

TRAINING STATEMENT

Task Force 8: Pediatric Cardiology Fellowship Training in Research and Scholarly Activity



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1. INTRODUCTION

1.1. Document Development Process

The Society of Pediatric Cardiology Training Program Directors (SPCTPD) board assembled a Steering Committee that nominated 2 chairs, 1 SPCTPD Steering Committee member, and 6 additional experts from a wide range of program sizes, geographic regions, and subspecialty focuses. Representatives from the American College of Cardiology (ACC), American Academy of Pediatrics (AAP), and American Heart Association (AHA) participated. The Steering Committee member was added to provide perspective to each Task Force as a “nonexpert” in that field. Relationships with industry and other entities were not deemed relevant to the creation of a general cardiology training statement; however, employment and affiliation information 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.

The writing committee developed the document, approved it for review by individuals selected by the participating organizations ([Appendix 2](#)), and addressed their comments. The final document was approved by the SPCTPD, AAP, and AHA in February 2015 and approved by the ACC in March 2015. This document is considered current until the SPCTPD revises or withdraws it.

1.2. Background and Scope

There has been substantial scientific progress relevant to pediatric cardiology in the 10 years since the last training guidelines for research were published (1). The prior guidelines and a National Institutes of Health (NIH) expert panel stressed that there remains a critical need for advancement and application of new knowledge in a breadth of disciplines relevant to the field (2). These guidelines begin with the principle that there is a compelling need to train pediatric cardiology fellows to develop new knowledge and to translate research findings into practice. Because research skills are relevant to all those trained in our field, it is essential to develop both core skills and knowledge to allow the realization of meaningful research that is matched to the trainee’s interests. Different pathways and training schedules must be considered to address the specific needs of each trainee with guidance from mentors. A discussion with each trainee early in fellowship may facilitate

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training pathways for those interested in advanced research training. Training of pediatric cardiology fellows requires that the sponsoring division and institution have appropriate resources for training fellows in research. As noted in a prior version of these guidelines, expertise and mentorship in a variety of scientific disciplines relative to pediatric cardiology are essential.

Although sufficient resources and dedicated time are critical to success, the expertise and commitment of the mentor is 1 of the most important elements of research training (3). The training program must ensure that trainees gain experience and develop career pathways with the advice and support of appropriate mentors from throughout the institution. Just as a program needs to have sufficient clinical volume to support a trainee, so too does a fellowship require an adequate number of well-qualified, established faculty mentors to ensure a successful research training experience. Early in the training fellowship, a faculty member, usually a pediatric cardiologist with extensive experience in research, should provide an overview of the research training including a list of potential mentors.

Once a trainee has identified their mentor, the Scholarship Oversight Committee (SOC) will assist in monitoring the trainee's progress. There are several key ingredients to successful mentorship (4,5), including: 1) a sensible matching process designed to link mentor/mentee according to shared research goals; 2) jointly established and realistic expectations, including timelines that are understood clearly by both parties; 3) a written contract or agreement between the mentor/mentee that identifies key skill development needs and objectives and signifies a commitment on both parties to dedicate the time and effort required to meet the other's expectations; 4) the allocation of specific time for regular mentor/mentee meetings; 5) an ongoing evaluation/feedback process that serves both parties; and 6) respect for sex and/or ethnic differences.

In most cases, it is advantageous for the mentor to be an established researcher rather than junior faculty. An established investigator may be better able to identify pitfalls and obstacles in study design, and an associate or full professor often has more stable resources to ensure successful completion of a project. However, in some cases, young faculty may do particularly well in mentoring roles. It is recommended that when a junior faculty member is assigned as a mentor, he or she should be paired with a more senior investigator to serve as co-mentors.

1.3. Levels of Expertise—Core and Advanced

In this statement, we discuss core training for all fellows enrolled in a traditional 3-year pediatric cardiology fellowship and advanced training for fellows who wish to

embark on a career in pediatric cardiology research. Core training is required for all trainees and is intended to ensure that fellows acquire the knowledge base and skills necessary to become a pediatric cardiologist able to conduct research and participate in scholarly activity. Advanced training guidelines are recommended for fellows who wish to commit a large part of their career to research.

