

**UNIVERSITY OF PITTSBURGH, SCHOOL OF MEDICINE  
DIVISION OF GENERAL INTERNAL MEDICINE  
CLRES 2140: Best Practices in Clinical Research**

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**Office Hours:** by appointment

**Time:** Two modules per week beginning April 4, 2010.

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### **GOALS**

This course is designed for investigators (new and current) to aid in the understanding of conducting research. Divided into two sections, the course begins with how research projects are implemented. The second section consists of a practicum that focuses on data analysis.

Conducting research is a life-long experiential learning process. As such, that experience can be shared with others so that new investigators learn from others' experiences. In order to initiate your learning about the research process and data analysis, the following goals are proposed that teach investigators how to:

1. review a grant proposal and ensure its adequacy
2. implement a research project
3. engage in quality research
4. avoid common pitfalls in research
5. coordinate an effective research team
6. understand the operation of research

### **RESOURCES**

Operations Manual, Center for Research on Health Care, University of Pittsburgh and supplemental readings. Provided below are also links to two rulings of research misconduct for your review.

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-026.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-142.html>

### **STRUCTURE**

This course will be taught using the Web. Our attempt is to walk you through the process from the time your proposal is funded until wrapping up the grant, presenting your results and preparing for the next grant. The assignment for each week is to read the corresponding chapter of the "Operations Manual" and complete the week's exercise(s). The exercises are quizzes, homework questions to be uploaded onto Courseweb or homework questions to be posted on the Discussion Boards. To get credit for the course you will need to complete each assignment. A separate document is included on Courseweb which provides you with a checklist of the tasks you need to complete.

## **COURSE OUTLINE**

**The course is designed under 8 topic areas. Two topics should be reviewed and assignments completed each week.**

### **Topic 1: The proposal is funded! Now what?**

- Introduce the course (case study approach, assignments, test)
- Review steps of research design
- Review and modify proposal as needed, including: design, sites/participants, timeline, budget
- Starting the project, what you need to do before you go into the field
- Importance of High Quality Research

### **Topic 2: Documenting**

- Preparing the Procedures Manual
- Documentation

### **Topic 3: IRB and HIPAA**

- IRB regulations
- Exempt, expedited or full board
- Submitting an IRB protocol
- Renewing the protocol
- Working with multiple sites
- Informed consent
- Confidentiality
- HIPAA
- Adverse events

### **Topic 4: The Study Protocol**

- Methods of data collection
  - Measurement
  - Data Collection forms
  - Pilot testing
  - Before you go into the field checklist

### **Topic 5: Personnel Issues**

- Staff structure and chain of command
- Creating effective and collaborative teams
- Getting to know your Human Resources Department
- Hiring project staff
- Job descriptions
- Resolving difficult issues

### **Topic 6: Data Quality and Study Implementation**

- Collecting and storing data
- Database development
- Data entry

- Verification issues
- Backup systems
- Confidentiality
- Before you enter the field checklist
- Minimizing missing data
- Editing surveys/instruments first by interviewer, then by project coordinator or PI
- Personnel issues
- Adverse participant outcomes
- Minimizing participant dropout
- Converting refusals to participants
- Maintain contacts with sites/clinics/staff
- Utilizing the calendar: maintaining the timeline
- Meetings/agendas/updates

### **Topic 7: Wrapping Up**

- Archiving data
- Working with your statistician
- Sharing your data

### **Topic 8: Presenting Results and Preparing for the Next Grant**

- Writing manuscripts
- Presenting findings
- Writing the next grant proposal