

TRAINING STATEMENT

COCATS 4 Task Force 15: Training in Cardiovascular Research and Scholarly Activity



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1. INTRODUCTION

1.1. Document Development Process

1.1.1. Writing Committee Organization

The writing committee was selected to represent the American College of Cardiology (ACC) and included a cardiovascular training program director, several active cardiovascular scientists and research methodology experts, early-career cardiologists, highly experienced research experts representing both academic and community-based practice settings, the chair of the ACC's Academic Cardiology Section Leadership Council, and a physician experienced in defining and applying training standards according to the 6 general competency domains promulgated by the Accreditation Council for Graduate Medical Education (ACGME) and American Board of Medical Specialties (ABMS) and endorsed by the American Board of Internal Medicine (ABIM). The ACC determined that relationships with industry or other entities were not relevant to the creation of this general cardiovascular training statement. Employment and affiliation details for authors and peer reviewers are provided in [Appendixes 1 and 2](#), respectively, along with disclosure reporting categories. Comprehensive disclosure information for all authors, including relationships with industry and other entities, is available as an [online supplement](#) to this document.

1.1.2. Document Development and Approval

The writing committee developed the document, approved it for review by individuals selected by the ACC, and then addressed the reviewers' comments. The document was revised and posted for public comment from December 20, 2014, to January 6, 2015. Authors addressed these additional comments from the public to complete the document. A member of the ACC Competency Management Committee served as lead reviewer. The final document was approved by the Task Force, COCATS Steering Committee, and ACC Competency Management Committee and ratified by the ACC Board of Trustees in March, 2015. This document is considered current until the ACC Competency Management Committee revises or withdraws it.

1.2. Background and Scope

Cardiology is a dynamic clinical field in which knowledge from basic and clinical research is continuously translated into clinical care. Knowledge generation and transfer accelerate as understanding of complex biological processes advances. As the science and process of healthcare delivery progresses, trainees need exposure to broad intellectual and scholarly concepts that have implications for clinical practice. An atmosphere of intellectual inquiry and support for the investigative process is critical to the development of a competent cardiologist. To maintain clinical competence and apply emerging knowledge, it is crucial to appreciate the concepts, methods, and limitations of the research process.

Cardiovascular research is defined broadly because advances in patient care come from diverse areas of medical science. All cardiovascular training institutions should offer opportunities for fellows to

participate in research, and every cardiovascular trainee is required to participate directly in some form of cardiovascular research or scholarly activity (CRSA). This should include exposure to the practical aspects of conducting research and the ability to critically evaluate published scientific data. Trainees should understand the elements of research design; informatics; data analysis; deductive and inductive reasoning; and basic principles of biostatistics, including the concepts of probability, uncertainty, and inference. Experiences in CRSA play a critical role in developing the skills and commitment required of all cardiovascular specialists for lifelong learning. Such experiences also foster integration of scientific investigation into the professional life of the emerging cardiologist and enable him or her to adapt practice as knowledge emerges (1). Additionally, many of the skills and experiences gained in the research domain are applicable to the team-based activities of quality improvement, an area that all clinical cardiologists will need to understand throughout their professional career.

The Task Force was charged with updating previously published guidelines for training cardiovascular fellows in CRSA on the basis of changes in the field since 2008 and as part of a broad effort to standardize training. This document does not provide specific guidelines for training fellows in advanced research techniques but more broadly describes opportunities for training in cardiovascular investigation. The Task Force also updated previously published standards to address the evolving framework of competency-based medical education described by the ACGME Outcomes Project and the 6 general competencies endorsed by the ACGME and ABMS. The background and overarching principles governing fellowship training are provided in the COCATS 4 Introduction, and readers should become familiar with this foundation before considering the details of training in a subspecialty like cardiovascular research and scholarly activity. The Steering Committee and Task Force recognize that implementation of these changes in training requirements will occur incrementally.

