

1

## Agenda

**8:30-9:00** Elements of a Research Protocol and Understanding the IRB Review Process (Kelley O'Donoghue)

**9:00-9:45** Informed Consent: Federal Regulations, Institutional Policy & Good Practice (Kelly Unsworth)

**9:45- 10:00** Break

**10:00-10:30** What's a Protocol Deviation and How to Avoid the Muddy Water (Linda Vineski)

**10:30- 11:00** Understanding Reportable Events and When to Report to the RSRB (Kelley O'Donoghue)

**11:00-11:30** Documentation: PI Oversight/Source Documents (Bill Kelvie)



UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---


---

2

## Elements of a Research Protocol & Understanding the RSRB Review Process

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

April 1, 2011



UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---


---

3

# Protocol

=

# Recipe or Plan



UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---

---

## 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

---

---

---

---

---

---

---

---

### 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



---

---

---

---

---

---

---

---

## Criteria for RSRB Approval

(45 CFR 46.111)

- 1) Risk minimized
- 2) Risks reasonable compared to benefits
- 3) Selection subjects equitable
- 4) Informed consent obtained
- 5) Informed consent documented
- 6) Data monitored appropriately to ensure safety of subjects
- 7) Privacy protected and confidentiality maintained

---

---

---

---

---

---

---

---

7

## Relating the Protocol, ROSS Application & Consent

**PROTOCOL** ≠ Protocol Document + Application + Consent

```

    graph TD
      P[PROTOCOL] --> RA[ROSS Application]
      P --> CF[Consent forms, Parental Permission forms, Assent forms]
      P --> RM[Recruitment Materials]
  
```

UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---

---

8

## Purpose of the Study

- State the specific scientific objectives/aims of the research
- Should concur with..
  - Background
  - Eligibility Criteria (inclusion/exclusion)
  - Study procedures
  - Analysis Plan

*What is your question?*

UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---

---

9

## Background/References

- State the problem and provide justification and rationale for the proposed research
- Provide information to support why this research is important
- Provide a summary of prior experience and/or history important for understanding the proposed study and procedures
- Include any relevant literature

*Why does that question exist?*

UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---

---

## Characteristics of the Research Population <sup>10</sup>

- Describe your study population
  - How many – Number of Subjects
  - Gender, Age, Racial/Ethnic Background, Vulnerable populations (children, prisoners, students)
  - Eligibility – Inclusion/Exclusion
    - BE SPECIFIC
    - Concur with purpose of the study
    - Based on scientific rationale
    - Does the subject have to have capacity to consent?

*Who does this question affect?*

---

---

---

---

---

---

---

---

---

---

## Methods and Procedures <sup>11</sup>

- State **ALL** procedures (sequentially, if possible)
  - Use a Schedule of Activities to demonstrate the study schedule
  - Describe the procedures: What will be done? How often? How will it be done?
  - Indicate the amount of each blood draw
  - What information will be collected from the medical chart?
  - What surveys will be done? When will the subject be interviewed?
  - Specify experimental vs. standard of care procedures
  - Provide detailed explanation or procedures for treatment, dose adjustments, etc.
  - Describe the randomization procedures, if applicable

*What needs to be done to answer this question?*

---

---

---

---

---

---

---

---

---

---

## Schedule of Activities... <sup>12</sup>

Study Procedure	Visit 1	Visit 2 (week 2)	Visit 3 (week 12)	Visit 4 (week 24) Final Visit
Consent	X			
Physical Exam	X			X
EKG	X			
Blood Draw	X			X
Beck Depression	X	X	X	X
Concomitant Medications				

---

---

---

---

---

---

---

---


---

---

13

## Data Analysis and Monitoring

- Data Analysis - clearly outline the following:
  1. how the data will be evaluated in relation to each of the objectives
  2. summarize the statistical approach to the analysis of the data gathered
  3. sample size justification
- Data Monitoring:
  - Who monitors the data? When?
  - Greater than minimal risk – **Data & Safety Monitoring Plan**, which is a system for appropriate oversight and monitoring safety and study conduct

 UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---

---

---

---


14

## Data Storage and Confidentiality

- What are the plans for maintaining the privacy and confidentiality of the information?
- Who will have access to this collected information?
- How long will the information be kept and what are the plans for destroying it once the study is completed?
- Are there any plans for coding or de-identifying the information to be collected?

