APPENDIX 2. PEER REVIEWER RELATIONSHIPS WITH INDUSTRY—ACCF 2008 RECOMMENDATIONS FOR TRAINING IN ADULT CARDIOVASCULAR MEDICINE CORE CARDIOLOGY TRAINING (COCATS 3)—TASK FORCE 6: TRAINING IN SPECIALIZED ELECTROPHYSIOLOGY, CARDIAC PACING, AND ARRHYTHMIA MANAGEMENT

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<th>Consultant</th>
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Task Force 7: Training in Cardiovascular Research

Joseph Loscalzo, MD, PhD, FACC, Chair
Gordon F. Tomaselli, MD, FACC, Douglas E. Vaughan, MD, FACC, Richard A. Walsh, MD, FACC

All cardiology training should be performed in institutions in which the opportunity to participate in research is available. The training site should be one that will provide an atmosphere of intellectual inquiry and support of the investigative process.

It is important that every cardiovascular trainee participate directly in research. Cardiology is a dynamic clinical field in which the rapid transfer of knowledge from basic and clinical research to clinical care will continue to occur. This pattern will only accelerate in the future. Cardiovascular research is defined in the broadest terms possible because recent history makes it abundantly clear that advances in the care of patients with cardiovascular disease have come from diverse areas of medical science. If the clinical cardiologist is to maintain clinical competence and improve clinical knowledge in step with the progress of the field, it is crucial to maintain a thorough understanding of the concepts, methods, and pitfalls of the research process.

Every trainee should have direct involvement in the practical aspects of research, with emphasis on learning how to review published data, research design, data analysis, and logical deduction. The research experience plays a unique role in developing the skills in continuing self-education needed by all cardiovascular specialists. Trainees contemplating a career in investigative cardiology bear a special responsibility to prepare effectively to advance understanding in the broad area of cardiovascular science and especially the clinical application of new knowledge.

General Standards

Training Institution

The training institution must have staff and facilities for research. Opportunities for research for the trainees should be available not only within the clinical cardiovascular division but also within the basic biomedical science departments of the institution. Availability of expertise in epidemiological methods, outcome evaluation, biostatistics, and biomedical ethics is essential. Optimally, cardiovascular training should be performed in a university teaching hospital or similar institution. Where this is not feasible, an active ongoing affiliation with a university is essential.
Preparation

Before their appointment, individual trainees should have appropriate preparation in the biological, epidemiological, and physical sciences basic to medicine. If additional course work is desirable and appropriate, it should be available, and trainees should be encouraged to avail themselves of it.

Faculty

Faculty of the training program must include several members with proven skill as investigators, demonstrated by published original research in peer-reviewed journals. The critical mass of the faculty requires several cardiovascular investigators, not all of whom need to be clinical cardiologists. At least 1 full-time faculty member from each training program should have demonstrated skill as a clinical investigator.

Content of Training Program

Research “Tracks”

Research training will ordinarily take place in 1 of 3 “tracks”:
- Level 1—Trainees entering the clinical practice of cardiovascular medicine.
- Level 2—Trainees planning a commitment to teaching and clinical investigation.
- Level 3—Trainees planning a substantive commitment to basic or clinically advanced cardiovascular research.

Components of Research

The trainee should develop skills in at least the following areas:

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 that statistical power is achievable;
3. development of the research plan and the protocol, including study design, importance of appropriate controls in clinical investigation, and recruitment of subjects, ethical considerations, informed consent and protection of privacy, data collection modes, full description of procedures, and institutional approval of human investigation, where appropriate, and writing a research grant;
4. data collection, including preparation of routine data forms;
5. development of analytic methods or procedural skills, as required, and particularly the handling of artifacts, missing data, outliers, and statistical inference;
6. presentation of results, preferably both oral and written, emphasizing that no investigation is complete until it is reported as a full paper in peer-reviewed journals;
7. risk–benefit analysis, regarding both patient (subject) and societal risk–benefit; and
8. research ethics, recognition of key concepts in the conduct of responsible research including but not restricted to data acquisition/management and protection, conflicts of interest, publication practices, and authorship and scientific conduct.

Clinical Investigation

Clinical investigation must be performed under the supervision of an experienced investigator and according to approved principles of biomedical ethics and institutional rules for patient protection. It must be recognized that clinical research is difficult because of the complexity of achieving valid scientific conclusions while working with a diverse population and simultaneously protecting the interests of each patient.

In the case of multicenter clinical trials, participation in the full range of activities outlined here is required. The clinician lacking expertise in these areas may be unable to interpret critical reports that have a direct bearing on his or her practice. New data may be accepted uncritically or important advances recognized tardily. The training program should provide frequent opportunities for faculty and trainees to review and analyze small- and large-scale clinical and basic research reports in depth.

Duration of Research Training

For trainees planning careers in the clinical practice of cardiovascular medicine (Level 1), 6 to 12 months (and in many instances up to 18 to 24 months) should be devoted to a specific project or projects. This research can be undertaken concurrently with other nonlaboratory clinical training and may not require a dedicated block of time. For those planning a substantive commitment to teaching and clinical investigation (Level 2), a minimum of 18 to 24 months should be devoted to clinical research. For those planning a substantive commitment to advanced clinical research (Level 3), a minimum of 2 full years should be devoted to mentored clinical research of which at least 1 year could

Table 1 Summary of Training Requirements for Cardiovascular Research

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<th>Task Force</th>
<th>Area</th>
<th>Level</th>
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<td>6 to 12*</td>
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occur during fellowship training. Training requirements for Levels 1, 2, and 3 are summarized in Table 1.

