DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service National Institutes of Health

John E. Fogarty International Center for Advanced Study in the Health Sciences

Advisory Board Summary Minutes

Date: September 12, 2006

Place: Lawton Chiles International House

National Institutes of Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service National Institutes of Health

John E. Fogarty International Center for Advanced Study in the Health Sciences

Sixty-fourth Meeting of the Advisory Board

Minutes of Meeting September 12, 2006

The John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) convened the sixty-fourth meeting of its Advisory Board on Tuesday, September 12, 2006, at 8:30 a.m., in the Conference Room of the Lawton Chiles International House, National Institutes of Health (NIH), Bethesda, Maryland. The closed session was held from 8:30 a.m. to 10:00 a.m., as provided in Sections 552b(c) (4) and 552b(c) (6), Title 5, U.S. Code, and Section 10 (d) of Public Law 92-463, for the review, discussion, and evaluation of grant applications and related information. The meeting was open to the public from 10:30 a.m. to 3:45 p.m. Dr. Roger I. Glass, Chair, Fogarty International Center Advisory Board, and Director, FIC, presided. The Board roster is appended as Attachment 1.

- I. Call to Order and Introductory Remarks
- II. Dates of Future Board Meetings
- III. Review of Confidentiality and Conflict of Interest
- IV. Review of Applications
- V. Minutes of Previous Meeting
- VI. Welcome to Strategic Planning Session and Introduction of Special Guests
- VII. Demonstration of FIC Prototype for Global Health Research Atlas
- VIII. FIC's Approach to Strategic Planning
- IX. Strategic Planning: A Roundtable Discussion
- X. Closing Remarks

Board Members Present:

Dr. Karen H. Antman

Dr. Elizabeth Barrett-Connor

Dr. Patricia M. Danzon

Dr. Wafaie Fawzi

Dr. Arthur Kleinman

Dr. Lee W. Riley

Dr. William A. Vega

Board Members Absent:

Dr. Linda Burhansstipanov

Dr. Luz Claudio

Dr. Douglas C. Heimburger

Dr. Ting-Kai Li (ex officio)

Dr. May L. Wykle

¹ Members absent themselves from the meeting when the Board discusses applications from their own institutions or when a conflict of interest might occur. The procedure applies only to individual applications discussed, not to *en bloc* actions.

Members of the Public Present:

- Dr. Charles Carpenter, University Medicine Foundation, Inc., Providence, RI
- Dr. Mariam Claeson, Program Coordinator HIV/AIDS, The World Bank, Washington, DC
- Dr. James W. Curran, Dean and Professor of Epidemiology, The Rollins School of Public Health, Emory University, Atlanta, GA
- Dr. Ciro A. de Quadros, President, CEO, and Director, International Programs, Albert B. Sabin Vaccine Institute, Washington, DC
- Dr. Pierce Gardener, Professor of Medicine, Emeritus, State University of New York, Stony Brook, NY
- Dr. Jack Killen, Director, Office of International Health Research, National Center for Complementary and Alternative Medicine, NIH, Bethesda, MD
- Dr. William J. Martin II, Associate Director, and Director, Office of Translational Research, National Institute of Environmental Health Sciences, NIH, Research Triangle Park, NC
- Dr. Gail Naimoli, Social Scientific Systems, Silver Spring, MD
- Dr. Derek Yach, Director, Health Equity (Global Health), Rockefeller Foundation, New York, NY

Federal Employees Present:

- Mr. Robert T. Berendt, FIC/NIH
- Mr. Kevin Bialy, FIC/NIH
- Ms. Danielle Bielenstein, FIC/NIH
- Dr. Joel Breman, FIC/NIH
- Dr. Ken Bridbord, FIC/NIH
- Mr. Bruce Butrum, FIC/NIH
- Dr. Stacey Chambers, NINDS/NIH
- Dr. Sherry Dupere, CSR/NIH
- Ms. Maria Ferreira, FIC/NIH
- Dr. Jean Flagg-Newton, FIC/NIH
- Dr. Henry Francis, FIC/NIH
- Dr. Dan Gerendasy, CSR/NIH
- Dr. Roger I. Glass, FIC/NIH
- Dr. John Haller, NIBIB/NIH
- Dr. Kathy Hebert, OGHA/DHHS
- Dr. James Herrington, FIC/NIH
- Dr. Karen J. Hofman, FIC/NIH
- Dr. Sharon Hrynkow, FIC/NIH
- Mr. Andrew Jones, FIC/NIH
- Dr. Flora Katz, FIC/NIH
- Dr. Danuta Krotoski, NICHD/NIH
- Dr. Linda Kupfer, FIC/NIH
- Ms. Hannah Leslie, FIC/NIH
- Ms. Judy Levin, FIC/NIH
- Dr. Yuan Liu, NINDS/NIH
- Mr. John Makulowich, FIC/NIH
- Ms. Julie Marquardt, FIC/NIH

Dr. Jeanne McDermott, FIC/NIH

Dr. Mark A. Miller, FIC/NIH

Mr. Richard Miller, FIC/NIH

Ms. Sherri Park, NICHD/NIH

Ms. Katie Rouhier, FIC/NIH

Dr. Joshua Rosenthal, FIC/NIH

Dr. Christopher Schonwalder, FIC/NIH

Dr. Manana Sukhareva, CSR/NIH

Dr. Cathy Wedeen, CSR/NIH

Dr. Karl A. Western, NIAID/NIH

Mr. Randolph Williams, FIC/NIH

CLOSED SESSION

I. CALL TO ORDER AND INTRODUCTORY REMARKS

Dr. Glass called the meeting to order at 8:30 a.m. and welcomed Dr. Karen Antman who was appointed to the Board in May 2006.

