

## Launching a New Fellowship for Medical Students: The First Years of the Doris Duke Clinical Research Fellowship Program

Elaine K. Gallin, Sylvie M. Le Blancq, and Clinical Research Fellowship Program Leaders

### ABSTRACT

As part of its commitment to increasing the pipeline of physicians pursuing careers in clinical research, the Doris Duke Charitable Foundation launched the Doris Duke Clinical Research Fellowship (CRF) Program for medical students in 2000. The program, which is based at 10 US medical schools, provides medical students from any US medical school with the opportunity to spend 1 year obtaining both didactic and “hands-on” mentored clinical research experience. This article describes the program and summarizes the early outcomes collected during the first 3.5 years of the program. Interest in the program among medical students has been robust and widespread, with 35% of CRF program fellows matriculated at non-CRF schools. Exit surveys of the first three classes of fellows totaling 174 fellows indicated that (1) 97% of the fellows felt that participating in the fellowship was a good decision; (2) commitment to a career in clinical research was increased among the 44% of fellows reporting that they were unsure about pursuing a clinical research career when they began their fellowship; (3) there was no difference in satisfaction level between the fellows who remained at the medical schools in which they were matriculated and those who completed their fellowship at a medical school in which they were

not matriculated; and (4) the majority of fellows responded that the didactic component of their fellowship was useful.

**Key Words:** mentors, physician-scientists, clinical research

The last few decades have been marked by unprecedented breakthroughs in the biomedical sciences that, if translated into new preventions, treatments, and cures, will significantly improve human health.<sup>1</sup> The translation of these discoveries requires a robust clinical research enterprise that includes adequate numbers of trained, committed personnel; an appropriate infrastructure, including shared databases and systems to protect human subjects; and collaborative networks that effectively bridge the interests of the public and private sectors.<sup>2</sup> Each of these areas requires attention and action. Since awarding its first grants in 1998, the Medical Research Program of the Doris Duke Charitable Foundation has directed much of its resources to ensuring an adequate clinical research workforce and, in particular, maintaining the pipeline of physician-scientists conducting clinical research.\*

Compared with the total pool of physicians, the pool of talented young physician-scientists conducting either basic or clinical research is diminishing.<sup>3</sup> An American Medical Association survey reported that between 1980 and 1997, there was a decrease in the number of physicians reporting research as their major professional activity, whereas the number of physicians involved in patient care doubled.<sup>3</sup> Not unexpectedly, there has been a parallel decrease in the proportion of National Institutes of Health (NIH) research project grants awarded to investigators with the MD degree under 46 years of age<sup>4</sup>; in 1997, 56% of the MDs holding NIH grants were older than 45 years compared with 44% in 1977.<sup>3</sup> Similarly, nominations of physician-scientists age 45 years or younger to honorary societies have declined by approximately 30% over the past decade.<sup>3</sup> Furthermore, surveys of matriculating medical students from 1985 to 1997 show a downward trend in their expectation of being involved in research during their career.<sup>3</sup> These trends are worrisome, particularly because

*From the Doris Duke Charitable Foundation (E.K.G., S.M.L.), New York, NY.*

*Clinical Research Fellowship Program leaders: Donald W. Landry, Columbia University College of Physicians and Surgeons; Dennis Ausiello and Ravi Thadhani, Harvard Medical School; Karen Zier and Steven Itzkowitz, Mount Sinai School of Medicine; Joel Palefsky, University of California, San Francisco, School of Medicine; Peggy Nopoulos, University of Iowa Medical School; Paul B. Watkins and Susan Pusek, University of North Carolina at Chapel Hill School of Medicine; Anil K. Rustgi and Josh Metlay, University of Pennsylvania School of Medicine; Michael McPhaul and Abhimanyu Garg, University of Texas Southwestern Medical School at Dallas; Michael R. DeBaun, Washington University School of Medicine in St. Louis; John N. Forrest Jr, Yale University School of Medicine.*

*Address correspondence to: Dr. Elaine K. Gallin, Doris Duke Charitable Foundation, 650 Fifth Avenue, 19th Floor, New York, NY 10019; tel: 212-974-7000; fax: 212-974-7590; e-mail: egallin@ddcf.org.*

*\*For more information, see <www.ddcf.org>.*

they have occurred during a period of unprecedented expansion in funding for investigator-initiated biomedical research.

