

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

Time: Online during the spring term

GOALS

This course is designed for principal investigators (newly funded or as a refresher) to aid in the process of conducting research, specifically implementing a funded research project and setting up a system to collect data for later 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 collection, the following goals are proposed that teach investigators how to:

1. review a grant proposal and ensure its adequacy
2. engage in quality research
3. implement a reliable data entry system
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 online over a one-month period. We will 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. There are 8 modules, two for each week. The task for each week is the read the corresponding chapter of the "Operations Manual" grant for each of the week's modules, read additional materials if applicable, and complete the week's assignments. The assignments are quizzes, homework questions to be uploaded to CourseWeb or homework questions to be posted to 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