**Additional items for Chart Reviews:**

- Are you linking two databases (Billing and Medical Chart)?
- What is the source of the medical information?
- Does the information that will be collected already exist in the chart (retrospective) or not (prospective)? If retrospective, indicate the date range for when data created.

 UNIVERSITY OF ROCHESTER

---

---

---

---

---

---


---

---


---

---

## 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?

 UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---

---


---

---

16

## Risk/Benefit Assessment

- **Potential Risk** - Describe the potential risks (section 77)
  - Physical, psychological, sociological, economic and legal
  - Retrospective Chart Review: Invasion of Privacy and/or Breach of Confidentiality
- **Protection Against Risks**. How will the study design/procedures prevent and/or minimize risks?
  - Trained Personnel
  - Withdrawal of the subject upon evidence of difficulty or adverse event
  - Referral for treatment, counseling or other necessary follow-up. State who will pay for treatment, counseling or follow-up
  - Chart Review: De-identification of data at some point, keeping the link to the subject's name separate from the data

 UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---


---

---

---

17

77. Risks and Benefits	
77.1	Check any applicable possible risks or potential harms to subjects:
	no Use of deception
	no Physical injury or discomfort
	no Stress
	no Manipulation of psychological or social variables such as social isolation or psychological stresses
	no Discovery of previously unknown condition (e.g. disease, suicidal intentions, depression, genetic predisposition): Specify condition and explain how this knowledge will be handled:
	no Invasion of subjects privacy
	no Invasion of privacy of individuals other than the subject
	no Risk to reputation or risk of financial harm
	no Social or legal risk
	no Materials that may be sensitive, offensive, threatening or degrading
	yes Other risks: If other risks, describe:
77.2	* Describe the protections that will be implemented to minimize risks or harms of all items checked:

 UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---

---


---

---

18

## Risk/Benefit Assessment

- **Potential Benefits** - Describe potential benefit, if any
  - DO NOT OVERSTATE!
  - If no anticipated benefits, this should be stated
  - Note: Payment is not considered to be a benefit
- **Alternatives to Participation**. Describe alternatives to participation in the research
  - Medical: treatment outside the research
  - Students: If the subjects are students who will receive academic credit for participation, describe the alternatives available to earn equivalent academic credit.

 UNIVERSITY OF ROCHESTER

---

---

---

---

---

---

---

---

---

---

## Subject Identification & Recruitment

- Methods to identify and recruit subjects
  - How
  - Where
  - Who
  - When
- Must protect subject's privacy and be free of undue influence.
  - No Cold Calling...initial contact treatment team
  - Recruitment of subordinates avoided or managed (own students, direct reports)
- Retrospective Chart review: explain how identifying charts to review (ICD codes, imaging database, etc.)
- Flyers, letters, brochures, etc should be explained and then provided in the RSRB application (section 66.1)

---

---

---

---

---

---

---

---

---

---

### 66. Subject Recruitment or Use of Subject Records/Specimens

66.1 Check all methods of recruiting subjects (or methods of collecting subject data/specimens) for this study:								
no Poster	no Information Letter <sup>1</sup>	no Brochure or Flyer	<sup>1</sup> Initial subject contact must be from treating clinician or referral source.  A final copy of all audio/video taped advertisements and commercially printed advertisements must be submitted after the RSRB has approved the copy to be used. This will be a stipulation for final RSRB approval and transmitting the approval letter.  For additional information regarding the process for using Research Match, click here.					
no Radio or TV Ad	no Email or Internet <sup>2</sup>	no Newspaper						
yes Clinic or Private Practices <sup>2</sup>	no Referrals <sup>2</sup>	no Medical Records <sup>2</sup>						
no School/Day Care Records <sup>2</sup>	no Psychology sign-up bulletin	no Telephone Script						
no Psychology Research Pool (PRP)	Research Match	no Other: If other, provide method below:						
<b>Upload Recruitment Materials:</b> Important: If you're revising or replacing the previously uploaded document, use the <b>Replace</b> link next to the file name. Do not delete any document after the study has been submitted to the RSRB.								
<table border="1"><thead><tr><th>name</th><th>Revision</th><th>Modified Date</th></tr></thead><tbody><tr><td colspan="3">There are no items to display</td></tr></tbody></table>			name	Revision	Modified Date	There are no items to display		
name	Revision	Modified Date						
There are no items to display								

