



**DEPARTMENT OF VETERANS AFFAIRS COOPERATIVE STUDIES PROGRAM
CLINICAL TRIAL DESIGN COURSE**

**JUNE 2-4, 2010
CHICAGO, IL**

Overview

VA Cooperative Studies Program (CSP) biostatisticians and clinical investigators will offer a 2 ½ -day course in the design of randomized clinical trials and development of study proposals, including CSP letters of intent (LOI).

Objectives

The immediate objectives of the course are to:

- Compare and contrast different types of clinical research designs
- Learn principles of basic randomized clinical trial design and related statistical methods
- Understand how trial design affects feasibility
- Learn elements for success in developing a randomized clinical trial proposal

The primary objective is to help VA clinicians interested in clinical trials to develop high quality proposals including ones submitted to the Cooperative Studies Program and the Cooperative Clinical Trial Award Program.

Content

The course will focus on the details of randomized clinical trial design. Specific components will include defining hypotheses, selection of subjects, specifying interventions and endpoints, statistical inference, sample size determination, and trial feasibility. A syllabus is attached to this announcement.

The course will consist of lectures, interspersed with breakout sessions in which students and faculty mentors will discuss ideas for studies proposed by the students. Students will develop their ideas into study proposals using the CSP Letter of Intent format, which will be critiqued the last day of the course in mock review sessions.

Time and Location

The course will be offered from Wednesday, June 2, 2010, through Friday, June 4, 2010. The first two days will consist of 3-5 lectures in the morning and breakout sessions in the afternoon. The last day will involve formal presentation and review of study proposals. The course is intensive. It is expected that students will be working on their letters of intent each evening.

The course will take place in Oak Brook, IL, just outside of Chicago.

Eligibility

Participants must be eligible VA investigators (see VHA Handbook 1200.15, "Eligibility for VA Research Support"). Additionally, participants who are VA clinicians will be expected to obtain release time from their local institutions. Enrollment will be limited to 60 students.

Cost

There are no tuition costs. Attendees who obtain travel support from their VA Medical Centers (VAMC) may be given priority. However, the VA Cooperative Studies Program may pay for travel and lodging expenses for selected applicants who demonstrate a strong commitment to clinical research.

Application

The following is required to be considered for the course:

- A cover letter from the applicant which includes his/her VA contact information (name, address, phone number, fax number, email address) and clinical research area of interest. Also, please note whether the VAMC will provide travel funds.
- A statement from the applicant's Research Office that s/he meets VA research eligibility requirements and can receive VA research funds.
- A letter from the applicant's supervisor indicating the supervisor will approve release time if the applicant is selected to take the course.
- A CV or biosketch in VA or NIH format.
- A one-two page document outlining an idea the student has for a randomized clinical trial. This should include background information on the clinical problem being addressed and its importance to the VA, the primary objective or hypothesis of the study, the types of patients to be considered for the study, a description of the experimental intervention(s) and control group, and possible outcome measures for the study.
- Letters of support or reference may be included, but are not required.

Applicants should send their application package to:

E-mail (preferred) via PDF attachment:

Linda Graham: Linda.Graham6@va.gov

Mailing Address

Linda Graham
Cooperative Studies Program Coordinating Center
Hines VA Hospital, CSPCC (151K)
5000 South 5th Avenue, Building 1, Room B240
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Applications will be accepted until **April 30, 2010**. Notification of selection of course participants will begin no later than April 19, 2010, and continue until the course is full.



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SYLLABUS

Day 1

- What makes a good study?
- Types of study designs and the randomized clinical trial
- The research hypothesis
- Defining the study population
- Interventions
- Outcome measures
- Break-out session (break for dinner, return for evening break-out)

Day 2

- Statistical concepts in clinical trials
- Sample size, power
- Recruitment, retention, and trial feasibility
- Break-out session
- LOI's due at 5pm
- Evening – read submitted LOIs

Day 3 (1/2 day)

- Presentation and review of LOIs
- Summation/next steps