For most areas of cardiovascular medicine, 3 levels of training are delineated:

- **Level I training**, which is the basic training required of trainees to become competent consultant cardiologists, is required of all fellows in cardiology, and can be accomplished as part of a standard 3-year training program in cardiovascular medicine. Level I CRSA training refers to competency in critically interpreting cardiovascular research literature and familiarity with methods used across a broad spectrum of cardiovascular research including, but not limited to, basic and translational science; molecular, genetic, and cellular research; animal studies; epidemiological studies; clinical trials; and meta-analyses. Level I training also
 - includes participation in such mentored research activities as data collection, analysis, and interpretation; scientific writing; and the evaluation of the quality of medical evidence. This document focuses on CRSA training in cardiovascular medicine regardless of the career objectives of the trainee.
 - **Level II training** typically refers to the additional training in 1 or more areas that enables some cardiovascular specialists to perform or interpret specific diagnostic tests and procedures or render more specialized care for patients and conditions. This level of training is recognized for those areas in which an accepted instrument or benchmark, such as a qualifying examination, is available to measure specific knowledge, skills, or competence. Level II training in selected areas may be achieved by some trainees during the standard 3-year cardiovascular fellowship, based on the trainees' career goals and use of elective rotations. It is anticipated that during a standard 3-year cardiovascular fellowship training program, sufficient time will be available for the trainee to receive Level II training in a specific subspecialty. In the case of CRSA, there is no defined Level II training, although advanced training (comparable to Level III) is available after the standard fellowship.
 - **Level III training** requires additional training and experience beyond the cardiovascular fellowship for the trainee to acquire specialized knowledge and competence. For CRSA, Level III training pertains specifically to those planning careers in cardiovascular investigation. Trainees contemplating careers in investigative cardiology bear a special responsibility to prepare effectively to advance knowledge in cardiovascular science. There are many pathways to a research career, all requiring additional training and experience to develop the skills necessary to conceive, design, implement, conduct, analyze, and communicate the results of laboratory, clinical, or population-based research. The goal of advanced training in research is to develop expertise in an area of investigation that enables the trainee to direct an independent research project or provide expertise in a collaborative research program. In most cases, advanced training should enable trainees to apply for competitive research funding. This advanced training requires experience dedicated to specialized research beyond the 3-year cardiovascular fellowship. Level III training is described here only in broad terms to provide context for trainees and clarify that this advanced knowledge is not addressed during the cardiovascular fellowship.
- The duration of exposure at each level of training is based on published competency statements as well as the experience and opinions of the writing group. It is assumed that training is directed by appropriately trained

mentors in an ACGME-accredited program and that satisfactory completion of training is documented by the research sponsor and program director. The types and extent of activities and duration of training required are summarized in [Section 4](#).

2. GENERAL STANDARDS

The ACC published educational objectives for fellowship training in cardiovascular research in 2008 (2). The 2008 recommendations have been updated and address faculty, facility requirements, research trends, and practice. Cardiovascular fellowship programs should satisfy these requirements. The intensity of training and resources required varies according to the level of training provided. We recommend strongly that candidates for the ABIM examination for certification in cardiovascular diseases review the specific requirements of the ABIM as they pertain to this aspect of training (3).

2.1. Faculty

The training program faculty must include several proven, skilled investigators who have obtained research funding and published peer-reviewed original research. At least 1 full-time faculty member from each training program should have demonstrated abilities as an independent investigator. The critical mass of faculty actually requires several cardiovascular investigators, however, some of whom may be clinical cardiologists, optimally with expertise and experience in a wide range of fields.

2.2. Facilities

The training institution must provide appropriate staff and facilities to conduct research. Research opportunities for trainees should be available not only in clinical cardiovascular medicine, but also in other departments, including basic biomedical and population health sciences. Expertise in epidemiological methods, outcomes evaluation, clinical trial design and methods, biomedical and clinical informatics, biostatistics, biomedical ethics, and regulatory science is essential for training in patient-oriented investigation. Optimally, cardiovascular training should take place in a university-affiliated teaching hospital or similar institution. When this is not feasible, an active affiliation with an academic CRSA mentor can complement community-based training. The training program should provide access to a medical library; Internet access to online compendia such as PubMed, Medline, and CardioSource; as well as statistical software such as Statistical Analysis System (SAS Institute, Cary, North Carolina), Matlab (MathWorks, Natick, Massachusetts), and Statistical Package for the Social Sciences (IBM, Armonk, New York).

