

## **TRAINING IN CARDIOVASCULAR RESEARCH**

### Mission Statement

One of the primary goals of the Cardiology Division of the University of Rochester is to train future clinician scientists. It is important that every Fellow participate directly in research: all future cardiologists must be cognizant of the principles and tools of research. Training in research requires the intense involvement of productive and established investigators. We endorse the statement of "Task Force 7: Training in Cardiovascular Research," from the Guidelines for Training in Adult Clinical Cardiovascular Medicine (Core Cardiology Training Symposium [COCATS]; JACC Vol. 25, No. 1; January 1995: 1-34).

### General Statement of Educational Objectives for Fellows

All Fellows are required to complete cardiovascular research training as part of their core curriculum. Cardiovascular research is defined in the broadest terms, and the Fellows may work in either basic science or clinical projects. Research may be performed in collaboration with faculty within the Cardiology Division or under the supervision of approved faculty in other departments at the University. Every Fellow should have direct involvement in all aspects of research. They should be able to:

- Identify a research problem,
- Critically analyze the existing literature to understand the current state of knowledge and gaps in that knowledge,
- Develop a hypothesis that will address one or more of these gaps in knowledge,
- Clearly state the research objectives and goals,
- Design a project that is feasible and will meet these goals,
- Conduct the project within the time period allotted,
- Utilize biostatistical methods to analyze its results,
- Make logical conclusions about the results and write a publishable manuscript.

The Fellow will exercise ethical methods in the conduct of research. Through the research experience, it is hoped that fellows will enhance their problem-solving skills, will increase their appreciation of evidence-based approaches to clinical and research problems, and will learn to benefit from peer review and constructive criticism of their work.

### Statement of Educational Goals Related to Training in Cardiovascular Research

The cardiovascular research curriculum is designed to promote six broad goals based on the six ACGME core competencies:

- (1) Medical Knowledge: exposure to cardiovascular research broadens the medical knowledge of trainees and allows them to develop investigatory and analytic approaches to medical problems. From basic science through clinical research, trainees will apply their existing knowledge and further build their competency in solving clinical problems.
- (2) Patient Care: involvement in cardiovascular research provides fundamentals for understanding the pathophysiology of diseases and improves decisions about diagnosis and therapy. Patient care remains the main source of ideas for clinical research, and cardiovascular research is focused on clinically relevant questions. Interactions with patients involved in clinical research is of major importance, and fellows will be involved in such research to further master their patient care skills.
- (3) Professionalism: successful management of research projects requires professionalism expressed at every level: from interaction with peers while designing project, through ethical principles pertaining to research, communication with patients and colleagues, and effective completion of projects. It is particularly important to demonstrate professionalism in team approaches to research. The above principles are paralleled by the highest standards of professionalism demonstrated in clinical services.
- (4) Interpersonal and Communication skills: The ability to successfully convey a message to patients and to colleagues is important in clinical medicine. The same principle applies to research where good communication creates conditions for effective development, realization, and completion of research projects. Direct and honest communication with patients, who serve as research subjects, cannot be under-appreciated since the challenge of patients participating in research is added to stress related to disease and its management.
- (5) Practice Based Learning: Participation in research projects enhances the ability of trainees to practice medicine in a manner open for new concepts and new solutions for diagnosing or treating patients. Increased awareness of basic and clinical studies underlying principles of evidence-based medicine is a continued objective for all physicians, but especially physicians in training. Involvement in and exposure to research also provides opportunities to apply the acquired knowledge to assess clinical studies and medical problems with proper statistical and clinical trial methodology.
- (6) Systems Based Learning: clinical research cannot be separated from overall health service systems, and it should be conducted while accounting for specifics of clinical operation. Designing clinical research projects needs to be realistic within frames of existing system and projects should be conducted in collaboration with services setting the rules.

## General Statement of Expectations of Fellows

All Cardiology Fellows will be required to complete an 8-9 month research rotation during the second and third years of cardiology fellowship. Opportunities for clinical and basic research are available not only within the Cardiology Division, but also within the other Divisions of the Department of Medicine and the basic biomedical science departments of the University.

Individual Fellows should have, before their appointment, appropriate preparation in the biologic, epidemiologic and physical sciences basic to medicine. If additional course work is desirable and appropriate, Fellows are encouraged to avail themselves of it.