2. PROGRAM RESOURCES AND ENVIRONMENT

2.1. Types of Research

For the field of pediatric cardiology to advance and address key questions in the coming decades, it is critical to carry out various types of research. Accordingly, the fellowship research programs should allow trainees to obtain structured training in a number of established or evolving disciplines. Most training programs have emphasized 3 primary avenues for research: 1) basic research in imaging sciences; molecular, cellular, and developmental biology; physiology; structural biology; genetics; genomics; proteomics; and biomarkers research; 2) patient-oriented research, including clinical trials, epidemiological studies, population-based studies, behavioral science, outcomes research, quality and safety research, biomedical ethics, medical informatics, and application of imaging technologies; and 3) translational research that bridges the gap by turning laboratory findings into new drugs, devices, or procedures, or bedside-to-bench studies that apply clinical observations to develop fundamental mechanistic studies. However, there are a number of emerging fields that may overlap with the 3 core approaches, yet increasingly require specialized skills or training. These fields include clinical cardiovascular genetics, health services studies, educational research, and health economics. By developing expertise in these fields, the next generation of pediatric cardiologists will be best equipped to address critical challenges.

2.2. General Expectations

The resources needed to foster a meaningful research training experience are considerable. Institutions should not underestimate the financial commitment and breadth of expertise that are needed to successfully fulfill these obligations.

2.3. Personnel

First and foremost, a training program needs a committed fellowship director. A fellowship director takes on many responsibilities in the fellowship program, so it may be valuable to designate a faculty member to oversee the research training. However, in some cases, the fellowship director may have the time, expertise, and interest to

direct this important endeavor. This director of fellowship research would be entrusted to assemble and monitor the SOC. The composition, structure, and function of the SOC have been defined by the American Board of Pediatrics (6). The director of fellowship research would also be responsible for assessing each trainee's progress.

2.4. Curriculum

The first requirement is to have a formal research education curriculum. This should be clearly defined and shared with trainees and other faculty members. The basic curriculum would include fundamental research principles such as protection of human subjects, evidence-based medicine, core biostatistics, clinical research design, and scientific writing. Many institutions have developed a core research program designed for fellows from various divisions. Such an approach is encouraged because it allows for shared expertise, collaboration, and efficient use of resources.

There should also be active research activities within cardiology and/or other groups that are involved in the care of pediatric cardiology patients. A faculty that is active in research will not only provide project opportunities and mentorship, but will also naturally bring out exchange of research ideas and reference relevant known research data in the course of patient care. The medium for scholarly exchange and interaction within cardiology should also be formal such as regularly scheduled journal clubs and research-in-progress updates. Protected time should be allotted for the trainee to attend these and other scholarly conferences and seminars.

Programs should provide the opportunity for fellows to collaborate or conduct multidisciplinary research with multiple investigators. Even if the cardiology program is active in research, a multidisciplinary approach will allow the trainee to leverage expertise from outside the division. The program director, research director, and SOC chair should assist the trainee in identifying these external resources.

2.5. Ancillary Staff

Critical elements of research training often include the firsthand preparation of an institutional review board submission, primary statistical analysis of research data, and grant application. The trainee needs to have knowledge of all of these areas. However, to support research endeavors, trainees engaging in complex research projects will often need assistance with data management, statistical analysis, and grant submission. A research training program should integrate with the larger divisional, departmental, or institutional research centers with access to research coordinators,

biostatisticians, and grant writing assistants to ensure success for the trainees.

2.6. Financial Resources

Most forms of research require financial resources to ensure success. Therefore, programs will need to provide support to pediatric cardiology trainees. This financial support may come from extramural grants or endowments available to the established faculty. Training grants may provide some support. Discretionary funds and local grants may be available. Program directors need to not only provide an inquisitive research environment and passionate mentors, but also ensure that mentors can provide adequate project support to accomplish the research aims. There should also be financial support for the trainee to attend scientific meetings, and trainees should be particularly encouraged to submit and present original research at important scientific meetings.

