

CREST
Clinical Research Enhancement through Supplemental Training
at the University of California, San Diego
Program Overview

A career in clinical research increasingly requires levels of preparation, training, and commitment similar to a career in laboratory-based research. While physicians/scientists dedicate several years of focused effort to master the techniques and strategies required for productive careers in laboratory research, individuals embarking on a career in clinical investigation only recently have had a similar opportunity to develop their skills. To a large extent this disparity is representative of the lack of structured training programs in clinical research. Recognizing this lack, the NIH has developed the K-30 series of grants to individual institutions. These grants enhance development of investigators with specialized clinical and laboratory skills who use rigorous methods to address research questions by directly working with human populations. UCSD has incorporated these concepts in the design of the CREST program. The main features for the program design are as follows:

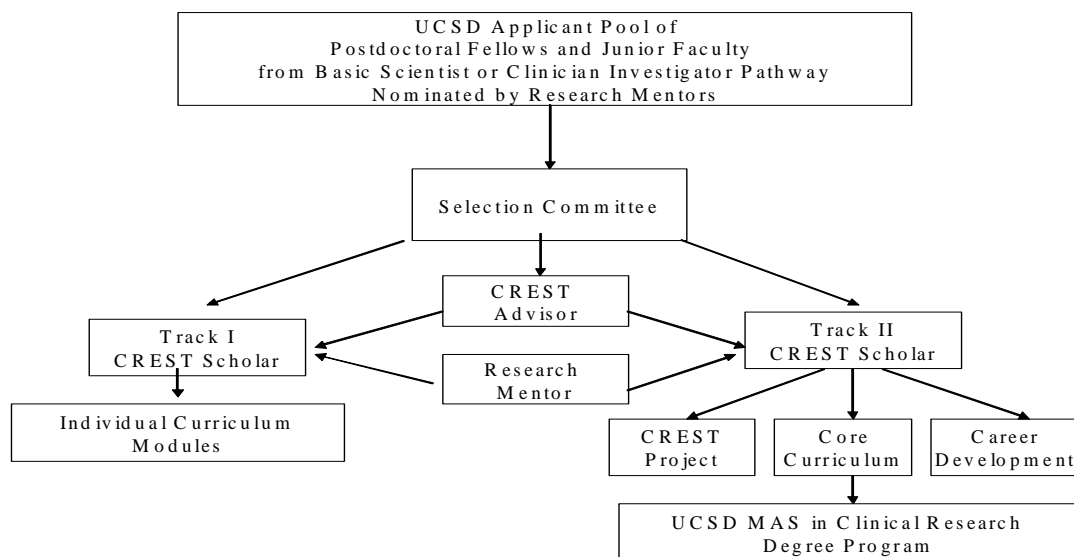
1. Integrated Design for State-of-the-Art Training: Three characteristics common to successful training, whether it be in clinical or laboratory research, are: a) training in research methods applicable to the area of investigation, b) application of these methods to a state-of-the-art research question, and c) collaboration with more experienced investigators. Well-trained laboratory researchers have the benefit of all three training components because their research mentors provide a laboratory environment for instruction in research methods, which the trainee uses in a specific project while interacting with other investigators in the field. Similarly, experienced clinician investigators utilize the clinic or hospital as a “laboratory” for their research. We have designed the CREST program to integrate the three components described above. The program requires the scholar to have an independent research project, provides the didactic and practical training required in the methods of clinical research, and creates an environment for the scholar to learn from a multidisciplinary faculty who provide individualized guidance for career development.

2. Broad-based Curriculum Encompassing Major Areas of Clinical Research: As clinical research is often multidisciplinary and multifaceted, a curriculum for instruction should be representative of the different components of clinical research as defined by the NIH. Taking this into account we have incorporated all major elements of clinical research in the design of the curriculum. The curriculum is designed to be delivered over two years and is comprised of eight modules which cover the principles of epidemiology, biostatistics, patient-oriented research (two modules each), health services/outcomes research, and career development (one module each). We strongly believe that the CREST scholar must not only have a strong basis in academic medicine, but must understand the worlds of academic medicine and bioscience/biotechnology to be an effective researcher. Consequently, we include professional development seminars that are offered throughout the two years and focused on key elements including grant writing, scientific communication, research management and time management.