II. DATES OF FUTURE BOARD MEETINGS

The following meeting dates are confirmed:

Tuesday, February 6, 2007 Tuesday, May 22, 2007 Tuesday, September 11, 2007

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Tuesday, February 5, 2008

Tuesday, May 20, 2008

Tuesday, September 9, 2008.

The Research Awards Subcommittee will meet on the Monday preceding each Board meeting to review of applications on behalf of the full Board.

III. REVIEW OF CONFIDENTIALITY AND CONFLICT OF INTEREST

The rules and regulations pertaining to conflict of interest were maintained.

IV. REVIEW OF APPLICATIONS

Dr. Glass chaired the portion of the meeting during which the Research Awards Subcommittee reported on its activities. The FIC Advisory Board reviewed a total of 86 scored competing applications at its September 12 meeting.² The applications were in the following programs:

- 16 applications for the Fogarty International Research Collaboration Award (FIRCA), out of a total of 33 applications, for \$524,664;
- 2 applications for the Ecology of Infectious Diseases (EID) program, out of a total of 4 applications, for \$643,933;
- 9 applications for the International Research Scientist Development Award for U.S. Postdoctoral Scientists (IRSDA), out of a total of 17 applications, for \$1,050,524;
- 16 applications for the International Research Ethics Education and Curriculum Development Award (BIOETH), out of a total of 30 applications, for \$2,459,101;
- 15 applications for the International Clinical, Operational, and Health Services Research and Training Award (ICOHRTA), out of a total of 20 applications, for \$2,412,737;
- 15 applications for the International Training and Research Program in Population and Health (POP), out of a total of 20 applications, for \$ 2,412,737; and
- 13 applications for the Framework Programs for Global Health (FRAME), out of a total of 24 applications, for \$1,416,899.

The Board concurred with the initial review group recommendations for 84 of the 86 applications.

OPEN SESSION

V. MINUTES OF PREVIOUS MEETING

The minutes of the Advisory Board meeting of May 23, 2006, were considered and approved unanimously.

² Applications that were noncompetitive, unscored, or not recommended for further consideration by initial review groups were not considered by the Board.

VI. WELCOME TO STRATEGIC PLANNING SESSION AND INTRODUCTION OF SPECIAL GUESTS

Dr. Roger I. Glass, Director, FIC

Dr. Glass welcomed everyone. He commented that he has been the FIC Director for almost 100 days and, during this time, has been taking two courses: NIH101 and Washington101. In the first course, he has been learning about NIH institutes and centers (ICs) and about his role in providing leadership to FIC—the smallest IC—and in engaging other ICs to be involved in global health. In the second course, he has been learning how to "survive" in Washington, DC, and in particular, the need to have and nurture a constituency.

Dr. Glass related two points: there is, as yet, no constituency in global health and FIC needs to begin strategic planning. He noted that although FIC is "a small minnow" in the NIH aquarium, it is one of the largest worldwide funders of global health. Strategic planning will give FIC an opportunity to provide leadership, delineate future directions, and define the FIC mission and attract others to the cause of global health.

Dr. Glass introduced Dr. Linda Kupfer, Evaluation Officer, Division of Advanced Studies and Policy Analysis (DASPA), FIC, who is guiding the new FIC strategic planning process. He invited the Board members and special guests at the meeting to introduce themselves. Dr. Glass asked the eight special guests, whom FIC invited to participate in the Board's roundtable discussion of strategic planning, for their general comments on FIC impact and directions.

FIC Impact and Directions: Comments

The guests noted that FIC has had a dramatic impact worldwide and is a tremendous model for other IC activities in global health. Through partnerships, FIC has leveraged its resources to major effect overseas. FIC has had a profound impact on research content, disease control, research collaborations, and scientists' career development. At NIH, FIC has had a major role and provided the vision in advancing a global approach to diseases such as HIV/AIDS and malaria. FIC provides leadership in the conduct of research training and has "tilled the soil" for research by developing the necessary human resources.

The guests suggested, for the future, that FIC continue to seek partnerships and develop long-standing global partnerships based on equity. As FIC redefines its training effort in coordination with the burgeoning interest in research training among universities and other organizations, FIC could promote training of researchers in surveillance and epidemiology and focus attention worldwide on the "next frontier" of health problems that are common to industrialized and developing countries (e.g., diabetes, obesity, smoking-related diseases). FIC could foster operational research and should continue to have a role in the Disease Control Priorities Project (DCPP).

VII. DEMONSTRATION OF FIC PROTOTYPE FOR GLOBAL HEALTH RESEARCH ATLAS

Ms. Hannah Leslie, Assistant, Office of the Director, FIC

Ms. Leslie demonstrated the FIC prototype of a global health research atlas. This atlas could be useful for communicating the nature and extent of FIC/NIH impact globally. Using GoogleTM Earth, a publicly available, 3-dimensional electronic interface, FIC has mapped research centers around the world that are receiving NIH and FIC funding. For the prototype, FIC mapped sites having more than eight NIH grants. Ms. Leslie demonstrated the use of the tool to visualize the distribution of NIH/FIC support worldwide and then to zoom in at the city level to NIH-supported sites in the city, to a specific research site, and finally to a list of the grants and amount of funding at the site. The user can then link to a web-site for specific data on the grants (e.g., abstracts) and search PubMed for grantees' publications.