Last, for conducting research, the training facility should have access to research administration that oversees research activities. This includes a human subject protection committee and assistance with grant proposals such as budget analysis. Free access to a library system with electronic access to most full-text articles and journals is mandatory. Additional support services may include standard computer hardware and statistical software.

2.7. Duration of Research Training

The Subspecialties Committee of the American Board of Pediatrics has stated that the principal goal of fellowship training should be the development of future academic pediatricians (6). To that end, it is recognized that a significant proportion (≥ 12 months) of the 3-year training program should be dedicated to scholarly activities and research training (6). The dedicated research time can be configured in various manners (see Section 5, Flexibility For Research Training) and should be protected time as much as possible.

For those trainees planning a career with a strong concentration in research, we recommend that the duration of research training should be considerably longer. To attain the needed skills, 24 months or more of dedicated research training should be undertaken. This will often require that the duration of fellowship training be extended beyond the 3 years.

3. CORE TRAINING: GOALS AND METHODS

3.1. Clinical Research

With appropriate mentoring, the trainee should develop skills in the following areas: literature critique, study design, funding, research implementation, and dissemination of results. For specific recommendations for each

TABLE 1 Core Curricular Competencies for Pediatric Cardiology—Clinical Research and Scholarly Activity

Medical Knowledge

- Know the methods of conducting a comprehensive and systematic search of the literature on a clinical problem.
- Know the basic statistical methods used in clinical research studies.
- Know the principles of summarizing and interpreting results of published studies including identifying potential sources of bias.
- Know the strengths and weaknesses of different clinical research study designs.
- Know the principles underlying a well-defined hypothesis formation and specific goal definitions.
- Know the principles behind optimal study design for addressing a clinical research question using a protocol that identifies inclusion and exclusion criteria, outcome measures, power analysis, and data analysis.

Evaluation Tools: reporting to and obtaining feedback from the Scholastic Oversight Committee, conference presentation, and in-training examination

Patient and Procedural Skills

- Have the skills to determine the resources needed and to implement a clinical research plan.
- Have the skills to identify gaps in knowledge within a research problem.
- Have the skills to evaluate selection bias, misclassification, and confounding variables.
- Have the skills to obtain informed consent and assent for enrollment.
- Have the skills to recognize and report adverse events.

Evaluation Tools: reporting to and obtaining feedback from the Scholastic Oversight Committee

Systems-Based Practice

- Know governmental or industry standard regulatory requirements in the study design.

Evaluation Tools: reporting to and obtaining feedback from the Scholastic Oversight Committee

Professionalism

- Have the ability to identify ethical challenges and potential conflicts of interest in clinical research.

Evaluation Tools: reporting to and obtaining feedback from the Scholastic Oversight Committee, and reflection and self-assessment

Interpersonal and Communication Skills

- Have the skills to write a grant for intramural or extramural funding.
- Have the skills to prepare an abstract for submission to a national meeting.
- Have the skills to prepare a manuscript for publication.
- Have the skills to present an abstract at a national conference.

Evaluation Tools: reporting to and obtaining feedback from the Scholastic Oversight Committee, mentor evaluation, and 360 evaluation

Adapted from the CTSA web site (7).

of these skill domains, organized in the ACGME core competency structure, please see **Table 1**. This table is adapted from more extensive charts of clinical/translational research core competencies that can be found at the NIH Clinical and Translational Science Award (CTSA) web site (https://ctsacentral.org/wp-content/documents/CTSA%20Core%20Competencies_%20final%202011.pdf).

