

**University of Hawaii at Manoa  
John A. Burns School of Medicine**

**Course Number:** Biomed 645

**Course Title:** Clinical Research Protocol Development and Scientific Writing

**Course Credit:** 3 credits

**Prerequisite:**

Permission of Instructor

**Placement in Curriculum:**

Second Year of Program

**Course Description:**

The goal of this course is to further enhance the career development of outstanding clinical researchers by providing didactic training in writing skills and proposal development. Other topics to be covered in this course include: governance structure of funding agencies; identifying appropriate funding opportunities; how funding decisions are made; peer review and secondary review; the NIH application processing; how to read a Request for Application; compliance issues covering fiscal, human subjects, and animal subjects; and awarding procedures. Instruction on the meaning of race, ethnicity, social class, and culture, and how these constructs affect the conduct and interpretation of clinical research as well as the types of questions that can be addressed with large administrative and clinical databases; gaining access to these databases; determining validity of information; risk adjustment; linking datasets; and building registries. Trainees will be judged on the merits of their mentored research proposals, which they will write as NIH Small Grant applications. Required reading will include individualized searches of relevant literature

**Course Objectives:**

At the conclusion of the course student will be able to:

- Describe the governance structures of funding agencies
- Identify funding opportunities of their own research program
- Read and Interpret an RFA
- Participate in a peer and secondary review process
- Apply an understanding of the NIH application process
- Apply knowledge related to compliance with IRB, HIPPA and DSMB criteria for both animals and humans

Document concepts related to the meaning of race, ethnicity, social class, and culture, and how these constructs affect the conduct and interpretation of clinical research  
Identify the types of questions that can be addressed with large administrative and clinical databases; gaining access to these databases; determining validity of information; risk adjustment; linking datasets; and building registries.  
Critique research protocols according to defined criteria  
Apply an understanding of award criteria  
Prepare an article for publication in an referred journal

### **Topical Outline:**

Structure of funding agencies  
Structure of RFA's  
The Peer Review process  
The NIH application  
Cultural Sensitivity  
Utilization of databases  
Participation in the Peer Review process  
Scoring criteria  
Award criteria  
Reading and Writing Research  
The poster presentation  
The podium presentation  
Preparing a publishable manuscript

### **Required Text:**

Individualized assignments will be made from the serials literature by the student's mentor

Students will conduct individualized searches of the data based literature related to their area of research interest with faculty assistance

\*Martin, G., Woods(Harrigan), R., & Pitkin, R. (1988). Reading, writing, reviewing, and presenting research. Washington, D.C.: National Perinatal Association.

### **Learning Experiences:**

Lecture, discussion, practicum

### **Evaluation**

Examination	30%
Project	70%