Basic Research

For those planning a career in basic research (Level 3), 2 to 3 full-time years working directly with an experienced mentor are now needed in most cases. Such training constitutes only the beginning of the education of an independent cardiovascular investigator.

Advanced Training for Trainees Considering Entering Investigative Cardiology

Trainees preparing for careers in research (Level 3) need an extensive foundation in scientific investigation. Some trainees will have obtained thorough research preparation in combined MD/PhD programs, but may lack the specific skills or tools that are appropriate to their personal research goals. These may be obtained in a post-doctoral research fellowship experience or as part of the cardiology traineeship. For full time training, the trainee should join the group or laboratory of a productive and active scientist, or clinical investigator (with an MD or PhD degree), in any qualified institution (not necessarily where he or she is obtaining direct training).

Trainees who aim for a career in investigative cardiology but who have not had the opportunity to obtain a PhD degree or equivalent training at the time they begin their cardiology traineeships should have the opportunity, and be encouraged, to obtain the necessary basic scientific analytic course work and laboratory or clinical research experience necessary for a productive research career. Current models of this type of training include the American Heart Association Clinician Scientist Award and the National Heart, Lung, and Blood Institute program for K08 (Mentored Clinical Scientist Development), K23 (Mentored Patient-Oriented Research Career Development), or K99/R00 (National Institutes of Health Pathway to Independence) awards.

Teaching and Manuscript Review

It is important that the trainee be introduced to the basic principles and skills of education because almost all academic cardiologists devote a significant amount of time to teaching. It is highly desirable to provide opportunities for the critical review and analysis of manuscripts that have been published or are being considered for publication.

Compensation

Compensation during the often prolonged period of research training should be sufficient to allow a full-time commitment to this training. Within this context, Congress recently passed the Clinical Research Enhancement Act, which mandates debt repayment for MDs or MD/PhDs engaging in research training.

Evaluation

Evaluation by the Training Director, Research Sponsor, or Both

Evaluation of a trainee’s progress and skills should be subjective as well as objective, based on agreed-upon criteria and standards, and should be ongoing throughout the training period. The process and documentation currently required for admittance to the American Board of Internal Medicine Subspecialty Board Examination serves as a model for such evaluation. Each trainee’s competence and understanding should be documented at the completion of training.

Publication

Trainees should be encouraged to publish substantive results, thereby providing an evaluation by peer-reviewed journals.

Flexibility

It must be appreciated that the education of future investigative cardiologists is a continuing process and that they usually remain in an educational institution where they are immersed in clinical cardiology. They often have unique demands that may require altering the sequence and exposure of clinical training, consistent with their previous clinical experience. Therefore, the program director should be afforded flexibility in the assignment of responsibilities for the years of training while guaranteeing full clinical competence.

Summary

It is vital to the future intellectual health of cardiovascular medicine and the welfare of patients with cardiovascular disease that all future cardiologists be familiar with the principles and tools of research. Training in research requires the intense involvement of productive and established investigators. Those trainees preparing for a career in investigative cardiology require a carefully developed but flexible educational plan that will permit them to be successful in their research careers over an extended period.

This is a revision of the 2002 document that was written by Robert Roberts, MD, FACC—Chair; R. Wayne Alexander, MD, PhD, FACC; Joseph Loscalzo, MD, FACC; and R. Sanders Williams, MD, FACC.

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Key Words: ACCF Training Statement • COCATS 3 • cardiovascular research • investigative cardiology.
APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY—ACCF 2008 RECOMMENDATIONS FOR TRAINING IN ADULT CARDIOVASCULAR MEDICINE CORE CARDIOLOGY TRAINING (COCATS 3)—TASK FORCE 7: TRAINING IN CARDIOVASCULAR RESEARCH

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Task Force 8: Training in Heart Failure

Endorsed by the Heart Failure Society of America

James B. Young, MD, FACC, Chair
William T. Abraham, MD, FACC, Robert C. Bourge, MD, FACC, Marvin A. Konstam, MD, FACC (Heart Failure Society of America Representative), Lynne Warner Stevenson, MD, FACC

Recognition, evaluation, and treatment of heart failure are essential components of clinical cardiology practice. In order to achieve competency in this subject, 3 distinct training levels are defined, with curriculum outlined, in this section (1–4). All cardiology fellowship training programs will provide, at the least, a Level 1 curriculum in heart failure. More specifically, Level 1 training will provide an understanding of the depth and breadth of the heart failure syndrome, as well as nuances of therapy including the important topic of heart failure prevention. Level 2 training will be for those individuals who wish to broaden their experience with heart failure patients, particularly those with more advanced and challenging syndromes. This curriculum can, in particular, provide the opportunity to learn to manage devices (other than circulatory support systems) implanted for heart failure therapy and arrhythmia or hemodynamic monitoring. Level 2 will also emphasize more detailed hemodynamic assessment of these patients. Level 3 training will be for those who anticipate focusing the majority of their subsequent clinical or research activities on the syndrome of heart failure with a curriculum requiring an additional 12 months of fellowship training above and beyond that required for cardiology specialization board examination. It is recognized that not all cardiology fellowship training programs will be capable of providing the most intense Level 3 training curriculum. Level 3 training will offer a range of programs that might, for example, include heart transplantation, mechanical circulatory support devices, and advanced heart failure electrophysiology, although not necessarily all of these.