Familiarity with these domains requires a fundamental knowledge of basic biostatistical methods, including diagnostic test performance (sensitivity, specificity, predictive value, and receiver-operating characteristic curves) and parametric and nonparametric data analysis, including comparison of proportions, power and sample size, correlation, linear and logistic regression, and multivariable analysis. During research training, the trainee will be required to undertake a scholarly project that meets requirements for subspecialty certification by the American Board of Pediatrics. Such scholarly activity may consist of a project in which the trainee undertakes a hypothesis-driven study or a project requiring substantive scholarly exploration and analysis. The scholarly activity must include active participation by the fellow that is mentored by faculty and results in the generation of a peer-reviewed publication, critical systematic review, or meta-analysis of the literature. Core research training in the domains could be obtained as part of a master's program in clinical investigation, public health, or some other structured degree program.

Competency in the skills noted in **Table 1** can be documented as part of the oversight of the trainee during his or her fellowship.

3.2. Laboratory/Basic and Translational Research

Although the minority of fellows pursue scholarly projects that involve laboratory-based research, these skills are important because of the broad impact of basic research on the field. A certain core knowledge base is relevant and important for a specialist in the field (7). These skills along with those for trainees who wish to pursue laboratory training are outlined in **Table 2**. A basic understanding of the genetic basis of disease and the impact on genomic variation on disease presentation is needed.

4. ADVANCED TRAINING: GOALS AND METHODS

Fellowship directors should communicate frequently with trainees regarding career goals. For those fellows who desire to commit a large part of their career to research, program directors should help configure the training to ensure success in this endeavor. Trainees preparing for clinical research careers in pediatric cardiology need a similar time commitment and similar advanced training as those pursuing careers in basic science research. Some trainees may have previously obtained advanced training as part of an MD/MPH or MD/PhD program in medical or postgraduate school, but

TABLE 2 Core Curricular Competencies for Pediatric Cardiology-Basic/Translational Research and Scholarly Activity**Medical Knowledge**

- Know the methods of conducting a comprehensive search of the literature on the biological basis of a pediatric cardiovascular disease, syndrome, or fundamental biological question.
- Know the principles of summarizing and interpreting the impact and potential sources of conceptual or methodological flaws of published basic/translational studies.
- Know what constitutes a well-defined research hypothesis for a laboratory/translational study.
- Know what constitutes a logical research approach for addressing a basic/translational research question.
- Know the principles behind optimal experimental protocols and methods that includes a rigorous research data analysis plan, expected results, limitations, and alternative technical approaches.
- Know the process for and how to assess, analyze, and replicate data to establish support or refutation of hypotheses.

Evaluation Tools: reporting to and obtaining feedback from the Scholastic Oversight Committee, conference presentation, and in-training examination

Patient and Procedural Skills*

- Have the skills to identify gaps in knowledge of the fundamental basis of a biological process, syndrome, or pediatric cardiovascular disease.
- Have the skills to accurately record and store research records.
- Have the skills to determine the resources needed and to implement a laboratory research plan.
- Have the skills to apply appropriate statistical analyses to laboratory data.

Evaluation Tools: reporting to and obtaining feedback from the Scholastic Oversight Committee, and in-training examination

Systems-Based Practice*

- Incorporate regulatory precepts into the execution of any laboratory study.

Evaluation Tools: reporting to and obtaining feedback from the Scholastic Oversight Committee

Practice-Based Learning and Improvement*

- Acquire requisite training and technical skills for experimental work, including all institutional review board requirements.

Evaluation Tools: reporting to and obtaining feedback from the Scholastic Oversight Committee, mentor evaluations, and 360 evaluations

Note: other sections listed under clinical research such as Professionalism and Interpersonal and Communication Skills should be applied to those undertaking basic/translational research.

*Competency required only for those undertaking translational and/or basic research. Adapted from the CTSA web site (7).

may need to develop specific skills for basic or clinical cardiovascular research. Others may need advanced training, including coursework in epidemiology, study design, and biostatistics. This may be obtained as part of an advanced degree program or as part of a separate career development plan. Advanced research training for clinical research should also include mentored investigational experience with an active and productive scientist working in an appropriate field, such as epidemiology, population science, behavioral science, quality and safety of care, or outcomes research. Often it is appropriate to assemble a mentoring team, which can provide a range of expertise and is directed by a senior mentor.