---

---

---

---

---

---

---

---

---

---

## Consent

- **Process of Consent/Documentation of Consent**
  - Who?
  - How?
  - Where?
  - When?
  - Describe how consent will be documented and how/where documentation will be stored
  - Retrospective Chart Reviews: Waiver of Consent/Waiver of Authorization and provide rationale for why it is needed
    - **DO NOT STATE: Not Applicable**
  - Explain how comprehension of the information will be determined/measured

---

---

---

---

---

---

---

---


---

---

22

**Consent – Capacity/Authorized Representative**

- **Subject Capacity** - Indicate if subjects will have the capacity to consent or be decisionally incapacitated
  - Describe the anticipated degree of impairment relative to their ability to consent to participate in research
  - Describe how capacity will be assessed
  - Describe who can be the authorized representative
  - Research with persons who have diminished capacity is limited by Institutional Policy

 UNIVERSITY of ROCHESTER

---

---

---

---

---

---

---


---

23

**Costs/Payments**

- **Cost** - Describe/justify costs the subject will incur
  - Clarify who will pay for procedures (Sponsor, department, etc)
  - Cost to a subject's insurance = Cost to the subject
  - Normally, subjects **should not** have to pay for research procedures
- **Payment** - Describe payments (cash, gift cards, extra credit, parking, bus tokens, movie tickets...)
  - How much? When received? How received?
  - Amount must be justified and not **coercive**
  - Prorate the payment based upon study procedures/visits completed

***BE CONSISTENT!!!***

 UNIVERSITY of ROCHESTER

---

---

---

---

---

---


---

---

24

**Little things go a LONG way...**

- Title and Principal Investigator on first page
- Page Numbering and RSRB # in footer
- Schedules of Activities
- Version control
  - Version dates
  - Amendments
- Track Changes

 UNIVERSITY of ROCHESTER

---

---

---

---

---

---

---

---

## RSRB Levels of Review

### Full Board or “convened meeting”

- Greater than minimal Risk
- Review and approval at convened meeting

### Expedited or “designated”

- Minimal Risk
- Review and approval by Chair/designee

### Exempt

- Little to No Risk
- Review and confirmation of exemption by RSRB Staff

---

---

---

---

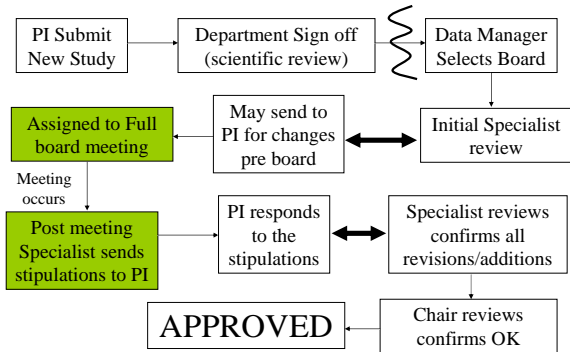
---

---

---

---

## Process for FULL BOARD Review




---

---

---

---

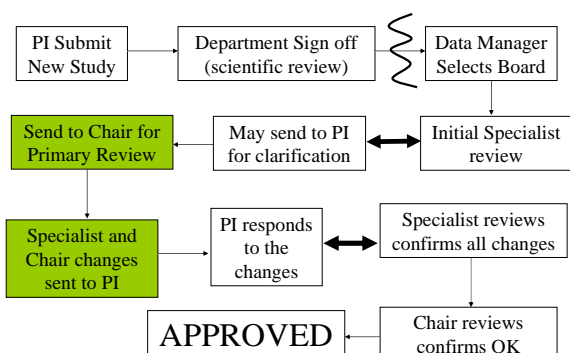
---

---

---

---

## Process for EXPEDITED Review




---

---

---

---

---

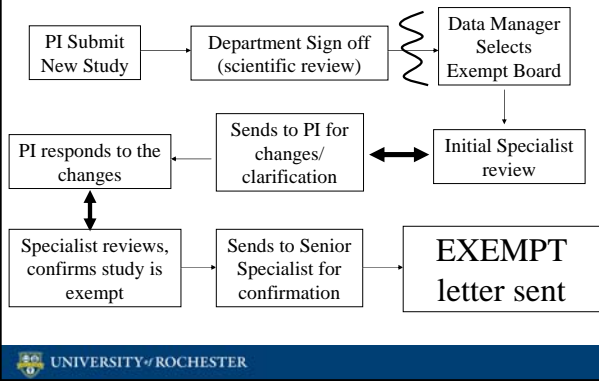
---

---

---

### Process for EXEMPT Review

28



---

---

---

---

---

---

---

---

### Questions

29



---

---

---

---

---

---

---

---