Ms. Leslie noted that the FIC prototype is publicly available. The necessary software and data can be downloaded directly from GoogleTM Earth (http://earth.google.com). Alternatively, Ms. Leslie offered to e-mail the prototype to Board members. Dr. Glass said that FIC would like to obtain funding to develop a comprehensive global health research atlas that would include the entire NIH database of foreign grants.

VIII. FIC'S APPROACH TO STRATEGIC PLANNING

Dr. Linda Kupfer, Evaluation Officer, DASPA

Dr. Kupfer addressed the rationale, components, process, and timeline for the new strategic planning exercise. The Board members and special guests received a packet of background materials prepared by staff, which included summaries of staff presentations at the meeting.

Dr. Kupfer cited the following four pressing reasons for FIC to undertake strategic planning: (i) The previous FIC Strategic Plan expired in 2003; (ii) FIC has a new director; (iii) FIC has to fulfill requirements of the Government Performance and Results Act, as legislated by the Congress and administered by the Office of Management and Budget; and (iv), in 2006, the Congress asked agencies to submit strategic plans and to use these plans to substantiate programmatic fiscal decisions. Dr. Kupfer noted that, in addition to the opportunities mentioned by Dr. Glass, strategic planning enables FIC to set new directions in response to needs and opportunities in global health research, to analyze FIC programmatic options, and to engage key constituencies and stakeholders.

FIC anticipates that the strategic planning process will last for 1 year and the strategic plan will be finalized in July 2007. During the process, FIC will seek input from the general public, key stakeholder communities, and FIC staff. In September, FIC is announcing the initiation of strategic planning in the *Federal Register* and posting questions on its web-site (www.fic.nih.gov) to solicit public input on areas and opportunities in global health. In October, FIC plans to hold a stakeholder conference at the Global Forum for Health Research, in Cairo, Egypt, which will be followed by a stakeholder conference at NIH on December 12–13 and meetings with IC directors. FIC staff had a planning retreat in August and will have another one in September. An outside contractor is analyzing the FIC portfolio of programs.

Dr. Kupfer noted that the Board's participation in the strategic planning process begins with the present meeting. She encouraged the members to respond to questions posted on the FIC website and to participate in the stakeholder conference at NIH. FIC intends to have the Board review the draft strategic plan at its February 6, 2007, meeting, and the final plan at its May 22, 2007, meeting.

IX. STRATEGIC PLANNING: A ROUNDTABLE DISCUSSION Dr. Linda Kupfer, Evaluation Officer, DASPA

Dr. Kupfer stated that the goal for the present meeting was to discuss five strategic planning areas—training, centers of excellence, acute/chronic diseases, intramural research, and DCPP implementation. She encouraged the Board members and special guests to engage in a lively discussion. For each area, an FIC staff member gave a brief presentation and posed questions for discussion, and Board members led the roundtable discussions.

Training: Gaps and Early Experiences

Presentation by Dr. Ken Bridbord, Director, Division of International Training and Research (DITR) Discussion led by Dr. Lee Riley, FIC Advisory Board

Dr. Bridbord described the challenges and opportunities facing FIC research training and capacity-building programs. He noted that FIC extramural programs have undergone extraordinary transformation and growth over the past 20 years. Beginning with the AIDS International Training and Research Program (AITRP), FIC instituted these programs to respond to global health threats by building research capacity in low- and middle-income countries. For all FIC research grants involving these countries, training and capacity building are explicit requirements.

Dr. Bridbord noted that the combining of training and research at FIC "broke the mold" of separating research and training at NIH. In 2001–05, in relation to NIH-defined award mechanisms, FIC invested approximately one-third of its appropriation in research project grants (RPGs) and approximately two-thirds in research training awards (D43, fellowship, and curriculum development awards).

Dr. Bridbord listed FIC research training and capacity-building programs and presented a timeline showing the growth in the extramural program from 1991 to 2005, as FIC initiated, continued, terminated, and/or combined programs. In 1993, FIC began to receive cofunding support, which has increased over time to total approximately \$200 million and, in recent years, to represent approximately 40 percent of the FIC extramural budget. Dr. Bridbord suggested that the continued strength of this cofunding is a testament to the value of FIC programs.

Among the characteristics of FIC research training programs which contribute to their success are flexibility, long-term commitment, research collaborations and institutional partnerships, re-entry support, response to local needs, empowerment, and networking. Dr. Bridbord highlighted the importance of empowerment and networking for transferring the center of gravity for research to foreign sites and fostering collaborations and shared experiences. The FIC approach to AIDS training has been a model that FIC has incorporated into many other

programs. The emphasis is on building capacity over decades to create sustainable, institutional research capability.

Dr. Bridbord described eight challenges and opportunities facing FIC research training programs. He suggested that FIC needs to (i) consolidate programs into a smaller number of annual program announcements; (ii) establish stable, long-term partnerships, to reduce the uncertainties of FIC dependence on cofunding, (iii) consider establishing an FIC peer review capability, to complement that of NIH's Center for Scientific Review (CSR); and (iv) expand recruitment of U.S. scientists into FIC programs, to increase U.S. involvement in global health. He suggested further that FIC needs to (v) fill the gap in research training opportunities for U.S. health scientists, from medical and doctoral students to career awards; (vi) better focus FIC investments geographically on leading research investigators and institutions in low- and middle-income countries; (vii) convene a global summit of research training funders; and (viii) expand efforts in non-communicable diseases, to address the changing burden of disease, without jeopardizing FIC's existing commitments.