The decreasing number of physician-scientists (compared with either the total number of physicians or the increasing number of PhD scientists) is thought to be due to a number of factors.<sup>3,5-7</sup> These include (1) the increasing debt burden of graduating medical students,<sup>8</sup> (2) a lack of adequate role models and exposure to clinical research,<sup>9</sup> (3) extensive clinical training requirements, and (4) the increasing demands for patient care resulting from changes in reimbursement policies.<sup>10</sup> Two additional factors affecting physicians conducting clinical research are the increased regulatory burden required for clinical research and the relative value placed by academic health centers on participation in clinical research.<sup>11,12</sup> Each of these factors is important and should be addressed either by enhancing existing programs, such as dual-degree programs, or by creating new initiatives, such as the NIH Clinical Research Career Awards (K23, K24, and K30)<sup>†</sup> and NIH Clinical Research Loan Repayment Program.<sup>13‡</sup>

Dual-degree MD-PhD programs<sup>§</sup> have been major contributors to the pipeline of physician-scientists,<sup>14,15</sup> but, in the past, the research interests of MD-PhD graduates, particularly from the NIH-funded Medical Scientist Training Programs (MSTPs), have veered toward basic science to a much greater extent than those of their counterparts with the MD degree alone.<sup>14,15</sup> Moreover, the percentage of medical school graduates receiving MD-PhD degrees decreased from 2.3% in 1998 to 0.9% in 2002 (National Residents Matching Program, 2003). Although it may be possible to retool MD-PhD programs to emphasize clinical research, the cost of MD-PhD programs and the length of training required are likely to continue to limit the numbers of MD-PhD graduates.<sup>16</sup> Hence, other complementary approaches will be needed to bolster the pipeline of physician-scientists conducting clinical research.

An alternative and less costly recommendation made by the NIH Panel on Clinical Research was to encourage medical students to commit an additional year to intensive clinical research training.<sup>17</sup> A number of excellent programs provide support for medical students to spend an extra research year during medical school. Table 1 lists some of these programs, including the Howard Hughes Medical Institute (HHMI) Medical Fellows Program and the Sarnoff Endowment Fellows Program, which have provided 1-year fellowships to medical students to conduct

research at any US medical school for more than 15 years. Two more recent programs, the Pfizer-supported Clinical Research Training Program (CRTP) and the HHMI-NIH Research Scholars Program (Cloisters Program), provide fellowships for medical students to spend a year at the NIH in Bethesda, Maryland. Nevertheless, with the exception of the NIH CRTP, most medical students participating in formal 1-year fellowship programs have focused on basic biomedical research. To address this disparity, the Doris Duke Charitable Foundation launched its Clinical Research Fellowship (CRF) Program in 2000.

## PROGRAM DESIGN

The Foundation's goal in launching a new medical student fellowship program was to bolster the pipeline of physician-scientists pursuing careers in clinical research by providing medical students with high-quality 1-year mentored clinical research<sup>||</sup> experiences that would be likely to increase their commitment to a clinical research career. To ensure that fellows were matched with outstanding mentors, the foundation established a network of CRF Programs at 10 US medical schools with strong clinical research programs. Participating schools select their own fellows and ensure that their fellows work with the best clinical research mentors.

In August 2000, 25 clinical research-intensive medical schools were invited to submit proposals to establish CRF Programs at their institutions. Each school applying for a CRF grant was required to contribute some of their own resources to the program and to provide fellows with both mentored "hands-on" and didactic clinical research experiences. The key features of the model are listed in Table 2. Although each CRF school is required to host a minimum of five fellows per year, ensuring that each school has a minimal cohort of students to interact with each other during the year, CRF schools are encouraged to accept more than five fellows if they can identify funding sources for the additional fellows. Each school is also encouraged to develop programs that take advantage of its own unique resources. Medical students matriculated at any US medical school are eligible to apply, and each CRF school is

<sup>†</sup>See <<http://grants1.nih.gov/training/careerdevelopmentawards.htm>>.

<sup>‡</sup>See <<http://lrp.info.nih.gov/>>.

<sup>§</sup>NIH-funded Medical Scientist Training Programs (MSTP) are established at 39 US medical schools. More than 60 US medical schools offer MD-PhD programs with support from non-MSTP sources.<sup>19</sup>

<sup>||</sup>The foundation defines clinical research broadly to include research conducted with human subjects or material of human origin in which the principal investigator (or a colleague) directly interacts with human subjects, including (1) studies on etiology and pathogenesis in humans; (2) therapeutic interventions; (3) clinical trials; (4) epidemiologic studies; (5) disease control research that investigates how scientific information on prevention, early detection, and early diagnosis can be efficiently applied; and (6) health outcomes research that either attempts to determine systematically the risks, benefits, and costs of various medical practices or attempts to use these results in defining more effective medical practice guidelines.