Although specific components of the research infrastructure will vary with the type and scope of projects at a

given institution and availability of funding, most institutions should have personnel experienced in developing research budgets, reviewing research contracts, ensuring sound financial management of research, and serving on an institutional review board that governs research involving human subjects. Where laboratory animal research is conducted, appropriate facilities include the staff and equipment necessary for safe and humane handling. Clinical research programs should include trained study coordinators. It is highly desirable that trainees engaging in research have access to a biostatistician or other quantitative scientists for collaboration and assistance in planning studies and analyzing research data.

3. TRAINING COMPONENTS

Trainees should have prior education in and exposure to the biological, physical, quantitative, and informational sciences fundamental to modern medicine. Additional coursework and opportunities for independent study and formal graduate training programs should be available, and trainees should be encouraged to avail themselves of these resources.

3.1. Didactic Program

The competent cardiologist must critically assess the scientific literature relevant to patient care. This involves understanding research methodology; fundamental concepts of research design; and the conduct, analysis, and interpretation that form the basis for evidence-based medicine. Because clinical practice guidelines and related documents form an essential basis for contemporary clinical care, training programs must provide trainees with an introduction to evidence assessment and synthesis and to the methodology underlying evaluation of the quality of scientific evidence. Trainees can obtain the required knowledge and skills in a variety of ways, including participation in lecture series (such as Web-based programs) and critical review and discussion of carefully selected articles at journal club conferences attended by both trainees and experienced faculty. The didactic portion of training in research and scholarly activity should incorporate issues of responsible conduct of research such as protection of human and animal subjects, transparent reporting and avoidance of conflicts of interest, independence of data monitoring committees, independence in analyses and publications, and integrity in assigning authorship.

3.2. Interpretation of Cardiovascular Research

The competent clinician must interpret scientific reports that pertain to clinical practice. New data should not be accepted uncritically, nor should the cardiologist fail to recognize and evaluate important scientific advances relevant to clinical practice. As a minimum Level I

requirement, the program should provide frequent opportunities for faculty and trainees to review and analyze in depth a broad variety of cardiovascular research reports.

3.3. Hands-On Research Experience

Research in cardiovascular science and medicine takes diverse forms. Although hands-on exposure to research is essential to advanced research training, introductory hands-on research experience is desirable but not mandatory for Level I training. This introductory experience could be as straightforward as learning to obtain informed consent from a patient considering participation in a clinical trial, collecting blood or tissue samples for basic or translational laboratory investigations, or learning to extract information from medical records for entry into a research database. All of these experiences should be conducted under the supervision of experienced research personnel, including faculty expert in the pertinent research methodologies.

3.4. Teaching

Because almost all academic cardiologists devote time and effort to teaching, the trainee should understand the principles of adult learning and acquire the skills necessary to effectively teach others, including patients. Academic practitioners teach medical students, residents, and fellows, whereas clinical cardiologists traditionally direct teaching activities toward advanced practice providers, nurses, and ancillary staff in hospital or outpatient office settings.

4. SUMMARY OF TRAINING REQUIREMENTS

4.1. Development and Evaluation of Core Competencies

Training and requirements in CRSA address the 6 general competencies promulgated by the ACGME/ABMS and endorsed by the ABIM. These competency domains are: medical knowledge, patient care and procedural skills, practice-based learning and improvement, systems-based practice, interpersonal and communication skills, and professionalism. The ACC has used this structure to define and depict the components of the core clinical competencies for cardiology. The curricular milestones for each competency and domain also provide a developmental roadmap for fellows as they progress through various levels of training and serve as an underpinning for the ACGME/ABIM reporting milestones. The ACC has adopted this format for its competency and training statements, career milestones, lifelong learning, and educational programs. Additionally, it has developed tools to assist physicians in assessing, enhancing, and documenting these competencies.