Dr. Bridbord posed two overall questions for the Board's discussion: (1) What have been the unique contributions of FIC research training programs, and how do these contrast with those of FIC research programs? How should one approach determining the relative emphasis given to research training versus research? (2) How can FIC achieve expansion into new areas (e.g., cardiovascular disease, obesity, diabetes, mental health), without harming its ability to meet critical commitments in other areas (e.g., infectious diseases, population and environmental health) in tight budget times? Dr. Glass suggested two additional, related questions: (a) How can FIC increase its budget overall? (b) Should FIC be training U.S. and/or foreign nationals?

Discussion Topics and Comments

RESEARCH VERSUS RESEARCH TRAINING. The discussants noted that research and research training go hand in hand and that FIC can have the greatest impact by spending its resources in areas such as research training, which is not a primary focus of other ICs. They encouraged FIC to *not* specify percentages for support of research or research training. The Board noted a need to systematically obtain information on FIC trainees' career development to better understand the local impact and other spin-offs of FIC training.

NEW AREAS AND ONGOING COMMITMENTS. The discussants said that current FIC programs and new areas of interest are not mutually exclusive—for example, the vectors for infectious and chronic diseases are similar. They suggested that FIC begin to identify research topics that bridge the current and new areas of interest. Two possibilities are to (i) probe causal links between infectious and chronic diseases and (b) pursue health systems research, as applicable to all disease categories.

CROSS-CUTTING ISSUES—IMPLEMENTATION SCIENCE. The discussants urged FIC to take the lead in addressing cross-cutting issues central to all diseases (e.g., health systems, adherence, scaling up of successful interventions). By addressing critical operational research questions, FIC could have an important catalytic role and a fundamental impact in framing multidisciplinary science on these issues to improve health globally. The participants suggested the term of implementation science and proposed that FIC place its imprimatur on this new field and obtain

funding from foundations to support the necessary research and research training. They agreed that implementation science is doable and fundable and would serve a unifying purpose. [See additional comments in the discussions under "Intramural Research at FIC – Directions" and "DCPP Implementation – Targeting Countries."]

INCREASING THE FIC BUDGET. The discussants encouraged FIC to "think outside the box" about ways to enlarge the FIC budget as much as fourfold. Changing the way FIC "does business" is one possibility—for example, FIC could increase its "soft" funding significantly through partnerships with large foundations, multilateral organizations, and other U.S. agencies and programs. By focusing on issues of interest to these organizations (e.g., public health research; integration of research, intervention, and care), FIC could attract funding from them.

The participants suggested that FIC staff go on a "listening tour" to meet with potential funders and identify way to match their interests with programmatic possibilities at FIC and NIH. Meeting with leaders in private industry, particularly in companies that are multinational and deal with employees' health problems in different countries, could be fruitful as well. Dr. Kupfer noted that FIC could interact with a new program on public—private partnerships in the Office of Science Policy Analysis, Office of the NIH Director.

A participant suggested that FIC study how success is defined in NIH, Congress, and the Administration to better understand how to "sell" FIC successes and needs. Dr. Glass commented that FIC can receive contributions through the NIH Foundation, the FIC Gift Fund, and potentially Friends of the FIC, which is under consideration.

TRAINING U.S. AND FOREIGN NATIONALS. The discussants encouraged FIC to support training of both U.S. and foreign nationals. A Board member suggested that FIC leverage countries with which it already collaborates to engage them in contributing support for training their nationals in the United States. The discussants commented that research training programs in public health are flourishing at U.S. universities and that a large proportion of students in public health are interested in global health. They noted that training U.S. scientists abroad (for short or long terms) would harness this growing interest and help build a constituency in global health. Two questions are: how can FIC focus this burgeoning interest into institutional growth, and what institutional mechanisms are needed to expand the constituency? Two possible strategies for FIC are to (i) create an umbrella organization of U.S. training programs in public health (similar to the Federation of Cancer Centers) and (ii) play a catalytic role in engaging the ICs in this regard.

Centers of Excellence

Presentation by Dr. Flora Katz, Program Officer, DITR Discussion led by Drs. Arthur Kleinman and William Vega, FIC Advisory Board

Dr. Katz described the development of a center of excellence at the Universidad Peruana Cayetano Heredia (UPCH), Lima, Peru, as a case study of FIC strategies for building institutional capacity. She suggested that the entire thrust of FIC programs is to develop research institutes into excellent centers of research, particularly in low- and middle-income countries. The four strategies that FIC has supported over the years are research training for foreign scientists, collaborative research, global health fellowships for U.S. scientists, and cross-cutting development of institutional capacity.

NIH support of research and research training at UPCH is a case example. For more than 35 years, NIH has funded research grants at the university. This support has grown from 3 awards in Fiscal Year (FY) 1970 to 22–24 awards each year in FY 2001–05. The FIC database indicates early support of a research grant in FY 1970 and substantial funding since FY 1998 through various FIC research and research training programs, fellowship programs for U.S. scientists, and an FIC "glue" grant (Framework Programs for Global Health).