**TABLE 1 One-Year Clinical Research Training Programs for Medical Students in the United States\***

<i>Program</i>	<i>Year Program Began</i>	<i>Research</i>	<i>Location</i>	<i>Number of Fellows/Year</i>
Clinical Research Training Program (supported by Pfizer since 1998) <a href="http://www.training.nih.gov/crtp/index.asp">http://www.training.nih.gov/crtp/index.asp</a>	1997	Clinical	NIH campus	30 <sup>†</sup>
Doris Duke Clinical Research Fellowship Program for Medical Students <a href="http://www.ddcf.org/mrp/crf">http://www.ddcf.org/mrp/crf</a>	2001	Clinical	10 US medical schools <sup>‡</sup>	A minimum of 50
Howard Hughes Medical Institute Medical Fellows Program <a href="http://hhmi.org/grants/individuals/medfellows.html">http://hhmi.org/grants/individuals/medfellows.html</a>	1989	Basic or clinical	Any US medical school or nonprofit research institution	60
Howard Hughes Medical Institute—National Institutes of Health Research Scholars Program (Cloister Program) <a href="http://www.hhmi.org/research/cloister/">http://www.hhmi.org/research/cloister/</a>	1985	Basic or clinical	NIH campus	42
National Center for Research Resources Mentored Medical Student Clinical Research Program <a href="http://www.ncrr.nih.gov/clinical/cr_crcd.asp">http://www.ncrr.nih.gov/clinical/cr_crcd.asp</a>	2001	Clinical	General Clinical Research Centers (GCRCs)	1 or more per GCRC <sup>§</sup>
Stanley J. Sarnoff Endowment for Cardiovascular Science Sarnoff Fellowship Program <a href="http://www.sarnoffendowment.org/fellowship.shtml">http://www.sarnoffendowment.org/fellowship.shtml</a>	1980	Basic or clinical	Any US medical school	Up to 18

NIH = National Institutes of Health.

\*This is not a comprehensive list of all medical student fellowship programs.

<sup>†</sup>The number of fellows increased from 15 to 30 in 2004–2005.

<sup>‡</sup>See Table 3.

<sup>§</sup>Thirty-three medical students are taking fellowships in 2004.

required to award at least two of its five annual fellowships to medical students matriculated outside the CRF school. All CRF schools provide the same core activities and support to their fellows irrespective of where the fellows are matriculated.

### PROGRAM IMPLEMENTATION

Twenty-one proposals were received, and in December 2000, a peer review panel cochaired by David Nathan and Jean Wilson (members of the Doris Duke Charitable Foundation Medical Research Program Scientific Advisory Council) selected seven schools to receive 4-year grants: Columbia University College of Physicians and Surgeons; Harvard Medical School; University of California, San Francisco, School of Medicine; University of Iowa Medical School; University of North Carolina at Chapel Hill School of Medicine; University of Texas Southwestern Medical School at Dallas; and Washington University School of Medicine in St. Louis. One year later, based on the success of the program in the first year, the three following medical schools were added to the program: Mount Sinai School of Medicine, University of Pennsylvania School of Medicine, and Yale University School of Medicine. One of the most important aspects of the program is the network of program leaders (and coleaders) and administrators at each

**TABLE 2 Key Features of the Doris Duke Clinical Research Fellowship Program for Medical Students**

Network of CRF Programs at 10 US medical schools
Medical students matriculated at any US medical school are eligible to apply
Year-long fellowship with didactic and mentored “hands on” clinical research training
Participating medical schools commit their own resources to their CRF Programs
National CRF meeting at the end of the fellowship year
Each CRF school
Provides at least 5 fellowships per year
Selects its own fellows
Awards at least 2 of their 5 annual fellowships to medical students matriculated outside the CRF school
Identifies a program leader(s) and an administrator
Recruits its best clinical research mentors
Offers didactic clinical research training to its fellows

CRF = Clinical Research Fellowship.

school who run the programs (Table 3) and provide the critical foundation for the program.

**TABLE 3 Doris Duke Clinical Research Fellowship Program Schools and Program Leaders**

Columbia University College of Physicians and Surgeons Donald W. Landry, MD, PhD
Harvard Medical School Dennis Ausiello, MD, and Ravi Thadhani, MD, MPH
Mount Sinai School of Medicine Karen Zier, PhD, Debbie French, PhD,* and Steven Itzkowitz, MD
University of California, San Francisco, School of Medicine Joel Palefsky, MD
University of Iowa Medical School Peggy Nopoulos, MD, and Allyn Mark, MD*
University of North Carolina at Chapel Hill School of Medicine Paul B. Watkins, MD, and Susan Pusek, MPH
University of Pennsylvania School of Medicine Anil K. Rustgi, MD, and Josh Metlay, MD, PhD
University of Texas Southwestern Medical School at Dallas Michael J. McPhaul, MD, and Abhimanyu Garg, MD
Washington University School of Medicine in St. Louis Michael R. DeBaun, MD, MPH, and Daniel Schuster, MD*
Yale University School of Medicine John N. Forrest Jr, MD

\*Former program leaders.