Overview of Two Year CREST Curriculum

Time Course	Core Module	Seminar Topics in Clinical Research
Year 1	1-1. Epidemiology I	1-5 Scientific Communication (Includes written and verbal presentations, and grant writing)
	1-2. Epidemiology II	
	1-3. Patient Oriented Research I	
	1-4. Patient Oriented Research II	
Year 2	2-1. Biostatistics I	2-5 Personal Development
	2-2. Biostatistics II	2-6 Research Management and Project Management
	2-3. Outcomes Research (HSRD)	
	2-4. Data management/Informatics	

Fig 1: CREST Application, Selection and Training Diagram



Each module is designed to be given over one academic quarter and is comprised of 10 weekly, 2-hour periods of instruction which are given in the early evening. The format for instruction includes a combination of didactic lectures, group discussions, and hands-on computer-based training. Once-a-week evening classes allow the scholars to focus on their primary research and training projects and clinical responsibilities during the major part of the work week with minimal interruption.

For individuals interested in completing the CREST curriculum in a shorter time period a one year option is available. This requires that both the first and second year courses be taken concurrently on two nights a week (Wednesday and Thursday) and at two different locations (Hillcrest and La Jolla) e.g. year 1 course on Wednesday in Hillcrest and Year two course on Thursday at La Jolla. However, the sessions must begin with the Winter session in January every year.

3. Eligible and Targeted Participants: The program is primarily directed towards postdoctoral candidates with an M.D. or Ph.D. degree interested in pursuing a career in clinical investigation or translational research. Potential applicants may have a primary research training focus either in basic science or in clinical research. Scholars are recruited from many departments and disciplines and range from graduate students working towards a Masters degree to individuals holding junior faculty appointments. Scholars differ in levels of prior training and experience in areas covered by the curriculum, in levels of commitment, and in interests.

In order to accommodate the varying needs we have incorporated two mechanisms to permit flexibility while retaining the benefits of structured modular instruction. First, most scholars spend the majority of their time working with a primary mentor (laboratory director) on basic or clinical research or with their clinical training program director on their clinical training.. Second, scholars are able to select from two training tracks for participating in the CREST program to supplement their training. Participants are assessed on application to the program for their goals and needs for training in specific areas.

For those with limited goals or commitment, Track I involves taking a limited number of modules. For example, fellows whose interest and training focuses on laboratory research may elect to take only the modules involving biostatistics, career development, and ethical and regulatory issues. Those who pursue Track II commit to the entire eight-module, two-year curriculum. These most committed scholars have priority for tutorial and mentoring resources from the program. Taking all eight modules is equivalent to approximately 16 semester credit hours. Track II scholars have the option to enroll in the UCSD Masters of Advanced Studies in Clinical Research by the end of the first year of training, but must commit at that time. CREST credits are then applied towards the Masters degree.

4. Career Development: A key feature of the program is that it addresses the continuum of learning experienced by the scholar. In addition to the curriculum, each scholar who enrolls in Track II or III is required to have an

individual research project supervised by his or her primary research mentor. In addition, each scholar is paired with a CREST faculty member, who serves as an advisor to help with their individual research project and to provide mentorship and career guidance. The CREST faculty interacts with the primary research mentor to ensure that scholars have the appropriate support and protected time to pursue their goals. In order to assign a CREST mentor to each applicant we require the applicant to complete a pre-course assessment form that provides information on content knowledge, needs and learning styles. These instruments are repeated at periodic intervals to track each applicant's progress through the duration of the training program.

5. Fees: UCSD residents, fellows (including laboratory-based fellows), and faculty pay a discounted fee. For residents and fellows the cost is \$400 per module, and for faculty it is \$600 per module. The fee covers the costs for lectures and course materials including books and computer software. For those who are interested in the Master of Advanced Studies in Clinical Research degree, there will be additional university fees for each quarter of enrollment. Details of the Masters Degree program and fees can be found at the web site <http://clre.ucsd.edu> (contact Krisztina Hershon at khershon@ucsd.edu).

Details of CREST Program can be found at <http://crest.ucsd.edu>, (Contact Seble Chernet at scherent@ucsd.edu)