

## Interview with Elaine Gallin, Program Director for Medical Research at the Doris Duke Charitable Foundation



*The Doris Duke Charitable Foundation (DDCF) is an independent private foundation devoted to improving the quality of people's lives through grants supporting four specific areas: the performing arts, wildlife conservation, medical research, and the prevention of child abuse. The foundation was established in 1996 and began awarding grants in 1997. By the end of 2004, more than 500 grants had been awarded to support work in the focus areas. In the area of medical research, the Doris Duke Charitable Foundation has established and developed a number of programs that have been designed to assist in the development of physician-scientists. We spoke with Elaine Gallin, PhD, program director for medical research since May 1999. As the Foundation's first such director, she has played an important role in the creation and management of the Doris Duke grant programs committed to support and strengthen clinical research.*

**JIM:** The Doris Duke Charitable Foundation has established a substantial presence supporting initiatives in the areas of clinical and translational research. Can you describe for us the range of activities that you support?

**Gallin:** Our overall goal is to support and strengthen clinical research in order to speed the translation of basic biomedical discoveries into new treatments, preventions, and cures for human diseases. We have developed four program strategies to help us achieve this goal.

The first strategy is to support physician-scientists conducting clinical research at three different points in their career ladder.

First, we offer Distinguished Clinical Investigator Awards to midcareer investigators. Recipients receive a 5- to 7-year grant of \$1.5 million to support their translational clinical research and mentoring activities. One-third of their funds need to be used to mentor junior investigators and trainees. This award focuses, in great part, on the need for more role models and mentors.

Second, we fund junior investigators who are just establishing (or about to establish) their own independent re-

search group. Seventy-one grants were awarded during our first five competitions. These grants, called Clinical Scientist Development Awards, provided up to 5 years of support. However, this year's grant recipients will only receive 3 years of funding. Unfortunately, we needed to reduce the length of the award because of financial issues.

Third, we fund a fellowship program for medical students. The fellowship enables students to take a year off to conduct clinical research. Our vision is that if we expose medical students to the rewards of clinical research, many of them will incorporate clinical research into their career plans.

The Foundation's Medical Research Program's second major strategy is to help push the frontiers of clinical research and to encourage innovative and, therefore, riskier research. To accomplish that goal, we have supported two different kinds of grants: the Innovation in Clinical Research Award (ICRA) program and the Clinical Interface Award Program (CIAP). The ICRA program was offered for 4 years. It provided \$200,000 2-year grants to investigators or pairs of investigators to sup-

port the "seed" funding for innovative projects not yet ready for National Institutes of Health (NIH) funding. Many of the recipients of these awards went on to compete successfully for NIH funding. In 2002, we launched a program called the Clinical Interface Award Program, which provides larger (up to \$2.25 million) grants to teams of investigators from different disciplines to work together to address an important clinical issue which can only be addressed if one crosses disciplines. One grant was awarded in 2003, and we will be announcing our 2005 grants shortly.

Those are our two major program strategies. However, some resources are also targeted to supporting two other program strategies. First, because we are interested in strengthening clinical research, we occasionally fund activities that examine the roadblocks and needs of the clinical research enterprise. Four years ago, we felt that more attention needed to be paid to ethical issues relating to the conduct of clinical research and to human subject protection. Therefore, we provided support to establish the Consortium to Examine Clinical Research Ethics, which brought together a

group of ethicists and researchers to examine these issues empirically and conceptually. The group has contributed to the discussion of the issues with a series of papers. One of their projects involved collecting the data on the cost of Institutional Review Boards.

Our last program strategy was formulated in response to the AIDS pandemic. With the encouragement of our Board of Trustees, the Medical Research Program has devoted about 10% of our resources over the last 4 years to supporting clinical research and the related infrastructure needed to determine how to best care for and treat AIDS patients in the developing world. Our grants have focused on sub-Saharan Africa, the region hardest hit by HIV/AIDS.

**JIM:** Some of the programs at DDCF are termed a "Clinical Research Career Ladder." Would you please describe for us the evolution of this integration and the successes or challenges that you have encountered in establishing such an integrated system?