Although each CRF medical school provides fellows with a mentored clinical research experience and didactic training and accepts its fellows at the same time, the programs at the participating schools differ. For example, the CRF programs at the University of North Carolina and the University of California, San Francisco are based in their General Clinical Research Centers (GCRCs), whereas other programs have looser affiliations with their GCRCs, and some have none. Similarly, although all of the schools have K30 Clinical Research Curriculum Awards, the extent to which the didactic component of the CRF Program is based in the K30 program varies. Most schools match students with mentors and research projects after they start their fellowship, but two programs (Washington University School of Medicine in St. Louis and the University of North Carolina at Chapel Hill) require fellows to identify their mentor and projects during the application process. This diversity, in both research and didactic components, fits with the foundation's aim to create a network of medical school fellowship programs with a common goal and shared key features while encouraging schools to flexibly build on their particular strengths. In this way, fellows are offered greater choices, and the network of 10 schools is more likely to spawn creative approaches.

To coordinate the network and launch the program, Daniel Federman, MD, the senior dean for alumni affairs and teaching at Harvard Medical School, was recruited to be the first national program leader. In that role, he served as an advisor to both fellows and program leaders, and his

office acted as a clearinghouse of information for potential candidates. During the second year of the program, Allyn L. Mark, MD, associate dean for research at the University of Iowa Carver College of Medicine, served in that role.

Although a complete assessment of the impact of the CRF Program will require a long time horizon, perhaps measured in decades, some early program metrics are available.

## INITIAL OUTCOMES

### Applicant Demographics

Recruitment of fellows has occurred in two ways: centrally by the foundation and locally by the participating schools. Centrally, the fellowship opportunity was posted on the foundation Web site and announcements were e-mailed to medical students through the dean of students' offices. Locally, each CRF medical school solicited applicants at its own school and, in many cases, at the nonparticipating medical schools in its geographic region. A common Web-based application form, which enables applicants to be tracked across all schools, is used by all 10 schools. The application process requires students to submit an official medical school transcript, letters from their dean's office and two faculty members, a description of their prior research experience, and a personal statement describing why the applicant is applying for the CRF fellowship. A few schools request additional information from applicants.

In addition to the central CRF Program Web site hosted by the foundation, each CRF school has a Web site that describes its program in more detail. Prospective students were encouraged to contact each CRF Program in which they were interested and speak to the program leader about potential research projects and mentors before they applied. Students were able to apply to multiple CRF Programs; those from non-CRF schools almost always applied to several schools. Over the first 4 years of the program, 57% of the applicants were matriculated at 1 of the 10 participating schools. Nevertheless, interest from students matriculated at other medical schools was robust, with students from 29 non-CRF medical schools applying for fellowships in 2001, the first year of the program. During the subsequent 3 years (2002–2004), applicants were drawn from a larger pool (36 to 38 non-CRF medical schools plus the 10 CRF schools). As shown in Table 4, the number of applicants to the program increased over the

**TABLE 4 Applicant Data**

Year	2001	2002	2003	2004
CRF school/ non-CRF school	49/41	77/47	75/66	81/62
Total number	90	124	141	143

CRF = Clinical Research Fellowship.



first 3 years of the program and then leveled off between 141 and 143 in the program's third and fourth years.

Each CRF medical school had its own selection process, but, in general, the selection was based on a record of academic excellence, the applicant's personal statement, prior research experience, the quality of the letters of support and perceived commitment of the applicant to pursue a career in clinical or translational research. The success rate of the applicants to each CRF school varied considerably depending on the schools. Generally, applicants matriculated at a CRF school and applying to that school had considerably higher success rates than applicants applying to schools at which they were not matriculated. In great part, this reflects the fact that CRF schools usually accepted more fellows from their own student body than from other schools.

In the common application form, all applicants were asked if they had had prior research experience and to identify the area of clinical research in which they were interested in working. Ninety-five percent of the 498 applicants indicated that they had prior research experience (these ranged from experiences of several weeks to graduate degree programs). Applicants expressed interest in a broad range of clinical research areas, from patient-oriented research in surgery and medicine to epidemiology and health outcomes studies. About half of the applicants identified several research areas that they would be interested in pursuing, whereas the remaining applicants had one specific, focused interest, such as otolaryngology, radiation oncology, cancer prevention, or human immunodeficiency virus (HIV) research. For students with very specific interests, such as an applicant who was interested in research on the acoustics of cochlear implants as a way to combine his interests in music and otolaryngology, the

varied opportunities in the network of participating schools usually enabled them to find excellent matches. Regardless of whether students had a focused interest or a more general interest, the program leaders at each school played a major role in helping students who were applying to their schools identify the researchers or groups of researchers at their institution that matched each student's interests.