The university is now a fairly mature research center receiving funds from NIH and other sources. Dr. Katz noted that the underpinning for this maturation process has been a number of early and long-term research collaborations established with U.S. research facilities and universities, which supported development of the core research and training enterprise. In addition, the university has interacted with a wide range of institutions, including other universities in the United States and United Kingdom, multilateral organizations, and U.S., Peruvian, and Latin American agencies. With the support of six ICs, including FIC, the university has acquired stable funding for research and training and a stable research infrastructure. The FIC glue grant, in particular, has added value by creating synergy across investigators and schools. Dr. Katz noted that UPCH is the only foreign institution solely receiving an FIC glue grant. It is using the funds to establish a network, directory, and web-site, which are fostering communication and collaborations across campus, and to develop new curricula in global health, including a master's degree program.

The development of this center of excellence has had national, regional, and international impact. Former research trainees are now principal investigators and researchers at UPCH and other Peruvian institutions and serve in hospitals, non-governmental organizations (NGOs), and the Ministry of Health. Long-term partnerships with the Johns Hopkins University, Baltimore, and the University of Washington, Seattle, have resulted in 68 trainees at the M.S. or Ph.D. level, 82 percent of whom now hold research positions in Peru. With NIH and other support, the university has provided research training for more than 500 students from other countries, principally in Latin America.

Dr. Katz commented that development of a center of excellence is much like planting and nurturing a seedling—which requires initial and sustained watering (funding) of the roots (collaborative relationships) to reach full blossoming of a tree (human and institutional capacity) that ultimately bears fruit (researchers, scientists). The 35-year data from Peru indicate three stages of institutional development—"emerging" (defined, in this case, as institutions having three or fewer NIH grants), "growing" (defined as institutions having four to seven NIH grants), and "mature" (defined as institutions having eight or more NIH grants). For FIC, in FY 2005, 45 percent of its awards were made to emerging research centers, 20 percent were made to growing research centers, and 35 percent were made to mature research centers.

Dr. Katz posed two questions for the Board's discussion: (1) What is the appropriate balance of FIC investments among institutions that are emerging, growing, and mature centers of research? Should this balance be driven solely by peer review or shaped through eligibility prerequisites or regional priorities? (2) How should Centers of Research Excellence be defined? Should they be a key part of FIC strategic planning, and if so, what role should they play?

Discussion Topics and Comments

BALANCE OF INVESTMENTS, PEER REVIEW. The Board noted that selection of research institutions to support as Centers of Research Excellence should not be determined through peer review and that FIC could specify research topics and geographic areas. A member suggested that establishment of Centers of Research Excellence in large low- to middle-income countries could result in a brain drain in-country and that fostering centers in less-developed areas of a country may be prudent.

INFRASTRUCTURE SUPPORT. The discussants emphasized that infrastructure support is important to the conduct of research. They suggested that FIC partner with NCRR and foundations to gain infrastructure support for FIC programs.

Center of Research Excellence needs further discussion and definition. Two points to consider are a center's responsibility beyond its home country and duration of funding. They suggested that FIC could (a) construct a full set of case studies to describe emerging, growing, and maturing centers; (b) identify features that contributed to the success of NIH-supported "have-not" research institutions; (c) purposefully seed research on chronic diseases in centers that currently focus on infectious diseases; and (d) integrate information on the health impact of FIC-supported centers to "sell" FIC and its successes in global health.

CENTERS VERSUS OTHER FIC PROGRAMS. The Board encouraged FIC to examine the potential payoffs from supporting Centers of Research Excellence versus other programs before deciding on an appropriate allocation of resources to these activities.

Acute/Chronic Diseases

Presentation by Dr. Karen Hofman, Director, Division of Advanced Studies and Policy Analysis (DASPA) Discussion led by Dr. Elizabeth Barrett-Connor, FIC Advisory Board

Dr. Hofman discussed the research agenda for chronic non-communicable diseases and potential roles for FIC. She noted that the public is increasingly aware of global health priorities and commonalities in chronic non-communicable diseases in industrialized and developing countries. Yet, current priorities for research funding by agencies and donors, including NIH, remain infectious diseases and emerging infections. Research on non-communicable diseases would meet the criteria for research priorities at FIC/NIH, which include burden of disease (magnitude of the problem), importance to the United States and developing countries, lack of duplication of effort, opportunity for action, and availability of potential partners. In FY 2004, approximately 25 percent of FIC funds supported research and planning in non-communicable diseases.

Dr. Hofman noted that the burden of non-communicable diseases is large and growing, accounting in 2005 for approximately 66 percent of the projected global distribution of total deaths. Projected crude death rates per 100,000 population for all ages, 2005–15, indicate that the burden of non-communicable diseases is increasing in low-income countries and is already high and rising in lower-middle income countries. Further, as recently documented, developing countries face a growing triple threat of communicable disease, non-communicable disorders, and injuries.

Dr. Hofman pointed out that developing countries have both an interest and some research capability in non-communicable diseases. Approximately 40 percent of published articles on non-communicable diseases in general journals are authored by investigators in developing countries. Chronic non-communicable diseases are listed on the web-sites of medical research councils in India, Mexico, and South Africa, and these councils are funding research on these diseases.

For the United States, studying non-communicable diseases in developing countries offers several advantages: (a) chronic diseases affect everyone, (b) issues affecting minority and immigrant populations in the United States and elsewhere may be similar, and (c) science-based solutions in developing countries could benefit industrialized countries. Examples of the research gaps and needs that could be addressed in developing countries include the following: quantification of major risk factors, trials to assess interventions (e.g., compliance with medications), transferability of cost-effective interventions, and best practices for health care delivery in settings with a dual burden of disease.