Table 1 delineates each of the 6 competency domains, as well as their associated curricular milestones for

training in CRSA. The milestones indicate the stage of fellowship training (12, 24, or 36 months, and additional time points) by which the typical cardiovascular trainee should achieve the designated level. Given that programs may vary with respect to the sequence of clinical experiences provided to trainees, the milestones at which various competencies are reached may also vary. Level I competencies may be achieved at earlier or later time points. Acquisition of Level II skills requires additional training, and acquisition of Level III skills requires training in a dedicated cardiovascular research program. The table also describes examples of evaluation tools suitable for assessing competence in each domain.

4.2. Components of Research

During Level I training, trainees should master the practices of:

1. *Literature review*, before undertaking new investigation to ascertain the current state of knowledge and understand a disease or condition, diagnostic technology, or therapy; and
2. *Ethical conduct* in carrying out responsible research, including but not limited to the protection of human subjects and recognition and the disclosure and management of potential conflicts of interest.

4.3. Duration of Research Training

The specific competencies expected to result from Level I training are delineated in **Table 1**. The minimum lengths of training required for Level I and advanced training in CRSA are summarized in the following text. A brief discussion of the competencies and training requirements also follows. At more advanced levels, the education of investigators is a continuous process, and research trainees usually remain in an educational institution to participate in both scientific and clinical endeavors. Advanced research training may lead to multiple career paths, ranging from permanent academic appointments to stints in private practice or vice versa.

4.3.1. Level I Training Requirements

Level I trainees planning careers predominantly in clinical practice should devote 6 to 12 months (and up to 24 months) to 1 or more scholarly or research projects. These activities can be undertaken concurrently with clinical training and may not require a dedicated block of time, although in most cases, some period of time should be available to pursue CRSA while unfettered by clinical duties. Although the training duration suggested is required by the typical trainee to obtain competency, trainees must also demonstrate achievement of the competencies as assessed by the outcomes evaluation measures.

TABLE 1 Core Competency Components and Curricular Milestones for Training in Cardiovascular Research and Scholarly Activity

Competency Component		Milestones (Months)			
		12	24	36	Add
MEDICAL KNOWLEDGE					
1	Know the roles and functions of DNA, RNA, and proteins.			I	
2	Know the principles of genetics, genomics, proteomics, metabolomics, and pharmacogenomics.			I	
3	Know the principles of epidemiological methods.			I	
4	Know the principles of outcomes evaluation.			I	
5	Know the basic principles of biostatistics.			I	
6	Know the principles underlying hypothesis formation, specific goals definition, hypothesis testability, and statistical power achievable.			I	
EVALUATION TOOLS: global evaluation, in-training examination, and multisource evaluation.					
PATIENT CARE AND PROCEDURAL SKILLS					
1	Skill to review published research data and assess the adequacy of research design, data analysis, and logical deduction.			I	
2	Skill to appropriately integrate scientific concepts and research advances in routine clinical encounters.		I		
3	Skill to routinely assess the quality of evidence in clinical decisions.		I		
4	Skill to apply principles of biomedical ethics as they pertain to human subject research in the identification of patients as potential research subjects, presentation of alternatives, obtaining of informed consent, and ensuring the security of clinical data used for research.		I		
EVALUATION TOOL: multisource evaluation.					
SYSTEMS-BASED PRACTICE					
1	Effectively access and utilize national registry data for research.		I		
2	Know the role of and how to interact with institutional review boards.		I		
EVALUATION TOOLS: direct observation and multisource evaluation.					
PRACTICE-BASED LEARNING AND IMPROVEMENT					
1	Identify knowledge and performance gaps and engage in opportunities to achieve focused education and performance improvement.		I		
2	Appropriately integrate new or emerging medical evidence.			I	
EVALUATION TOOLS: multisource evaluation, and reflection and self-assessment.					
PROFESSIONALISM					
1	Demonstrate sensitivity to patient autonomy and safety in research.	I			
2	Practice with integrity in the conduct of research, including understanding issues relating to relationships with industry.		I		
3	Interact respectfully with ancillary and support staff.	I			
EVALUATION TOOLS: conference presentation, direct observation, and reflection and self-assessment.					
INTERPERSONAL AND COMMUNICATION SKILLS					
1	Communicate with fellow trainees and faculty about cardiovascular science and how this might impact clinical care (e.g., through journal clubs).		I		
2	Effectively communicate study results during presentations.		I		
EVALUATION TOOLS: direct observation and multisource evaluation.					

