

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

Agenda

- 1:45-2:15 Protocol & Investigator Responsibilities
Kelley O'Donoghue, MPH, CIP
- 2:15-2:45 Informed Consent: Federal Regulations, Institutional Policy & Good Practice
Presented by: Kelly Unsworth, MS, CCRC
- 2:45-3:15 Study Approval: What's Next?
Presented by: Kathleen Buckwell, CIP

Protocol & Investigator Responsibilities

Kelley O'Donoghue, MPH, CIP
Executive Director
Research Subject Review Board (RSRB)

September 22, 2011

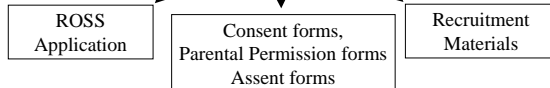
Protocol
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Recipe or Plan

Planning is KEY

- Plan ahead
- REALLY** think about...
 - logistics
 - access to the subject population
 - What data is **NEEDED** to accomplish the research
 - What will be done with the data



PROTOCOL



- Protocol should contain **all information** about the study
- From the protocol:
 - Answer all questions in the ROSS application
 - Create your consent documents
 - Create your recruitment materials

What:

- Purpose of the study

Why:

- Background/References

Who:

- Characteristics of the Populations

Where, When, and How:

- Methods and Procedures
- Risk/Benefit Assessment
- Statistical Analysis
- Subjects Identification, Recruitment and Consent/Assent



Elements of the Protocol

- Purpose - *What is your question?*
- Background - *Why does that question exist?*
- Characteristics of the Research Population – *How would you describe your study population, specifically?*
- Methods and Procedures - *What needs to be done to answer this question? How will data be collected?*
- Data Analysis – *How are you going to analyze the data?*
- Data Storage and Confidentiality - *How are you going to protect the collected data?*

Privacy Vs. Confidentiality

- Privacy
 - Protect access to data/samples
 - Access to an individual's information
 - “How did you get my name?”
- Confidentiality
 - Protect the research data once it is collected
 - Who has access to the research records? How is the laptop that contains the data protected? Are the CRFs in a locked room?

Elements of the Protocol

- Potential Risk - *What are the potential risks to the subjects participating in your study?*
- Protection Against Risks – *How will the study design/procedures prevent and/or minimize these risks?*
- Potential Benefits – *What are the potential benefits, if any? DO NOT OVERSTATE!*
- Subject Identification & Recruitment – *Who? How? Where? When?*
- Process of Consent/Documentation of Consent - *Who? How? Where? When?*

Little things go a LONG way...

- Title and Principal Investigator on first page
- Page Numbering and RSRB # in footer
- Table for the schedules of activities
- Amendments
 - Version control (use version dates)
 - Use “Track Changes” function in WORD to represent additions and deletions in all documents (protocol, consents, etc.)

Investigator Responsibilities

- Oversight of & Involvement in the study
- Qualified & trained individuals conducting research
- Communication with IRB & Reporting
 - Approval before
 - Communication throughout (Continuing reviews, reportable events, etc.)
 - Notification of Closure

Investigator Responsibilities

- Protocol Compliance
 - Ensure study team is following the protocol
 - Oversight of staff
 - Training of staff
 - Report to the IRB any deviations that might put the subject at risk **immediately**
 - Loss of identifiable data (stolen laptop), subject concerns

Investigator Responsibilities

- Informed Consent obtained and documented

- Study Documentation
 - Accurate, complete, legible, timely
 - Source Documents
 - Regulatory files

Questions

