**Course Title: Methods in Clinical Cancer Research**

**Description:** Dr. Garrett-Mayer has served for ten years on the AACR/ASCO Methods in Clinical Cancer Workshop, held annually in Vail, Colorado since 2002. For the years 2008-2010, she was one of the course directors, specifically responsible for the statistical design components of the workshop. From these experiences, she has knowledge regarding the necessary training that junior investigators require for developing protocols and succeeding in the academic clinical cancer arena. She has developed and will be the primary instructor for a clinical cancer research training course which she has modeled partly on the Vail workshop. Didactic lectures will cover the following areas: (1) clinical and statistical design of phase I, II and III trials; (2) incorporation of correlative and biomarkers in clinical trials, (3) considerations in chemotherapy, surgery, radiation and multimodality trials, (4) quality of life and other patient reported outcomes in cancer research, (5) the protocol review and IRB process, (6) informed consent, (7) data collection, trial monitoring and investigator responsibilities, (8) the grants process and mentoring. Other topics are incorporated as well, (e.g., disparities research). The class will meet twice a week for a semester (Spring 2015 is the proposed first semester it will be offered). Dr. Garrett-Mayer and selected HCC researchers will give lectures based on their own expertise. When deemed appropriate, an external speaker may be brought in to address a relevant topic. A list of topics and the number of lectures allotted is provided in Table 1.

In addition to the didactic portions of the training, each trainee will have a clinical research proposal which will be developed into a “letter of intent” (LOI) for a clinical trial. For students in the Paul Calabrese Translational Clinical and Translational Oncology K-12 training program, the LOI will be used during the latter part of the students’ training and will be further developed (with a mentorship team) into a protocol to be submitted to HCC.

In addition to the didactic sessions listed in table 1, other contact hours will take the form of a journal club where clinical research papers from journals such as Clinical Cancer Research or Journal of Clinical Oncology are discussed, and protocols that are being undertaken at HCC are reviewed and discussed. Papers and protocols for these sessions will be selected jointly by a trainee and either Dr. Garrett-Mayer or another instructor (listed below). Lastly, trainees will also be required to attend and take part in the HCC Protocol Review Committee’s monthly meetings (meetings occur every 3 weeks). This will allow the trainees to be exposed to a variety of studies ranging from Phase I to III cancer trials, in addition to observational, translational and qualitative research studies. Trainees will also be encouraged to attend one or more of the HCC Data Safety and Monitoring Board meetings to gain exposure to issues of trial review and monitoring.

**Primary Instructor:** Elizabeth Garrett-Mayer

**Other Instructors:** The following instructors may be called upon to give one or two lectures based on their experiences in clinical cancer trials and/or epidemiologic trials: Carolyn Britten, Michael Lilly, Graham Warren, Anthony Alberg, Marvella Ford, Kristin Wallace, Katie Sterba, Rob Stuart

**Course Objectives:**

At the end of the course, students should be able to:

1. Understand the key components required for designing, activating and implementing a cancer clinical trial.
2. Write a proposal for a cancer clinical trial, including objectives, endpoints, trial design, patient population selection, and have some understanding of the required sample size and analytic techniques used to analyze the data at the end of the trial.
3. Effectively review and critique clinical trial protocols and published cancer clinical trials research.

**Prerequisites:** eligible students must satisfy at least one of the following criteria:

1. The student is enrolled in the MSCR program,
2. The student is a Paul Calabresi K-12 training grant scholar.
3. The student is enrolled in a masters or PhD program in the Dept. of Public Health Sciences
4. The student has received consent of the instructor.

**Textbooks:** None required.

**Suggested texts for reference:**

* Clinical Trials: A Methodologic Perspective (Piantadosi)
* Oncology Clinical Trials (Kelly & Halabi)
* Principles of Anti-Cancer Drug Development (Hidalgo, Eckhardt, Garrett-Mayer, Clendennin)

**Proposed Course Content:** The course content will follow the general curriculum of the AACR/ASCO Methods in Clinical Cancer Research with greater attention given to trial design and statistical issues. The proposed sequence of topics and hours/lectures devoted to each is shown in Table 1. Note, however, journal club discussions will be interspersed with didactic lectures and not all occur at the end of the semester.

**Table 1: Course topics and hours devoted to each topic.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Topics** | **Number of lectures** | **Cumulative hours\*** | **Instructor** |
| Trial Designs and Analysis |  |  |  |
| Phase I | 3 | 4.5 | EGM, Britten |
| Phase II | 3 | 9 | EGM |
| Phase III | 3 | 13.5 | EGM |
| Prevention and Control | 1 | 15 | Alberg |
| Observational studies | 1 | 16.5 | Wallace |
| Endpoint selection | 1 | 18 | EGM |
| Power calculations | 1 | 19.5 | EGM |
| Correlative studies | 1 | 21 | EGM |
| Imaging in clinical trials | 1 | 22.5 | Ravenel |
| Trials in specific treatment modalities | 1 | 24 | Warren |
| Quality of life and other patient reported outcomes | 1 | 25.5 | Sterba |
| Informed Consent | 1 | 27 | Stuart/Britten/Lilly |
| Protocol Review and IRB process | 1 | 28.5 | Warren/EGM |
| Data collection and privacy | 1 | 30 | EGM |
| Trial monitoring and investigator responsibilities | 1 | 31.5 | Britten |
| Grants and mentoring | 1 | 33 | Warren |
| Disparities research | 1 | 34.5 | Ford |
| Protocol review meetings | 2 | 37.5 | -- |
| Journal club discussion\*\* | 5 | 45 | EGM |
| **TOTAL** | **30** | **45** |  |

\*each lecture will be 1.5 hours in length

\*\* journal club discussions will include discussion of actual submitted clinical trial protocols and published clinical cancer trials in journals such as Journal of Clinical Oncology and Clinical Cancer Research.

**Assessment of Students:** Students will be graded based on the following components where each assignment is given numeric score, according to the Merit Grades for the MUSC grading system.

1. Written reviews of protocols, given as assignments. There will be 3-4 protocols assigned and the review will be structured with particular questions about appropriateness of study design, clarity of the study aims, incorporation of early stopping rules in the trial design, etc. (45% of grade)
2. Oral presentation of journal article presenting results of a cancer clinical trial. The article will be selected by the student and Dr. Garrett-Mayer. The student will present to the class an overall summary of the trial and provide a critique of the methods employed. (25% of grade)
3. Submitted LOI: The LOI will be submitted twice. First, a draft will be submitted about two-thirds through the course. Dr. Garrett-Mayer will provide feedback. This first draft will constitute 15% of the total grade. The final LOI will be submitted as the ‘final’ and will also count for 15% of the course grade. Total: 30% of grade

The three components will be combined (using the percentages indicated) to arrive at a final merit grade for the course.