



Clinical Research Skills Development Program Description

Overview:

The Duke University Clinical Research Skills Development Program for surgical residents and junior faculty was created in order to train future cardiothoracic surgeons in the skills of clinical research. Current surgical training includes only minimal didactic and experience-based education in biostatistics, research design, research management, and the ethical conduct of research among other important topics for today's clinician-researcher. Utilizing resources from the world-renowned Duke Clinical Research Institute (DCRI) and the joint Duke-NIH Clinical Research Training Program (CRTP), the Clinical Research Skills Development Program fosters a better understanding of how to perform multiple types of clinical research.

The Program Director is Dr. Peter K. Smith, Professor of Surgery and Chief of Cardiovascular and Thoracic Surgery at Duke University. Dr Smith has been involved in numerous clinical trials as well as being a member of the Cardiothoracic Surgical Trials Network (CTSN) steering committee. The co-Program Director is Dr. John H Alexander, Associate Professor of Medicine and Co-Director of Cardiovascular Research at the DCRI. He is a previous graduate of the Duke-NIH CRTP program, and has extensive experience in the management and execution of clinical trials.

Each trainee that is selected to complete the Clinical Research Skills Development Program receives both formal training via the CRTP program, as well as extensive experience through multiple resources present at the DCRI. The expected training time is two-academic years, although this may be extended for junior faculty who have extensive clinical obligations.

Application Process:

Interested applicants should communicate their interest with Dr Smith at least one year prior to the expected start time. Applicants should submit the following items: 1) A letter of interest, 2) A formal training plan including proposed mentorship, 3) A Curriculum Vitae, and 4) Plans for additional funding sources (whether obtained or pending). Acceptance will be based on the applicant's previous experience, future career plans, and the formation of a promising training plan. All interested applicants are suggested to begin searching out additional mentorship early in the process. In order to enroll in the program, each applicant is required to identify a formal mentor who has the resources and time available to properly guide the trainee through the program.

Core Coursework:

All trainees are required to enroll in the Duke-NIH CRTP program with the goal of obtaining a Masters of Health Sciences in Clinical Research (MHSc). This degree requires 24 credits of course work and a 12 credit formal research project. There are five required courses including Introduction to Statistical Methods, Principles of Clinical Research, Statistical Analysis, Responsible Conduct of Research, and Research Management. The required coursework satisfies 16 of the 24 required credits. The remaining 8 credits can be fulfilled through classes geared towards the trainee's interests, but can include Health Services Research, Clinical Trials, and Longitudinal Data Analysis among others. The formal research project may utilize a project the trainee is currently working on with outside mentorship, but must follow a strict formal project plan concluding in the defense of a Masters thesis.

Additional Responsibilities:

Through the DCRI, the trainee will become involved in other projects and responsibilities in order to further develop experience with clinical research. Trainees will be involved in event adjudication of clinical trials currently underway at the DCRI. This provides valuable instruction in the management and administration of clinical trials. Furthermore the trainees will work with DCRI statisticians to support current trials and registries based at the DCRI. For example, the Society of Thoracic Surgeons (STS) houses its national database at the DCRI. The DCRI is also the primary analytic data center for the STS. Trainees attend weekly meetings, help with clinical questions, and coordinate communication between the DCRI, outside investigators, and the STS leadership.

Mentorship:

Each trainee is required to have a primary mentor who will guide their progress over the two-years in the Clinical Research Skills Development Program. In addition, trainees will often have 2-3 secondary mentors with which they work on various clinical projects. Each primary mentor is expected to meet with the trainee at least once a week to discuss current projects, future plans, and the didactic coursework. Mentors are traditionally either cardiologists or cardiothoracic surgeons who are on faculty at the DCRI. Additionally, the trainees work closely with other trainees within the DCRI in order to provide peer-based mentorship.

Conferences:

Trainees are required to attend a variety of weekly conferences. This includes both general cardiothoracic and general surgery weekly conferences hosted by the department of surgery, as well as a number of weekly conferences hosted by the DCRI. These include fellow-based conferences in which research-related issues and methods are discussed, as well as DCRI-wide conferences in which external clinical investigators from a variety of backgrounds discuss current projects and other related topics.

Productivity:

Although there is no formal requirement for productivity, each trainee is expected to present at national conferences as well as publish multiple manuscripts during their time in the program. Through

the trainee initiated projects, as well as through collaboration with other researchers at the DCRI, it is expected that each trainee will be very experienced in both presentation delivery and manuscript authorship by the completion of the program.

Previous Trainees:

Previous trainees have been very successful, authoring an average of 9 manuscripts during their time within the program not including manuscripts that have been published after the programs completion but based on work performed during the program. These trainees have also presented extensively at national meetings, and have been involved in numerous important clinical trials, many of which are still under way.

Conclusion:

The Duke University Clinical Research Skills Development Program for surgical residents and junior faculty has demonstrated a history of success in training cardiothoracic surgeons in the skills necessary to become productive clinical researchers. Trainees and junior faculty members who are accepted into this program will undergo a rigorous didactic and experience-based education that will provide them with the tools necessary to perform an assortment of clinical research projects.