Dr. Hofman emphasized that research on non-communicable diseases does not have to be separate from research on infectious diseases. Evidence of a continuum between infectious and non-infectious diseases is accumulating—for example, between toxoplasmosis and schizophrenia, food-borne toxigenic fungi and cancer, dental caries and cardiovascular disease, antiretroviral therapy and cardiovascular disease, tobacco and HIV/AIDS and tuberculosis. Further, anti-inflammatory agents are used to prevent and treat cancer.

Dr. Hofman listed the many potential partners with which FIC could collaborate to support research and training in non-communicable diseases. These include other ICs, U.S. Government agencies, medical research councils in developing countries, the private sector, foundations, NGOs, World Health Organization (WHO), and Oxford Health Alliance. Dr. Hofman noted that the alliance is convening sectors for action in this area, has modest research support for community-based interventions, and is funding a "Grand Challenges" agenda for non-communicable diseases.

Dr. Hofman posed three questions for the Board's discussion: (1) Is the rising burden of non-communicable diseases adequately reflected in the FIC portfolio of research and research training? (2) Does it make sense for FIC to shift emphasis to promote an integrated communicable and non-communicable agenda? (3) Are there key partners not yet identified?

Discussion Topics and Comments

CHRONIC DISEASES: A GROWING BURDEN. The Board mentioned that infectious diseases and chronic non-communicable diseases have long been treated together in clinics across the developing world. Even though non-infectious, chronic diseases are increasing worldwide and will be major killers, those that are not yet treatable tend to be adult diseases. Capturing the world's attention about these diseases is much more difficult than it is for children's infectious diseases. In this sense, chronic diseases have an "identity problem."

PARTNERSHIPS AGAINST CHRONIC DISEASES. The discussants noted that the opportunity to address non-communicable diseases (e.g., cardiovascular disease, stroke, diabetes) is increasing.

They suggested that FIC identify likely partners for this effort and tag onto the rising opportunities for partnerships in global health (e.g., the Clinton Initiative).

STUDYING CHRONIC DISEASES OVERSEAS. The discussants noted that there must be, and there are, strategic advantages for conducting research on chronic diseases overseas. They commented that the natural history of chronic diseases, such as diabetes and cancer, can be better studied in other countries and the findings would be relevant to the United States, even if the specific expression of disease differs. Noting that social justice and health inequalities are the great issues at this time, a discussant urged FIC to continue to relay the message that "global health is important because global health is important."

Two Concerns: Environmental Toxins, Populations Living in Slums. The Board encouraged FIC to plan its research program in terms of disease directions 5–10 years hence, in order to have an impact. Two particular concerns are populations' exposure to environmental toxins and residence in urban slums.

International epidemiological studies of environmental exposures are needed, for environmental toxins are implicated in many non-communicable diseases (e.g., breast cancer, lymphomas, tobacco-related diseases) and the variant expression of diseases observed in different continents may be environmental, not genetic. The long-term public health effects of tobacco smoking are a particular concern. In China, an estimated 30–40 percent of the population currently smokes tobacco, and the rates of cancer and cardiovascular disease are projected to increase significantly by 2020. To accurately measure environmental exposures, new technology is needed. Because most environmental exposures currently occur outside of the United States, partnerships and collaborations are essential.

The Board noted that the infrastructure of slums in many countries contributes to a large proportion of chronic diseases observed in these countries. In Brazil, for example, hypertension is common among poor slum populations and results in end-stage congestive heart failure, myocardial infarction, and stroke. The projections for cancer and cardiovascular disease in these populations are far worse than those for HIV/AIDS, and these diseases will be a tremendous economic drain in these countries.

ADEQUACY OF THE U.S. PUBLIC HEALTH MODEL FOR OTHER COUNTRIES. Important macro-level questions that FIC could address, in tandem with health economists, include the following: Is the current U.S. public health/treatment model sustainable and better than alternative models (in other countries) for preventing and treating chronic disease? Why do models in some other countries (e.g., Singapore) foster better public health than the U.S. model? Particular questions might include, for example: Is the "polypill" effective? Is application of the U.S. model for tobacco control adequate for other countries? How can countries best prevent their populations from smoking?

Intramural Research at FIC – Directions

Presentation by Dr. Mark Miller, Director, Division of International Epidemiology and Population Studies (DIEPS) Discussion led by Dr. Karen Antman, FIC Advisory Board

Dr. Miller summarized the history of research at FIC, current activities, and alternatives for the future. Since FY 1991, FIC has supported various extramural research award programs and, between FY 2000 and 2003, initiated support for several investigator-initiated (R01) research grant programs. In FY 2000, FIC established DIEPS and DASPA, an in-house research program and an internal "think tank," respectively. Although an initial goal was to allocate approximately 5–10 percent of the FIC budget to DIEPS, Dr. Miller noted that the actual budget, in FY 2001–03, was much more modest, totaling approximately \$0.6–0.8 million, which included cofunding from other ICs and individual project support from the NIH Foundation Gift Fund. FIC does not receive funding for DIEPS from the NIH intramural budget line.

Dr. Miller mentioned that having an in-house research program enables FIC to advance critical overlooked areas of science, increase the prestige and attention given to the center, and fulfill a service function for NIH, the U.S. Department of Health and Human Services (DHHS), and the global community. As part of NIH, DIEPS is able to take a longer-term, biologically and ecologically based view of controversial issues in international health, compared with other agencies and organizations operating with different missions. Dr. Miller noted that, in FY 2000, FIC established an overall research program plan to cross-fertilize FIC research activities with other IC activities in three broad areas: demographics and human ecology studies, translational research on health interventions, and policy research on disease burden and economics. At the time, FIC envisaged serving NIH as an international "IOM."