**Gallin:** As I just noted, one of our major focus areas has been the physician-scientist conducting clinical research. That focus originated with advice from Jim Weingarten and David Nathan—two outstanding and wise clinical investigators—and other advisors who counseled the foundation about the pivotal role physician-scientists played and noted that their numbers had been progressively decreasing. Over two decades ago, Jim Weingarten wrote a paper describing physician-scientists as an endangered species. Unfortunately, the concerns he voiced then are still present today. Thus, in 1998, our first grants targeted junior-level physician-scientists conducting clinical research.

That got us thinking about physician-scientists. From there, we looked for other needs in the development of physician-scientists. One of the needs is for more role models and mentors. Therefore, we decided to invest in some of the best people and provide them with large enough grants to significantly increase their translational clinical research efforts and mentor activities.

The next natural step was to think about medical students who had not yet committed to a career path. Waiting to provide clinical research opportunities after medical school is often too late. Almost all of the existing programs

providing medical students with an extra year for research focused on basic research. We hypothesized that there was an unmet need for a national fellowship program focusing on students interested in clinical research. Those students would not necessarily want to clone the next gene or determine the structure of a protein, but they would be interested in clinical questions. Therefore, we launched the medical student program. Happily, there was a great interest in it.

It has been extremely rewarding that many of our Distinguished Clinical Scientist awardees have served as mentors to our junior investigators, and both our senior and junior level grantees have mentored our medical student fellows. We have an incredible group of committed, talented grantees. Our programs are informally integrated by the natural mentoring activities that occur among them. Our grantees are busy clinical investigators who are already balancing research with their patient care, teaching, and administrative responsibilities, so we try to keep our requests for their time to a minimum. Nevertheless, we do ask our Distinguished Clinical Scientist awardees to help us review and select our Clinical Scientist Development Award recipients. We also are beginning to ask some of our first (1998 and 1999) Clinical Scientist Development Award grantees to serve on review panels. Lastly, we convene our grantees at least every other year.

**JIM:** How do you plan to assess the success of your efforts in fostering interest in clinical research and facilitating the training of clinical researchers? What are the expectations of the DDCF toward these programs?

**Gallin:** Ultimately, the success of our programs will be measured by whether our grantees (and fellows) stay in clinical research and contribute significantly to their fields. That will take a decade, if not several decades, to determine. Our grantees are already beginning to assume positions of leadership in clinical research, and we hope they will mentor other leaders. We plan to track our grantees over time. Of course, we also will monitor their scientific output. But we won't be doing a controlled laboratory experiment—taking 20 applicants all scoring highly by an expert panel and choosing not to give 10 of those applicants grants. Nevertheless,

there are informative ways that we can benchmark our grantees against other similar groups of grantees.

In this regard, a number of foundations have recently formed an alliance—the Health Research Alliance (HRA)—to work together on issues of mutual interest. One of those is best practices in evaluation. I am the co-chair of the Evaluation Subcommittee for HRA. Most funders try to track their grantees so that we can report to our respective boards. However, we do not often coordinate our efforts or share data to inform the community. We are beginning to do that now.

**JIM:** How are the priorities of the Medical Research Program at the Doris Duke Charitable Foundation established? Through what mechanisms are these priorities adjusted or integrated with efforts ongoing at the NIH and at other private foundations?

**Gallin:** Ultimately, DDCF's funding decisions are made by its Board of Trustees. The Medical Research Program's staff, working with its own Scientific Advisory Council, develops its strategies and program suggestions and presents those to the Board of Trustees for approval. Originally, the Scientific Advisory Council was chaired by Jim Weingarten. Now it is chaired by David Nathan. It is made up of from six to nine different outstanding clinical investigators.

We are a minor funder, given the vast size of the biomedical research enterprise. So we work closely with our advisors to determine how best we can make a difference and not simply try to be a "mini-NIH." We also now have a cohort of extraordinary grantees from whom we solicit feedback.

All funders continually face the tension between staying the course (and supporting programs like our Clinical Scientist Development Award for enough years to make a difference) and the desire to respond to new compelling opportunities. The new research opportunities today are extraordinary. Deciding if it is more valuable to support those opportunities or stay the course is a continual challenge.

**JIM:** What needs do you perceive that are still unmet in the areas of clinical research training and clinical research career development?