## Fellows

Table 5 presents data on the four classes of fellows enrolled in the program. Almost all of the participating schools identified additional funding sources that enabled them to accept more than the five required fellows. Thus, between 2001 and 2004, the total number of fellows participating in the program was 252, or 36% higher than expected. Sixty-five percent of these fellows were matriculated at 1 of the 10 participating medical schools, with most (147) of these students remaining at the same school where they were matriculated for their fellowship. The program was designed so that at least two (40%) of the required minimum of five fellows at each school would be matriculated at a different school. Schools that expanded their program beyond the required five students were not constrained to recruit beyond their schools for the additional fellows. Despite the fact that many schools took students in excess of the required five per year, 35% of the fellows during the first 4 years of the program were matriculated at nonparticipating medical schools. The percentage of women has increased steadily, so that 51% of the 2004 class of fellows were women. Between 2001 and 2004, the percentage of underrepresented minorities has ranged from 10 to 17%.

**TABLE 5 Clinical Research Fellowship Program Fellows**

Year	Total Fellows (n)	Medical School Year Completed* (Second/Third)	Matriculated at, n (%)			Women/Men, n (%)	Underrepresented Minorities, <sup>§</sup> n (%)
			CRF School (Home <sup>†</sup> )	CRF School (Away <sup>‡</sup> )	Non-CRF		
2001	42	11/29	26 (62)	4 (10)	12 (29)	11/31 (26/74)	4 (10)
2002	65	17/44	37 (57)	4 (8)	24 (35)	28/37 (43/57)	11 (17)
2003	67	17/40	35 (52)	6 (9)	26 (39)	33/34 (49/51)	7 (11)
2004	78	18/58	49 (63)	3 (4)	26 (33)	40/38 (51/49)	12 (15)

\*Note that some fellows had completed their final year of medical school prior to the fellowship.

<sup>†</sup>Fellows in the Clinical Research Fellowship (CRF) Program at the same school in which they are matriculated.

<sup>‡</sup>Fellows matriculated at a CRF school but enrolled in the CRF Program at a different school.

<sup>§</sup>Underrepresented minorities include Hispanic Americans, African Americans, Pacific Islanders, and Native Americans.

---

**TABLE 6 Fellows' Exit Survey Instrument\***

---

*Survey Statement or Question†*

---

1. My overall experience with the fellowship is positive.
  2. It was a good decision to add a year to my medical training to do this research fellowship.
  3. At the time of my application to this program, I was sure that I wanted to plan a career that combines research and medicine (clinical research).
  4. The fellowship year has increased my commitment to a career in clinical research.
  5. I am satisfied with the level of administrative support that I received from my fellowship institution.
  6. The medical school in which I am enrolled encouraged me to apply for this fellowship.
  7. I am satisfied with the amount of access I had to a mentor during the fellowship period.
  8. Were you monitored by a single individual or a team?
  9. I am very satisfied with the quality of mentoring that I received during the fellowship period.
  10. The fellow seminars and other program activities were a significant addition to the fellowship year.
  11. I spent approximately  % of my time taking clinical research courses.
  12. The formal course work was very useful.
  13. The formal course work took too much time away from research.
  14. The research question(s) I examined was sufficiently challenging.
  15. The research question(s) was well suited to the time I had available.
  16. My research experience during my fellowship has been positive. Yes/No
  17. My research project(s) required seeing patients. Yes/No
  18. I would have preferred not having any course work. Yes/No
  19. My research project required IRB approval. Yes/No
  20. I spent approximately  % of my time interacting with patients.
- 

IRB = Institutional Review Board.

\*Administered to the fellows via a Web linkage 2 weeks prior to the fellows' meetings for the 2002 and 2003 classes.

†Responses to each statement and question were of three types: using a scale of 1 to 5 (1 = strongly disagree; 2 = disagree; 3 = no opinion; 4 = agree; 5 = strongly agree); selecting yes or no; and filling in the blank.

### Exit Survey of the First Three Classes of Fellows

Each fellowship year has culminated in a fellows' meeting at which the current class of fellows presents its research, listens to presentations by senior clinical investigators, and participates in discussions regarding careers in clinical research. At the first meeting, in June 2002, 40 fellows filled out an anonymous 24-question "exit" survey,<sup>#</sup> which was used to assess the program. Each participating school received the average results from the entire group of fellows, as well as the results from its own class of fellows. Similar anonymous exit surveys with most of the same questions and some additional queries were administered via a Web linkage to the second and third CRF classes 2 weeks before their respective June fellows' meeting. The first 20 questions and statements from the survey instrument are listed in Table 6. The aggregate responses of the fellows to the various questions and statements relating to

---

<sup>#</sup>The first part of the survey was designed in collaboration with the HHMI and given to HHMI medical student fellows, as well as the Doris Duke Charitable Foundation CRF Program fellows.

whether the fellowship year was satisfactory and met their expectations were extremely positive. The following is a synopsis of the responses of 172 fellows to some of the questions and statements in the survey.

