Overview and Objectives:

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

Responsibilities:

Each week, students are expected to read the chapter of the "Operations Manual" corresponding to each of the week's two modules, read additional materials if applicable, and complete the week's assignments. The assignments and quizzes are to be uploaded to CourseWeb.

When files are submitted to fulfill assignments, the following file naming standard should be followed:

LastName_FirstName_Module#_Assignment

If multiple files are submitted, _File# should be added, e.g., _File1, _File2, etc.

Course Requirements:

Final letter grades will be determined based on the following:

To receive credit for individual assignments, work must be completed in full. Letter grades for individual assignments as well as the final letter grade will be determined by the overall completeness and quality of work submitted.

Assignment Policy:

Students in this course are expected to complete their work on their own. Assignments should be turned in via CourseWeb by 12 midnight on the due date indicated.
Textbooks and Readings:

Required:

No required textbook. All course readings will be delivered via CourseWeb.

Journal Readings: References will be provided for all journal readings. To access journal readings with PubMed IDs (PMIDS), please visit http://www.ncbi.nlm.nih.gov/pubmed/ and enter the PMID after the "/" in the URL.

Website Resources:

Operations Manual, Center for Research on Health Care, University of Pittsburgh and supplemental readings available via CourseWeb.

Below are also links to two rulings of research misconduct for your review:


Course Grading Scale:

Final letter grades will be assigned based on the following grading scale:

A+ = 100-100, A = 94-99, A- = 91-93, B+ = 88-90, B = 84-87, B- = 81-83, C+ = 78-80, C = 74-77, C- = 71-73, D+ = 68-70, D = 64-67, D- = 61-63, F = 0-60

Attendance Policy:

Students are expected to complete two modules per week during the 4 week long course.

Recording Policy:

ICRE Produced Recordings: ICRE faculty and/or staff may video and/or audio record this course (hereby referred to as "Recordings"). By enrolling this course, you hereby give the University of Pittsburgh and the Institute for Clinical Research Education, through its faculty, employees, agents, licenses or assigns, the irrevocable and worldwide right to use your name, voice, likeness and/or image in all forms and media (to include internet websites and online course website). You waive your right to inspect or approve the finished version(s) of the Recordings, including any copy that may be created in connection therewith. You understand that you will not be paid for your participation in the Recording and that you are not entitled to your own copy of the Recording. You understand that the University of Pittsburgh is not responsible for any unauthorized use of the Recording. You have read this syllabus and have no questions about the contents and are an adult over the age of 18.

Student Produced Recordings: To ensure the free and open discussion of ideas, students may not record classroom lectures, discussion and/or activities without the advance written permission of the instructor, and any such recording properly approved in advance can be used solely for the student's own private use.

Academic Integrity:

Students in this course will be expected to comply with the University of Pittsburgh’s Policy on Academic Integrity (http://www.provost.pitt.edu/info/aic.html). Any student suspected of violating this obligation for any reason during the semester will be required to participate in the procedural process, initiated at the instructor level, as outlined in the University Guidelines on Academic Integrity. This may include, but is not limited to, the confiscation of the examination of any individual suspected of violating University Policy. Furthermore, no student may bring any unauthorized materials to an exam, including dictionaries and programmable calculators.
Disabilities:

If you have a disability for which you are requesting an accommodation, you are encouraged to contact both your instructor and the Office of Disability Resources and Services, 140 William Pitt Union, 412-648-7890 / 412-383-7355 (TTY), as early as possible in the term. Disability Resources and Services will verify your disability and determine reasonable accommodations for this course.
Module #1

The Proposal is Funded! Now what?

At the conclusion of this session, the student will be able to:
1. Identify the components of a research project
2. Develop a timeline for a research study

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

Competencies:
Methodology: Design basic features of research protocols based on specific research questions, appropriately addressing bias and confounding.
Methodology: Design studies to include diverse populations.
Sampling: Identify appropriate study populations and sample size, control and comparison groups, and possible sources of bias and confounding for research problems.
Measurement: Address cultural diversity issues when selecting or adapting measurement instruments.
Multidisciplinary Teamwork: Engage in self-assessment, recognizing and addressing strengths and weaknesses in their research skills.
Management: Demonstrate behaviors needed to be an effective project manager including: oversight of fiscal regulations; recruitment; human resource management; and quality assurance activities.

Required Readings:
1. Best Practices Chapter 1

Homework:
Module 1 Assignment to be completed via CourseWeb.

Module #2

Documenting

At the conclusion of this session, the student will be able to:
1. Identify the important components for study documentation
2. Develop an operations manual for a research study

Topics:
1. Preparing the Procedures Manual
2. Documentation
Competencies:
*Written Communication:* Write about research and findings for a range of audiences, and respond in writing to constructive criticism and questions.

*Ethics and Professional Norms:* Identify violations of professional integrity, safeguard procedures in all phases of the research process, and explain appropriate reporting procedures.

*Ethics and Professional Norms:* Explain the importance of following procedures for the identification, prevention, and management of financial, intellectual, and employment conflicts of interest.

*Ethics and Professional Norms:* Provide examples of the norms of professional integrity with regard to designing and conducting research, including: data collection, sharing, and protection; and reporting of findings.

**Required Readings:**
1.  [Best Practices Chapter 2](#)

**Homework:**
Module 2 Assignment to be completed via CourseWeb

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**At the conclusion of this session, the student will be able to:**
1. Submit an IRB protocol for exempt, expedited, or full board review
2. Utilize a HIPAA waiver
3. Draft an informed consent

**Topics:**
1. IRB regulations
2. Exempt, expedited or full board
3. Submitting an IRB protocol
4. Renewing the protocol
5. Working with multiple sites
6. Informed consent
7. Confidentiality
8. HIPAA
9. Adverse events

**Competencies:**
*Ethics and Professional Norms:* Identify violations of professional integrity, safeguard procedures in all phases of the research process, and explain appropriate reporting procedures.