The following guidelines will be utilized to fulfill the requirements for research training:

1. A Research Committee composed of a minimum of three members of the Cardiology Division at the University of Rochester Medical Center will oversee the research. Faculty will be appointed by the Chief of the Cardiology Division. The Research Committee will approve, guide, and oversee research conducted by Fellows.
2. Early in the first year of fellowship, each first year fellow will be assigned a mentor, who is a member of the Research Committee. It will be the responsibility of the mentor to assure that the Fellow becomes knowledgeable about current research efforts underway within the institution, and to facilitate contact with faculty working in areas of interest to the Fellow, and, to assure that project development with a faculty member (sponsor) of the Fellow's choosing is suitably underway. Deciding upon an appropriate project and faculty sponsor should be accomplished in a timely fashion (by September or October of the first year). The research mentor will remain in contact with the sponsor and monitor the progress of the project. He or she (the mentor) will report on that progress to the Research Committee quarterly.
3. Fellows will be exposed to research undertakings by members of the Cardiology faculty, and faculty in other Departments (who would be willing to sponsor a Cardiology fellow's research) through a series of invited presentations early in the first year.
4. The nature of the proposed research will be decided by the Fellow, with the approval of a faculty sponsor. The responsibility of the sponsor will be to monitor the day-to-day progress of the proposal development and of the conduct of the research, to report that to the research mentor, and, at the end of the research year, to judge the adequacy of the research effort (and recommend promotion of the Fellow). The scope and nature of the research will not be limited by the Committee so long as it is related to cardiovascular physiology, disease, or treatment. Projects expected to require unreasonable funding or more than one year to complete should be avoided. Projects expected to require less than the 8-9 months devoted to research will be allowed, although it is expected that the research sponsor will assign (or the Fellow will create) additional projects to reasonably occupy the period. Studies must be carried out according to approved principles of biomedical ethics and institutional guidelines for patient and animal protection.

5. It is expected that the Fellow will attempt to secure funding for the proposed research. Some funding will be available from the Cardiology Division, but this will be limited; decisions about funding will be made by the Research Committee, in conjunction with the Division Chief, based upon merit of the project and amount requested. Fellows may improve their chances for funding by applying to external sources; if that is attempted, deadlines for submission will likely be earlier than those listed below. The scientific rigor demanded by external funding sources usually enhances the value of a research proposal, and the Cardiology Division strongly endorses such submissions. Such proposals, if favorably reviewed but unfunded by such external reviewers, will receive advantageous consideration for internal (Division) funding.
6. The research concept will be presented in a 15-30 minute oral presentation to members of the Cardiology faculty in mid-to late-November of the first year.
7. A rough draft of the proposed research will be presented to the Research Committee by December 1 of the first year.
8. By January 1, two members of the Committee will have reviewed each proposal, will have approved or rejected it, and made suggestions for modification.
9. A final draft of the proposed research (written in the format of AHA fellowship applications) will be due to the Committee by February 1 of the first year. Further modifications may be suggested by Committee members at that time. Formal Committee approval must be obtained before the project is undertaken.
10. Approval by institutional regulatory agencies will be the conjoint responsibility of the Fellow and sponsor, and application must be made sufficiently early to allow a July 1 start date.
11. All Fellows should have an approved research project prior to the beginning of the second year of fellowship. Failure to do so will jeopardize the Fellow's continuation in the program.
12. The Fellow should develop skills in the following areas (Taken from American College of Cardiology Task Force report, 1995):
  - 1) Literature study, to ascertain the exact state of knowledge before undertaking new investigation.
  - 2) Formulation of hypothesis and specific goals, ensuring that the hypothesis is testable, that the goals are appropriate and statistical power is achievable.
  - 3) Development of the research plan and the protocol, including study design, recruitment of subjects, choice of animals for study, ethical considerations, informed consent and protection of privacy, data collection modes, full description of procedures, and institutional approval of human and animal investigation.
  - 4) Data collection, including preparation of routine data forms.
  - 5) Development of analysis methods or procedures skills, as required, and particularly the handling of artifacts, missing data, outlier and statistical inference.
  - 6) Presentation of results in both oral and written format. No investigation is considered complete until it is reported in peer-reviewed journals.

- 7) Risk-benefit analysis, regarding subject (humans and animals) risk and benefit and societal worth.
13. Research will occupy a total of 8-9 months of the second and third years; duties other than research may not occupy more than 10% of the Fellow's time (of a 40-hour work week) during months devoted to research. "Moonlighting" approved by the Program Director and scheduled after hours will not be prohibited by the Committee.
14. Periodically, the Fellow will present a formal research seminar and oral defense of his/her research to the Cardiology Division, and other interested faculty. Promotion to the third year of fellowship (a decision of the Division Chief) will be, in part, contingent upon the Fellow's successful engagement in research. Adequacy of the research effort will be judged by the sponsor, and he/she will recommend approval or disapproval to the Committee.