### RESEARCH EXPERIENCE

The research projects of the first three classes of fellows have spanned the spectrum of clinical research,\*\* ranging from health outcomes studies, to pharmacogenetics projects, to clinical trials. Despite this range, 87% of the fellows' projects required Institutional Review Board (IRB) approval, and the majority (65%) of fellows saw patients as part of their research project (Table 7). Furthermore, an additional 17% of the fellows chose to spend some time during their fellowship year seeing patients even though their research did not require patient contact. In contrast, in 2003, a similar exit survey of HHMI medical student fel-

---

\*\*Titles of research projects are available on our Web site at <<http://www.ddcf.org/mrp/crf>>.

lows indicated that none of the HHMI fellows saw patients during their fellowship and only 28% (11 of 38) of the HHMI fellows worked on projects that required IRB approval (Anh-Chi Le, Howard Hughes Medical Institute, personal communication, 2004).

Table 8 shows the distribution of research mentors by department or specialty area. At the end of each year, all fellows submitted at least one abstract of their work to the annual CRF meeting. The 184 abstracts (a few fellows each year submitted more than one abstract) submitted during the first 3 years of the program were distributed among the following three broad types of clinical investigation: natural history of disease and/or disease pathogenesis (53%); therapeutics, interventions, and/or clinical trials (30%); and health outcomes or health services research (17%). Although it is too early to present comprehensive data on publications from the fellows' research, the CRF schools self-reported that fellows were coauthors on 96 articles published or in press as of December 2003.

**TABLE 7 Research Experience of Fellows**

<i>Fellowship Experience</i>	<i>2001 Fellows, %</i>	<i>2002 Fellows, %</i>	<i>2003 Fellows, %</i>
% fellows mentored by team	41	33	37
% projects requiring IRB approval	80	91	87
% fellows seeing patients as part of their research project	70	64	62

IRB = Institutional Review Board.

**TABLE 8 Breakdown of Clinical Research Fellowship Projects by Mentor Specialty**

<i>Mentor's Specialty/Department</i>	<i>2001 Fellows</i>	<i>2002 Fellows</i>	<i>2003 Fellows</i>	<i>2004 Fellows</i>
Medicine	12	25	28	25
Surgery	13	11	6	15
Radiology	1	6	5	3
Pediatrics	2	5	7	8
Neurology	5	4	6	9
Obstetrics/gynecology	0	3	1	3
Dermatology	2	2	7	7
Ophthalmology	3	2	4	3
Anesthesiology	2	2	0	1
Psychiatry	1	2	2	2
Genetics	1	2	1	0
Health policy/public health	0	1	0	2
Total	42	65	67	78

Ninety-seven percent of the fellows agreed with the statement that their research experience was positive (see Table 6, statement 16). Nevertheless, only 82% of the fellows felt that the research question they pursued was well suited to the time available; 18% of the fellows did not (see Table 6, statement 15). This finding was confirmed by informal discussions with many of the program leaders, who indicated that matching fellows to projects was an imperfect process and that, unlike basic research, there were instances when regulatory requirements and patient accrual delayed the start of the research projects. Program leaders reported that although it was desirable to assign fellows to new projects, many clinical research projects are not amenable to being initiated and completed within 1 year. Program leaders often worked with mentors to circumvent this problem by assigning a fellow to two projects, one that was just beginning and another that was already under way.

### **SATISFACTION WITH THE FELLOWSHIP AND CHANGE IN COMMITMENT TO CLINICAL RESEARCH**

Ninety-nine percent (170 of 172) of the fellows agreed or strongly agreed (mean score 4.7) with the statement that their fellowship experience was positive, and 97% (167 of 172) of the fellows agreed that it was a good decision to add a year to their medical school training to pursue the research fellowship (mean score 4.7) (see Table 6, statements 1 and 2). Overall, 87% (148 of 171) of the responding fellows reported that the fellowship year had increased their commitment to a clinical research career (see Table 6, statement 4). Eighty-two (48%) of the responding fellows indicated that they had had some degree of uncertainty when they applied to the CRF program about whether they would pursue a career combining research and medicine (clinical research) (see Table 6, statement 3). Ninety percent (55 of 61) of the 2002 and 2003 fellows who expressed this uncertainty at the start of the fellowship reported an increased commitment at the end of the fellowship (the data collected from the 2001 fellows did not allow direct comparison between these answers).

### **MENTORING**

The program leader at each CRF school and his or her advisory committee were responsible for identifying the clinical researchers that they thought would be the best mentors and matching those mentors with their fellows. Ninety-two percent (158 of 171) of the fellows over the first 3 years of the program responded that the mentoring they received during their fellowship year was satisfactory (mean score 4.6) (see Table 6, statement 9). By the end of the first year of the fellowship program, it became apparent that some schools found it helpful to assign two mentors to a fellow, particularly if those fellows were doing research that bridged two areas. To better capture this

information and determine if students who were mentored by a team versus an individual expressed more satisfaction, exit survey questions were added on individual versus team mentoring in the second and third years of the program (see Table 6, statement 7 and question 8). Of the 132 fellows in the second and third classes of the program, 46 (35%) were mentored by teams. There was no difference in satisfaction between those mentored by teams or individuals (93% vs 95%, respectively).