In their research, DIEPS staff have focused on areas in which NIH has invested greatly (e.g., vaccine development); agents having the greatest epidemic potential (e.g., emerging diseases and rapidly transmissible viruses such as influenza); agents having the greatest endemicity (e.g., malaria); and controversial policy issues (e.g., disease eradication, bioterrorism, "programmatic iatrogenesis"). To date, DIEPS staff have authored or coauthored more than 150 manuscripts in these areas. In FY 2006, DIEPS staff is addressing two program areas: (i) integration of policy, economics, and epidemiology, and (ii) computational biology and modeling (e.g., of genomic drift, life cycles of host/vector systems).

Dr. Miller described the strengths and hurdles of maintaining an in-house research program at FIC. Potential strengths include access to scientific excellence at FIC and NIH, the flexible administration at FIC, availability of space and flexibility of operation, and the institutional willingness of FIC to partner with other agencies. Two major limitations for DIEPS have been the restricted research management and support (RMS) budget and failing to reach a critical threshold of activity in-house, as projects catalyzed by DIEPS are embraced by other NIH components. The hurdles DIEPS faces include having to compete with other interests and constituencies to develop a novel research program, potentially needing a quantum leap to move beyond being a catalyst, overcoming an NIH perception that epidemiology is not intramural research, and not being rewarded within government for efficiency.

Dr. Miller proposed three alternative paths for the future: (i) capitalize on DIEPS momentum to recruit top scientists into the program, (ii) partner with IOM and other funding

sources, and (iii) regroup, remain small, focus on the two current program areas, and concentrate on being a catalyst. He posed two questions for the Board's discussion: (1) Is there a utility of FIC having an in-house research function? Should there be a true intramural program? (2) If there is utility, at what level of funding?

Discussion Topics and Comments

IMPACT OF DIEPS. The discussants noted that DIEPS should be lauded for its research. DIEPS' studies of influenza, for example, "jump started" other ICs' research in mathematical modeling of the disease and influenced Japan's policy of vaccinating children for influenza. They urged DIEPS to better communicate the impact of its research and products.

IN-HOUSE RESEARCH: FUTURE ROLE. The discussants suggested that FIC in-house research should be expansive, robust, and supportive of the FIC agenda. It should be sufficiently strong to complement and add value to the uniqueness of FIC. The discussants noted that DIEPS and FIC are well positioned to undertake high-quality epidemiology and to apply systems biology to the development of public health policy and the understanding of complex relationships in health and disease.

IMPLEMENTATION SCIENCE—A New FIELD. Dr. Glass noted that the "epidemiology of global health" is a relatively new area for FIC and needs to be better defined. For example, is it metrics of disease burden, implementation research, or evaluation research? He noted that during the strategic planning process, FIC will identify research areas that have a particular strategic advantage for FIC. One possibility is to study disease interventions that are and are not effectively delivered. The Board suggested that FIC convene a 1-day meeting of health economists, biomedical and behavioral scientists, and congressional staffers to discuss and define the field of implementation science and the research and research training needed.

DCPP Implementation – Targeting Countries

Presentation by Dr. Joel Breman, Senior Scientific Advisor, DIEPS Discussion led by Dr. Patricia Danzon, FIC Advisory Board

Dr. Breman reported on DCPP activities since the publication and launch of the three DCPP volumes in Beijing, China, in April 2006. These volumes—*Disease Control Priorities in Developing Countries, Priorities in Health*, and *Global Burden of Disease and Risk Factors*—and continuing information on the implementation of DCPP are available on the DCPP web-site (www.dcp2.org). The Board was encouraged to visit this user-friendly web-site, which has received 30,000 user "hits" each month since April. The web-site has downloadable slides and briefs on diseases and DCPP topics. Two articles about DCPP, which were published in *The Lancet* in April and May, were provided to the Board.

The overall goal of DCPP is to impact peoples' lives. The two objectives are (i) to decrease illness, disability, death, and economic burden by developing an evidence base to inform decision making and (ii) to communicate major findings. More than 1,000 individuals and more than 300 authors and their institutions have been involved in DCPP. The researchers estimated the cost-effectiveness and impact of interventions, defined disease burdens, and summarized experiences with implementation. Based on careful analysis, they defined "best buys" and "worst buys" and

disseminated the results—all to stimulate countries to set national priorities and to implement programs, projects, and action. The five DCPP partners are the FIC, World Bank, WHO, Population Reference Bureau, and Bill & Melinda Gates Foundation.

Dr. Breman mentioned several activities that have taken place worldwide since April. These included conference plenary sessions on the DCPP, one of which, in Alexandria, Egypt, was moderated by Dr. Elias Zerhouni, Director, NIH; U.S. congressional briefings; and spin-off analytical and implementation efforts. He also noted that DCPP has provided seed grants of \$150,000 each to two investigators to support implementation activities in India and Malawi. In addition, the Bill & Melinda Gates Foundation has awarded grant monies to the Population Reference Bureau, for dissemination efforts, and to the World Bank, for information and implementation activities.