Add = additional months beyond the 3-year cardiovascular fellowship; DNA = deoxyribonucleic acid; RNA = ribonucleic acid.

4.3.2. Advanced Training Requirements

Trainees preparing for careers in research need an extensive foundation in scientific investigation. Some will have obtained preparation in combined-degree programs (e.g., MD/PhD, MD/MPH, MD/MS) but may lack the specific skills or experience necessary to achieve their research objectives. These advanced skills may be obtained in a postdoctoral research fellowship or as part of cardiovascular training. For additional 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 a qualified institution (which is not necessarily where he or she is enrolled for fellowship training).

Trainees seeking careers in investigative cardiology who have not obtained an advanced degree should be encouraged to obtain the necessary scientific analytic coursework and laboratory or clinical research experience to promote a productive research career. Current models of this type of training include the AHA Clinician Scientist Award and the National Heart, Lung, and Blood Institute programs for K08 (Mentored Clinical Scientist Development), K23 (Mentored Patient-Oriented Research Career Development), and K99/R00 (National Institutes of Health Pathway to Independence) awards.

4.3.2.1. Basic Research

For those planning a career in basic laboratory research, 3 years working directly with an experienced mentor—beyond the 2 clinical years—are needed in most cases. Such training constitutes only the beginning of an independent cardiovascular investigator's education.

4.3.2.2. Clinical Research

For trainees planning a substantive commitment to advanced clinical research, at least 2 to 3 full years devoted to mentored clinical research are generally needed, of which 1 or more years can occur during fellowship training. Advanced research training requires didactic training, including formal coursework in research methods. The pursuit of an advanced degree (e.g., PhD, MS, MPH) in a specific scientific field is optional. The advanced degree is especially valuable to trainees

considering careers as independent investigators directing a laboratory or leading a scientific research program.

4.3.2.3. Compensation

Compensation during the often prolonged period of research training should be sufficient to support a full-time commitment. In this context, the U.S. Congress passed the Clinical Research Enhancement Act, which eases debt repayment for candidates with MD or MD/PhD degrees engaging in advanced research training (4).

5. EVALUATION OF COMPETENCY

Evaluation tools in cardiovascular research and scholarly activity include direct observation by instructors, in-training examinations, case logbooks, conference and case presentations, multisource evaluations, trainee portfolios, and reflection and self-assessment. Analytical, ethical, judgment, interpretive, and, as appropriate, research laboratory skills must be evaluated in every trainee. Reliability; judgment, decisions, or actions that result in questions about data or analytical integrity; interactions with other physicians, researchers, statisticians, patients, or research laboratory support staff; initiative; and the ability to make appropriate decisions and ask appropriate questions independently should be considered. Trainees should, as appropriate, maintain laboratory notebooks, well-annotated statistical code, and records of participation and advancement in the form of a Health Insurance Portability and Accountability Act (HIPAA)-compliant electronic database or logbook that meets ACGME reporting standards and summarizes important research-related information for each project and/or encounter.

Under the aegis of the program director, the faculty should record and verify each trainee's experiences, assess performance, and document satisfactory achievement. The program director is responsible for confirming experience and competence and for reviewing the overall progress of individual trainees with the Clinical Competency Committee to ensure achievement of selected training milestones and identify areas in which additional focused training may be required.