For trainees seeking careers with a major emphasis on basic or laboratory research, additional focused training will be needed. There will be a wide variation in skills that trainees bring in based on previous training and experience. For those with minimal or no prior laboratory training, the need for didactic course work is greater, as is a more prolonged training experience. Formal entry into a PhD training program may be considered.

There are often institutional or individual research training grants (T32, F32) to support the research training and career development, including coursework and mentored research training. The NIH Loan Repayment Grant can help support the focused early investigator.

The advanced research training should be viewed as only the beginning of the training experience. Individuals who pursue this path will need counseling on finding academic positions, protected time, and resources

required to support the development of meaningful research projects.

5. FLEXIBILITY FOR RESEARCH TRAINING

Fellowship research training should allow significant flexibility to accommodate diverse career paths. For some trainees, consecutive months of dedicated research training may provide the best environment for growth. However, for others, it may be best to alternate some periods of clinical training with dedicated research time. This may be valuable, for example, when planning a clinical investigation that requires several distinct phases such as protocol development, institutional review board submission, and recruitment/enrollment. This approach may be necessary when trying to integrate structured course work from the academic calendar year into the training program. This may be especially relevant for those who obtain a concomitant master's level training degree (such as in epidemiology or public health). Meeting the demands of both clinical and research training poses a great challenge to any training program; thus, the time devoted to research should be assigned to allow the trainee the best opportunity for success. The breadth of training opportunities must allow fellows the flexibility to configure their research training in ways that best meet individual career goals. Fellows should be allowed to work with program directors to design their schedule and commitments to foster time management skills and career planning that will be critical in their early career.

6. EVALUATION AND DOCUMENTATION

Ongoing evaluation of progress in advanced research training is important. Inherent within the tables for core training are basic tasks that must be accomplished for successful completion of the research portion of fellowship. Overall evaluation should include specific goal setting and review of progress made on those goals. Research knowledge, skills, and commitment should include both objective components, such as skills and knowledge in analyzing literature and appropriately applying statistical tests, and subjective components, such as creativity, drive, and problem solving. This evaluation should be based on criteria that have been developed and agreed upon by the trainee, the SOC, and the mentoring team. The competence and accomplishments

should be clearly documented at the completion of training. This evaluation should include the success of the trainee as indicated in producing a meaningful scholarly work product that hopefully results in at least 1 publication.

SUMMARY

Research training represents a critical component of the pediatric cardiology fellowship training. To successfully carry out the mission of training, academic pediatric cardiologist programs must provide a structured research experience lead by dedicated mentors. There are a number of varied, yet fulfilling, pathways to pursue in research, and trainees should tailor the research training experience to meet their career goals.

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**APPENDIX 1. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—
TASK FORCE 8: PEDIATRIC CARDIOLOGY FELLOWSHIP TRAINING IN RESEARCH AND
SCHOLARLY ACTIVITY**

Committee Member	Employment	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional/ Organizational or Other Financial Benefit	Expert Witness
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For the purpose of developing a general cardiology training statement, the American College of Cardiology (ACC) determined that no relationships with industry (RWI) or other entities were relevant. This table reflects author's employment and reporting categories. To ensure complete transparency, authors' comprehensive healthcare-related disclosure information—including RWI not pertinent to this document—is available in an [online data supplement](http://www.acc.org/guidelines/about-guidelines-and-clinical-documents/relationships-with-industry-policy). 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.

**APPENDIX 2. PEER REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)—
 TASK FORCE 8: PEDIATRIC CARDIOLOGY FELLOWSHIP TRAINING IN 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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Carole Warnes	Mayo Clinic—Professor, Medicine	ACC BOT	None	None	None	None	None	None
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ACC indicates American College of Cardiology; ACPC, Adult Congenital and Pediatric Cardiology; AHA, American Heart Association; BOT, Board of Trustees; and CMC, Competency Management Committee.