*Ethics and Professional Norms:* Understand and explain Federal regulations regarding human subject research, and prepare an IRB application.

*Multidisciplinary Teamwork:* Demonstrate behaviors necessary to be an effective member of a multidisciplinary team.

*Sampling:* Identify appropriate study populations and sample size, control and comparison groups, and possible sources of bias and confounding for research problems.
Required Readings:
1. Best Practices Chapter 3
3. Example of Scientific Misconduct

Supplemental Readings:

Homework:
Module 3 Discussion Board to be complete via CourseWeb.

Module #4

The Study Protocol

At the conclusion of this session, the student will be able to:
1. Develop a study using different data collection methods
2. Review data collection forms
3. Conduct a pilot study
4. Begin data collection

Topics:
1. Methods of data collection
2. Measurement
3. Data Collection forms
4. Pilot testing
5. Before you go into the field checklist

Competencies:
Methodology: Design studies to include diverse populations.
Measurement: Address cultural diversity issues when selecting or adapting measurement instruments.

Required Readings:
1. Best Practices Chapter 4
Supplemental Readings:

Homework:
Module 4 Assignment to be completed via CourseWeb.

Module #5
Personnel Issues

At the conclusion of this session, the student will be able to:
1. Hire appropriate staff for your study
2. Handle personnel issues as they arise
3. Create a job description
4. Create an effective investigative team

Topics:
1. Staff structure and chain of command
2. Creating effective and collaborative teams
3. Getting to know your Human Resources Department
4. Hiring project staff
5. Job descriptions
6. Resolving difficult issues

Competencies:
Management: Demonstrate behaviors needed to be an effective project manager including: oversight of fiscal regulations; recruitment; human resource management; and quality assurance activities.
Multidisciplinary Teamwork: Demonstrate behaviors necessary to be an effective member of a multidisciplinary team.

Required Readings:
1. Best Practices Chapter 5
2. University of Pittsburgh Job Description
3. Case Study

Homework:
Module 5 Discussion Board to be completed via CourseWeb.

Module #6
Data Quality and Study Implementation

At the conclusion of this session, the student will be able to:
1. Create a database
2. Understand the components of data management
3. Understand the importance of data verification
4. Confidently enter the field and begin data collection
5. Address recruitment problems
6. Enhance participant participation

Topics:
1. Collecting and storing data
2. Database development
3. Data entry
4. Verification issues
5. Backup systems
6. Confidentiality
7. Before you enter the field checklist
8. Minimizing missing data
9. Editing surveys/instruments first by interviewer, then by project coordinator or PI
10. Personnel issues
11. Adverse participant outcomes
12. Minimizing participant dropout
13. Converting refusals to participants
14. Maintain contacts with sites/clinics/staff
15. Utilizing the calendar: maintaining the timeline
16. Meetings/agendas/updates

Competencies:
Sampling: Identify appropriate study populations and sample size, control and comparison groups, and possible sources of bias and confounding for research problems.
Data Management and Biomedical Informatics: Identify pertinent issues in the construction of effective data and safety monitoring plans and provide examples of best practices for protecting privacy throughout a study.
Management: Demonstrate behaviors needed to be an effective project manager including: oversight of fiscal regulations; recruitment; human resource management; and quality assurance activities.

Required Readings:
1. Best Practices Chapter 6
3. Before You Go Into the Field
4. Qualtrics Guide

Homework (Due 3/26/2017):
Module 6 Assignment 1 to be completed via CourseWeb.
Module 6 Assignment 2 to be completed via CourseWeb.
Wrapping Up

At the conclusion of this session, the student will be able to:
1. Wrap up your study
2. Begin summarizing your results

Topics:
1. Archiving data
2. Working with your statistician
3. Sharing your data
4. Identifying problems with published research to topics

Competencies:
Data Management and Biomedical Informatics: Identify pertinent issues in the construction of effective data security and management plans for various research designs.
Ethics and Professional Norms: Provide examples of the norms of professional integrity with regard to designing and conducting research, including: data collection, sharing, and protection; and reporting of findings.
Multidisciplinary Teamwork: Describe the functions and roles of multiple disciplines with which one interacts.

Required Readings:
1. Best Practices Chapter 7

Supplemental Readings:
Please see Module 7 Assignment Article Summary on CourseWeb.

Homework:
Module 7 Assignment: Article Summary to be completed via CourseWeb.

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Module #8

Presenting Results and Preparing for the Next Grant

At the conclusion of this session, the student will be able to:
1. Prepare your first manuscript for publication
2. Start work on your next grant submission

Topics:
1. Writing manuscripts
2. Presenting findings
3. Identifying criteria for authorship
4. Writing the next grant proposal

Competencies:
Written Communication: Write about research and findings for a range of audiences, and respond in writing to constructive criticism and questions.
Written Communication: Organize and report statistical results.
Problem Formulation: Propose hypothesis-driven research questions using, where appropriate, different disciplines and community engagement.
Required Readings:
1. Best Practices Chapter 8

Supplemental Readings:
These readings are articles that give hands-on advice on how to construct a manuscript, and what to do if a manuscript is rejected.

6. Here also is a helpful link if you consider applying for NIH funding: http://www.niaid.nih.gov/researchfunding/grant/strategy/pages/default.aspx

Homework:
Module 8 Discussion Board to be completed via CourseWeb.