### **COURSE WORK**

Although the CRF programs at each school had a didactic component that offered students at least two courses or formal seminar series relating to clinical investigation, the didactic component differed among the 10 schools. For example, at some schools, the fellows primarily integrated into parts of existing K30 training programs, whereas other schools used specialized seminars, such as the Clinical Champion seminar series developed at Harvard Medical School. In addition, many fellows chose to attend one or more specialized graduate-level courses related to their research interests. The mean time spent taking courses for the 2002 and 2003 fellows was 12.85%. Eighteen (of 132) of the 2002 and 2003 fellows reported spending 25% or more of their time on course work (see Table 6, question 11). Whereas the majority of the fellows in the first three classes strongly agreed or agreed with the statement that their course work was very useful, 15% of the fellows disagreed with the statement (see Table 6, statement 12). Despite the fact that the required course work varied among the 10 schools, the fellows who did not find their course work satisfactory did not cluster in particular schools.

### **FELLOWS MATRICULATED AT NON-CRF SCHOOLS**

Seventy-six fellows (44%; 76 of 174) spent their fellowships at a medical school other than the medical school at which they were matriculated, and 62 of them (36%; 62 of 174) were matriculated at non-CRF medical schools (see Table 5). These fellows were indistinguishable from the other fellows in terms of their satisfaction with the fellowship program and their commitment to a career in clinical research. Their survey responses differ in one notable way: fellows matriculated at CRF schools, with very few exceptions, reported that they were encouraged to apply for the fellowship program, whereas 40% of medical students matriculated at non-CRF medical schools indicated that their schools did not encourage them to apply for the program (see Table 6, statement 6).

### **CONCLUSIONS**

There is a consensus that the pipeline of physician-scientists pursuing careers in clinical investigation needs to be

strengthened and that an effective strategy is to begin recruiting individuals to this career path as early as possible.<sup>6,18</sup> Recent analysis of data from the HHMI's two 1-year research training programs for medical students indicates that 1-year fellowship training provides "an effective imprinting experience on medical students' research careers."<sup>19</sup> A number of excellent fellowship programs enable medical students to spend an extra year during medical school to undertake research (some of these are listed in Table 1). One of the significant differences among the programs is how they are structured. For example, medical students participating in the HHMI Medical Fellows Program and the Sarnoff Fellowship Program apply centrally and can take their fellowship to any US medical school, whereas the CRTP and Cloisters Program fellowships are all located on the NIH campus. The Doris Duke Charitable Foundation CRF Program was designed to combine the strengths of both approaches through establishing CRF Programs at 10 medical schools. Each CRF site provides its fellows with local expertise and guidance, as well as the camaraderie of being in a group, whereas the network of 10 CRF schools offers diversity and a range of opportunities and approaches.

In 2000, when the Doris Duke Charitable Foundation CRF Program was launched, only one other program existed that focused exclusively on clinical research, the CRTP at the NIH, which was started in 1997. At that time, it was unclear if the CRF Program would generate sufficient interest either from medical schools that were required to devote some of their own resources to the program or from medical students who would need to commit an extra year to their medical education to obtain clinical research experience. Our apprehension regarding the interest and commitment of medical schools was quickly dispelled by the fact that 21 of the 25 medical schools responded to the invitation to submit a proposal to host a CRF Program at their school. The experience suggests that with the appropriate incentives, a significant number of US medical schools are willing to devote resources to provide clinical research training and research experiences to medical students. It has been gratifying that almost all of the CRF schools have identified additional funds that have enabled their programs to expand beyond the required five fellows per year.

Despite only minimal advertising of the CRF Program beyond each CRF school's internal advertising, the first four application and selection cycles indicate that there is a cadre of highly qualified medical students throughout the United States who are interested in devoting an additional year during medical school to obtain clinical research experience. Importantly, a significant portion of CRF applicants were matriculated at non-CRF schools, many of which were non-research-intensive medical schools. With regard to CRF fellows matriculated at non-CRF schools, both exit survey results and informal discussions indicate that more work is needed to encourage non-



CRF medical schools to support their students' interest in 1-year research fellowship programs.

