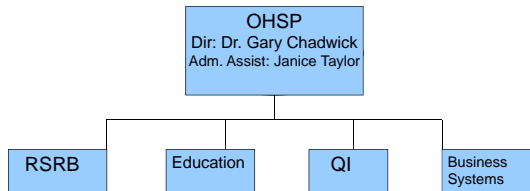
***Understanding the OHSP QI Process and
Improving the Research Process***

Linda Vineski, MS, CCRC, CCRA
Manager, Research QI
Office for Human Subject Protection

Goal

- Improve transparency of the QI process
- For sites to consider process improvements
- Increase awareness of resources available to all University researchers
- To allow a safe forum for asking questions

OHSP ?



QI Goals

Through assessment and education...

- Assist the PI in ensuring subjects are protected and that the study is conducted as promised (contract, 1572, IA) and required (UR policy & IRB) = external audit ready

We all want:

Researchers to be role models for best practice

Subjects to have a positive experience.

Sponsors/Funders to want you.

Education: what rules apply

- University Federal Wide Assurance (FWA)
 - <http://www.rochester.edu/rsrb/>
- HSPP/ EPRP training – Protecting Human Research Volunteers
- Sponsor / Funder requirements
- IRB approval letter requirements

RSRB Approval Letters

“This approval is contingent upon the investigation being conducted in compliance with the approved study protocol including all requirements and/or determinations of the RSRB.”

PI responsibilities:

Requesting an proposed changes – Changes must be approved prior to initiation unless to eliminate immediate hazard....

Maintaining all approved study documents in your study file

QI Review Process

- Routine reviews (department or category)
- Directed/For-cause reviews
- Requested
- [http://rsrb01.urmc.rochester.edu/rsrb/Rooms/DisplayPages/LayoutInitial?Container=co m.webridge.entity.Entity\[OID\[AC482809EC03C442A46F2C8EECD75D3\]\]](http://rsrb01.urmc.rochester.edu/rsrb/Rooms/DisplayPages/LayoutInitial?Container=co m.webridge.entity.Entity[OID[AC482809EC03C442A46F2C8EECD75D3]])
- <http://www.rochester.edu/rsrb/>
- <http://www.rochester.edu/ohsp/>

Review Steps

- Memo sent electronically
- Site visit (scheduled & conducted)
 - Study file
 - Sampling or full review IC and subject files
 - QI review not sponsor monitoring
- PI meeting
- Draft observations/
- PI response including preventive action
- Final report

Study File Review

- IRB requirement to maintain approved documents
 - Approval letters, Continuing reviews, corresp
 - All approved protocol and consent versions
 - Delegation of authority log (recommended)
 - Study specific
- Why?

Consent Form Requirements

- Where does it say what's expected?
 - WIRB and RSRB approval letters
 - Investigator guidance
 - New RSRB Online training
 - Research consent is different from other types !

Clinical trials:

<http://intranet.urmc-sh.rochester.edu/policy/smhpolices/section09/9-2-4.PDF>

<http://intranet.urmc-sh.rochester.edu/Policy/SMHPolicies/section07/7-7.pdf>

Consent form review

- Enrollment/data and signed consent #s agree
- Correct version (watermark/letterhead) why?
- Proper signatures / dates (Best practice v. req)
- Approved personnel (COIMP)
- Consent prior to data collection
- Why?

Subject Data File Review

- Sampling
- Source documentation is identified to support data collected. (ie)
- Research is conducted per protocol
 - Inclusion/ exclusion criteria
 - Data collection
 - Follow-up /safety
 - AE/ Protocol deviation reporting

Subject Data File Review cont'd

- Evidence of Investigator oversight
 - Study procedures
 - Adverse event determinations of expected /relatedness
 - Staff meetings and training

The Elephant in the Room Errors



My disclosure...

Focus: Improving Research Process

- Ric Masten's The Way to Teach – it isn't so much having a question to ask, it's having the ability to create one." ref by Charles Hatem 3.2.11
- Consider your research and ask- Has this occurred, how, what can we do to prevent it from happening, is it effective?

**Obj #3: Improving Research
with Resources and Preventive Action**

- Four Categories of common errors:
 - Protocol Deviations
 - Study File
 - Lack of documentation of PI oversight
 - Informed consent errors

**#1 Error Category
Protocol Deviations**

- Failure to follow the approved protocol
 - Missed time points
 - Process and procedures not conducted as stated
 - Subject does not meet inclusion/exclusion

**#2 Error Category
Not Maintaining Study File**

- Lack of understanding of the requirement
 - Goal – Make it simple!
 - Make it simple
 - Delegation of responsibility
 - Electronic / paper – your choice

3 Error Category
Lack of Documentation

- PI oversight
 - Training of research personnel
 - Inclusion/ Exclusion criteria
 - Meaningful review of study procedures
 - Clinical lab review for integrity
- Supporting documentation
 - Determine what your source doc will be
 - Email communication

4 Error Category:
Informed Consent Errors


- Signature and date lines not completed correctly
- Full signed consent not retained
- Incorrect version (exp, not current, no WM)
- Personnel not approved by RSRB

University Resources

- **OHSP**- Education, QI
- **RSRB** – Specialists, Director
- **ORS** – Joan Adamo, University wide resource
- **RSA** - Nancy Needler
- **CHET**- Karen Rabinowitz, Assoc. Dir. Collaborations
- **ORPA** – UR research policies
- **Research Billing** – Mike Ritz
- Departmental resources / collaborations
- **CTSI** – Navigator program /Research Help Desk
- **SCORE**

Recommendations


- Ask questions early using available resources
- Share information with other research staff not able to attend.

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Upcoming Education
April 1, 2011
8:30- 11:30a Whipple Aud 2-6424

"Conducting Human Subject Research at the UR: Writing and Implementing Research"

Topics: Protocol writing and the review process
Informed consent
Protocol deviations/ AE reporting
Source documentation and PI oversight

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