**Gallin:** Many areas would benefit from more attention and support. I will

just touch upon a few. One of these is the increasing regulatory burden. Our grantees tell us that it is getting harder to conduct clinical research without necessarily improving human subject protections. Regulations across agencies need to be harmonized and tools put in place to facilitate the reporting requirements and paperwork. Foundations can only work around the periphery of these issues by sponsoring convenings and supporting data collection, which might be useful to government and policy makers. The real progress needs to be made by the Food and Drug Administration (FDA), the NIH, and other government agencies working with the research community and patients on the issues.

In terms of human resources and the career development of clinic researchers, more attention needs to be paid to the role of PhDs as clinical research investigators. Certainly, MDs play a critical role in clinical research, but PhDs also can play an important role. In the 1980s and 1990s, the Markey Foundation had supported a number of programs focused on providing clinical research training to PhDs. However, when the Markey Foundation spent down their money and ceased operations, most of these programs ceased. The issue of sustainability is very important. It is nice to see that the Howard Hughes Medical Research Institute has decided to focus resources in this area.

Lastly, it is discouraging that despite the multitude of new drug targets, the

pipeline of new drugs is decreasing. There are many reasons for this, but creating programs to train individuals involved in drug development, pharmacogenomics, bioinformatics, and other related fields would help.

**JIM:** The Doris Duke Charitable Foundation supports initiatives in a variety of targeted areas. How does the Foundation integrate these areas and apportion responses to needs in areas as diverse as the arts, the environment, and so on?

**Gallin:** You are correct. The Medical Research Program is just one of four grants programs supported by the Foundation. It supports other excellent programs in the environment, the performing arts, and the prevention of child abuse. The number of program staff at the foundation has been quite small (less than 10), so it is easy for us all to interact to discuss management issues and funding strategies. Nevertheless, because each of our programs serves very different communities, there have been relatively few opportunities to integrate across granting programs. The Board of Trustees decides the right balance between the foundation's investments in its different grant-making programs.

**JIM:** How do you view the role of foundations in the research community?

**Gallin:** The biomedical research community is enormous. NIH's budget is over \$28 billion, and the budget of for-profit private research is even greater. So the question is Can the rela-

tively small contributions of foundations make a difference? I think the answer is yes. If funders have a vision, pick their niche carefully by looking for gaps, and if they are comfortable taking on some hard or risky projects, they can make a big difference. Foundations can move quickly. They do not need approval from stockholders or the voting public. So they should be more willing to take more risks than the other funders. In this country, we have a long history of foundations making a difference. Rockefeller Foundation not only helped to eradicate hookworm at the turn of the twentieth century, but they established the first clinical research hospital at Rockefeller University.

Even if the problems are enormous, if foundations are thoughtful and willing to take on risk, they can serve as effective catalysts. We have tried to do this within our international AIDS portfolio. Three years ago, in response to the need for cheaper diagnostics for AIDS care and treatment, we gave small grants to 10 teams of investigators to support the development of inexpensive diagnostics to monitor CD4 counts and viral load. Now that funds are finally available to purchase highly active antiretroviral therapy (HAART) in low-resource regions, inexpensive diagnostics that can help determine when to start and stop HAART are critically needed. We have our fingers crossed that at least one of the teams our foundation has supported to develop these low-cost diagnostics will be successful.

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**Doris Duke Charitable Foundation Medical Research Programs <http://www.ddcf.org/page.asp?pageld=12>**

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*Clinical Research Fellowship for Medical Students*

<http://www.ddcf.org/page.asp?pageld=292>

This program is designed to encourage medical students to pursue careers in clinical research by giving exceptional students the opportunity to take a year to experience clinical research firsthand.

*Clinical Scientist Development Award*

<http://www.ddcf.org/page.asp?pageld=291>

These awards provide grants to junior physician-scientists to facilitate their transition to independent clinical research careers.

*Distinguished Clinical Scientist Award*

<http://www.ddcf.org/page.asp?pageld=297>

This award recognizes outstanding midcareer physician-scientists who are applying the latest scientific advances to the prevention, diagnosis, treatment, and cure of disease and enables them to mentor the next generation of physician-scientists conducting clinical research.

*Clinical Interfaces Award Program*

<http://www.ddcf.org/page.asp?pageld=299>

This program intends to catalyze activity at the interface of clinical and other research disciplines.

*Innovation in Clinical Research Award (currently inactive)*

<http://www.ddcf.org/page.asp?pageld=300>

These grants were awarded to support innovative clinical research in targeted disease areas.

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