Evidence of the effectiveness of 1-year fellowships for the career development of physicians-scientists was reported in a recent study that compared research career outcomes for the awardees of the two HHMI fellowship programs from 1987 to 1995 with the unsuccessful applicants to the HHMI programs and MD-PhD students over that same time period.<sup>19</sup> The study showed that "participation in both HHMI programs increased the likelihood of receiving NIH postdoctoral support."<sup>19</sup> Fang and Meyer also found that women and underrepresented minorities were significantly more likely to participate in the year-long fellowships.<sup>19</sup> The proportions of women and underrepresented minorities participating in the CRF Program during its first 4 years (see Table 5) are similar to those seen in the two HHMI year-long fellowship programs.<sup>19</sup> Thus, our preliminary data support Fang and Meyer's suggestion that 1-year fellowship programs may be more effective than multiyear programs for recruiting women and minority medical students into careers in both basic and clinical research.<sup>19</sup>

The exit surveys indicated that the vast majority of the CRF fellows were happy with their decision to take a 1-year clinical research fellowship and were pleased with their research experience. A successful clinical research fellowship experience depended not only on the identification of an outstanding mentor but also on the careful choice of a clinical research project or a portfolio of projects that took into consideration possible delays owing to issues such as regulatory approvals and patient recruitment. In many cases, students were assigned to two projects: one that had not yet received IRB approval and a second ongoing project, in which the regulatory requirements had been completed. Guidance and advice from dedicated on-site program leaders were essential to the success of this process. Hence, the design of the CRF Program was particularly suited to deal with the challenges inherent in a fellowship program focused on clinical research. The exit survey data indicate that the fellows overwhelmingly felt that it was a good decision to take a year off from medical school to participate in the CRF Program. Moreover, most of the fellows who expressed that they were unsure about pursuing a career that included clinical research at the start of the fellowship reported that the fellowship year increased their commitment to clinical research.

The CRF Program has joined an array of research fellowship programs that are available to medical students. Although it is too early to know whether it will achieve its goal of recruiting more physicians into careers in clinical investigation, its focus on clinical research has clearly enhanced the diversity of opportunities for interested medical students, and the initial outcomes are very positive. Thus, the foundation has recently renewed its commitment to this program and will be supporting new classes of CRF Program fellows through 2007.

## ACKNOWLEDGMENTS

We thank Cathie Plouzek, Jennifer Petitt, and Arati Deshmukh for data collection and analysis.

## REFERENCES

1. Bloom FE. Science as a way of life: perplexities of a physician scientist. *Science* 2003;300:1680–5.
2. Sung NS, Crowley WFJ, Genel M, et al. Central challenges facing the national clinical research enterprise. *JAMA* 2003;289:1278–87.
3. Zemlo T, Garrison HH, Partridge NC, Levy TJ. The physician-scientist: career issues and challenges at the year 2000. *FASEB J* 2000;14:221–30.
4. Goldman E, Marshall E. NIH grantees: where have all the young ones gone? *Science* 2002;298:40–1.
5. Forrest JN. The decline in the training of clinical investigators: data and proposals from the 1970's. *Clin Res* 1980;28:246–7.
6. Nathan DG. Clinical research: perceptions, reality, and proposed solutions. National Institutes of Health Director's Panel on Clinical Research. *JAMA* 1998;280:1427–31.
7. Nathan DG. Careers in translational clinical research—historical perspectives, future challenges. *JAMA* 2002;287:832.
8. Ley TJ, Rosenberg LE. Removing career obstacles for young physician-scientists—loan-repayment programs. *N Engl J Med* 2002;346:368–72.
9. Steiner JF, Lanphear BP, Curtis P, Vu KO. Indicators of early research productivity among primary care fellows. *J Gen Intern Med* 2002;17:845–51.
10. Kaplan SH, Sullivan LM, Dukes KA, et al. Sex differences in academic advancement. Results of a national study of pediatricians. *N Engl J Med* 1996;335:1282–9.
11. Oinonen MJ, Crowley WFJ, Moskowitz J, Vlasses PH. How do academic health centers value and encourage clinical research? *Acad Med* 2001;76:700–6.
12. Pober JS, Neuhauser CS, Pober JM. Obstacles facing translational research in academic medical centers. *FASEB J* 2001;15:2303–13.
13. Nathan DG, Wilson JD. Clinical research and the NIH—a report card. *N Engl J Med* 2003;349:1860–5.
14. Sutton J, Killian CD. The MD-PhD researcher: what species of investigator? *Acad Med* 1996;71:454–9.
15. National Institutes of General Medical Sciences. The careers and professional activities of graduates of the NIGMS Medical Scientist Training Program. Bethesda (MD): National Institutes of General Medical Sciences, National Institutes of Health; 1998.
16. Varki A, Rosenberg LE. Emerging opportunities and career paths for the young physician-scientist. *Nat Med* 2002;8:437–9.
17. Nathan DG, Varmus HE. The National Institutes of Health and clinical research: a progress report. *Nat Med* 2000;6:1201–4.
18. Solomon SS, Tom SC, Pichert J, et al. Impact of medical student research in the development of physician-scientists. *J Investig Med* 2003;51:149–56.
19. Fang D, Meyer RE. Effect of two Howard Hughes Medical Institute research training programs for medical students on the likelihood of pursuing research careers. *Acad Med* 2003;78:1271–80.