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KEY WORDS ACC Training Statement, clinical competence, COCATS, fellowship training, research

**APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—
COCATS 4 TASK FORCE 15: TRAINING IN CARDIOVASCULAR RESEARCH AND SCHOLARLY ACTIVITY**

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional/ Organizational or Other Financial Benefit	Expert Witness
Robert A. Harrington (Chair)	Stanford University—Arthur L. Bloomfield Professor of Medicine; Chair, Department of Medicine	None	None	None	None	None	None
Ana Barac	MedStar Heart and Vascular Institute—Director, Cardio-Oncology Program	None	None	None	None	None	None
John E. Brush, Jr.	Sentara Cardiology Specialists—Consulting Cardiologist	None	None	None	None	None	None
Joseph A. Hill	UT Southwestern Medical Center—Professor of Medicine and Molecular Biology	None	None	None	None	None	None
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Michael S. Lauer	National Heart, Lung, and Blood Institute—Director, Division of Cardiovascular Sciences	None	None	None	None	None	None
Chittur A. Sivaram	University of Oklahoma Health Sciences Center—Program Director, Cardiovascular Section	None	None	None	None	None	None
Mark B. Taubman	University of Rochester Medical Center—Charles A. Dewey Professor and Chairman of Medicine	None	None	None	None	None	None
Jeffrey L. Williams	The Good Samaritan Hospital and Lebanon Cardiology Associates—Medical Director, Clinical Cardiac Electrophysiology	None	None	None	None	None	None

For the purpose of developing a general cardiology training statement, the ACC determined that no relationships with industry or other entities were relevant. This table reflects authors' employment and reporting categories. To ensure complete transparency, authors' comprehensive healthcare-related disclosure information—including relationships with industry not pertinent to this document—is available in an online data supplement. Please refer to <http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy> for definitions of disclosure categories, relevance, or additional information about the ACC Disclosure Policy for Writing Committees.

ACC = American College of Cardiology.

**APPENDIX 2. PEER REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—
COCATS 4 TASK FORCE 15: TRAINING IN CARDIOVASCULAR RESEARCH AND SCHOLARLY ACTIVITY**

Name	Employment	Representation	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional/ Organizational or Other Financial Benefit	Expert Witness
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Dhanunjaya Lakkireddy	Kansas University Cardiovascular Research Institute	Official Reviewer, ACC Board of Governors	None	None	None	None	None	None
Howard Weitz	Thomas Jefferson University Hospital—Director, Division of Cardiology; Sidney Kimmel Medical College at Thomas Jefferson University—Professor of Medicine	Official Reviewer, Competency Management Committee Lead Reviewer	None	None	None	None	None	None
Alex Auseon	The Ohio State University Wexner Medical Center	Content Reviewer, Academic Cardiology Section Leadership Council	None	None	None	None	None	None
John Canty	University at Buffalo Clinical and Translational Research Center—Albert and Elizabeth Rekatte Professor and Chief	Content Reviewer, Academic Cardiology Section Leadership Council	None	None	None	None	None	None
Larry Jacobs	Lehigh Valley Health Network, Division of Cardiology; University of South Florida—Professor, Cardiology	Content Reviewer, Cardiology Training and Workforce Committee	None	None	None	None	None	None
Andrew Kates	Washington University School of Medicine	Content Reviewer, Academic Cardiology Section Leadership Council	None	None	None	None	None	None
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For the purpose of developing a general cardiology training statement, the ACC determined that no relationships with industry or other entities were relevant. This table reflects peer reviewers' employment, representation in the review process, as well as reporting categories. Names are listed in alphabetical order within each category of review. Please refer to <http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy> for definitions of disclosure categories, relevance, or additional information about the ACC Disclosure Policy for Writing Committees.

ACC = American College of Cardiology; AHA = American Heart Association.

APPENDIX 3. ABBREVIATION LIST

ABIM = American Board of Internal Medicine
 ABMS = American Board of Medical Specialties
 ACC = American College of Cardiology
 ACGME = Accreditation Council for Graduate Medical Education
 COCATS = Core Cardiovascular Training Statement
 CRSA = cardiovascular research or scholarly activity
 HIPAA = Health Insurance Portability and Accountability Act
 SAS = Statistical Analysis System
 SPSS = Statistical Package for the Social Sciences