FIC has begun to stimulate convergence on research themes through its research training networks and collaborations with ICs and outside groups. The themes being discussed include cardiovascular diseases and interventions; neonatal, child, and maternal health; auto safety; and tobacco burden. As DCPP continues, FIC will be engaged in suggesting country-specific priorities, updating DCPP materials, and disseminating materials relevant to FIC and other research-training networks. For the future, FIC will continue to serve as DCPP secretariat and foster linkage of FIC-supported research with DCPP priorities.

Dr. Breman posed two questions for the Board's discussion: (1) Should there be an extension of DCPP? If so, what activities should FIC assume? (2) What mechanisms are possible to address the DCPP research agenda?

Discussion Topics and Comments

MOVING DCPP FORWARD. The Board noted that the DCPP books are an incredible contribution to knowledge and need to be read, applied, and continually updated. Moving forward, there is still a huge amount to learn—for example, how can this knowledge base be moved into implementation? What are the costs and problems of implementation? How will policymakers use DCPP? Will governments shift their priorities as a result of DCPP?

FIC ROLE. The discussants noted that DCPP describes a huge agenda for global health. For FIC, key questions include the following: How can FIC help to move the DCPP forward? Should the DCPP secretariat remain at FIC, possibly as a division? Could FIC be useful in maintaining the DCPP "bible" and obtaining funding to support DCPP implementation? Could FIC use DCPP to develop its own cross-cutting research agenda for the next 10–20 years and to acquire additional resources? How can FIC engage the other DCPP partners in this effort?

The discussants suggested that FIC undertake three specific tasks: (i) launch consultations on critical intervention topics (e.g., diarrheal disease, microbicides) and foster consultations on other topics (e.g., core public health functions); (ii) foster partnerships with the World Bank to identify credible scientists for consultations and discussions at the country level; and (iii) conduct selected in-country impact evaluations of interventions. Other suggested actions for FIC included (a) modeling of the potential long-term impact (10–20 years) of governmental shifts in priorities (in

five or six industrialized and developing countries) as a result of DCPP, and (b) identifying areas of research duplication among funding partners' programs. Within NIH, FIC could take responsibility for developing a research agenda, based on DCPP, to advance health in low- and middle-income countries and could expand its unique role in research training to support the training of individuals in implementation science.

DCPP AND NIH. Two questions pertinent to NIH are: What is the NIH research agenda regarding DCPP? Who would be potential funders, other than Congress, of this agenda? The discussants noted that DCPP is a product that Dr. Zerhouni can tout and that DCPP could serve to focus a global health and implementation research agenda at NIH. The DCPP could be linked with or included as an initiative in the NIH Roadmap, and FIC could both identify and help resolve infrastructural barriers to IC engagement in implementation research and catalyze IC involvement in global health research. Dr. Glass, in his role as Associate Director for International Research, could coordinate and "grow" implementation research at NIH.

Dr. Glass noted that the DCPP books have been provided to the ICs and that he is meeting with all IC directors to encourage them to become involved in global health issues. In addition, FIC is giving visibility to DCPP issues at its monthly meetings of IC international representatives.

X. CLOSING REMARKS

Dr. Glass thanked the Board and special guests for their very helpful comments at this meeting for launching the FIC strategic planning process. He noted that all will be invited to the December 12–13 stakeholder conference at NIH. During the coming months, FIC will be soliciting input broadly from the extramural community and holding a series of consensus meetings with medical and public health faculty and health economists.

XI. ADJOURNMENT

There being no further business, the meeting was adjourned at 3:45 p.m. on September 12, 2006.

CERTIFICATION

I hereby certify that, to the best of my knowledge, the foregoing minutes are accurate and complete.

Roger I. Glass, M.D., Ph.D. Chairperson, Fogarty International Center Advisory Board, and Director, Fogarty International Center, and Associate Director for International Research NIH Jean Flagg-Newton, Ph.D. Executive Secretary, Fogarty International Center Advisory Board, Fogarty International Center

ATTACHMENT

Board Roster

Abbreviations Used in the Minutes

AIDS - Acquired Immunodeficiency Syndrome

AITRP - AIDS International Training and Research Program
BIOETH - International Research Ethics Education and Curriculum

Development Award

CSR - Center for Scientific Review

DASPA - Division of Advanced Studies and Policy Analysis

DCPP - Disease Control Priorities Project

DHHS - U.S. Department of Health and Human Services

DIEPS - Division of International Epidemiology and Population Studies

DITR - Division of International Training and Research

EID - Ecology of Infectious Diseases

FIC - John E. Fogarty International Center for Advanced Study in the

Health Sciences

FIRCA - Fogarty International Research Collaboration Award

FRAME - Framework Programs for Global Health

FY - Fiscal year

HIV - Human immunodeficiency virus

ICOHRTA - International Clinical, Operational, and Health Services Research and

Training Award

ICs - Institutes and centers

IRSDA - International Research Scientist Development Award for U.S.

Postdoctoral Scientists

NGOs - Non-governmental organizations

NIAID - National Institute of Allergy and Infectious Diseases

NIBIB - National Institute of Biomedical Imaging and Bioengineering
NICHD - National Institute of Child Health and Human Development

NIH - National Institutes of Health

NINDS - National Institute of Neurological Disorders and Stroke

OGHA - Office of Global Health Affairs

POP - International Training and Research Program in Population and

Health

RMS - Research management and support

RPGs - Research project grants

UPCH - Universidad Peruana Cayetano Heredia

WHO - World Health Organization

FOGARTY INTERNATIONAL CENTER ADVISORY BOARD ROSTER

(All terms end January 31)

September 2006

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