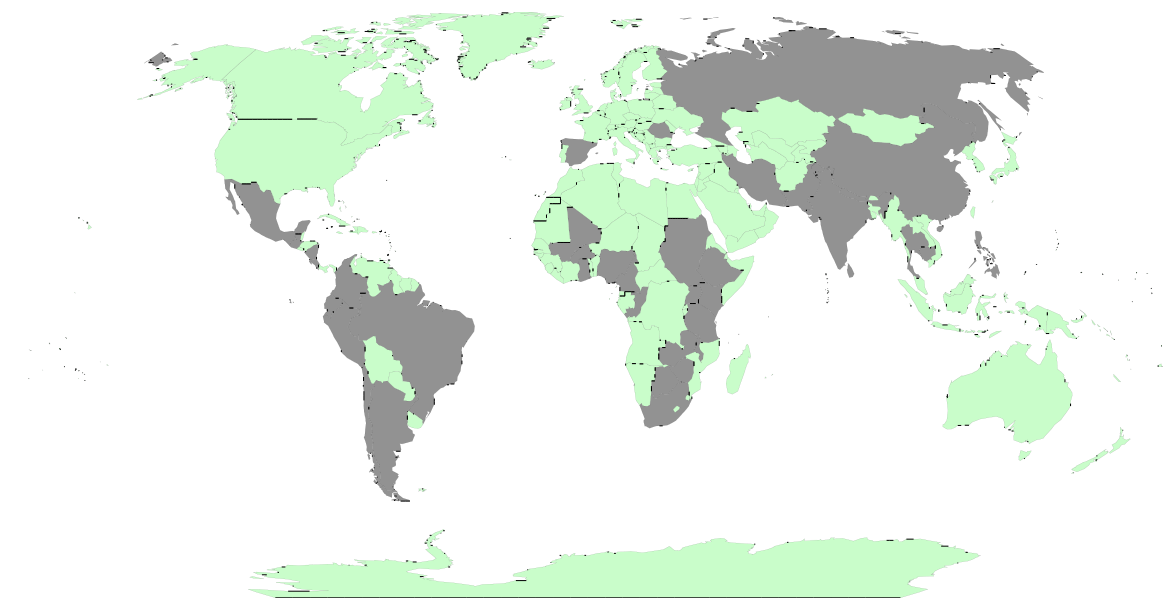




FINAL REPORT

Expert Review Panelists:

David A. Borasky Jr., CIP
Dafna Feinholz Klip, MA, PhD
Bernard Lo, MD (Chair)
Bella Starling, PhD
David Thomas Stern, MD, PhD
Angela Amondi Wasunna, LLB, LLM



Darkened countries are those with at least one long-term trainee participating in an International Bioethics Education and Career Development Award program.

Table of Contents:

Letter of Transmittal	3
Executive Summary	4
Background on the International Bioethics Education and Career Development Award Program.....	9
A. Background.....	9
B. Program Mission	12
C. Bioethics Program Review Process.....	12
I. Program Planning	13
II. Program Management.....	16
III. Partnerships and Communication.....	19
IV. Results: Re-entry and Post-Training Activities.....	21
V. Results: Outcomes and Metrics of Success.....	23
VI. Conclusion.....	25
Appendix A - Letter to the Chair.....	26
Appendix B – Review Panelist Profiles	27
Appendix C – Bioethics Program Interviewees	29
Appendix D – Supplementary Program Data.....	30
Appendix E – List of Publications by Program.....	35

Letter of Transmittal

University of California
San Francisco



Program in Medical Ethics
School of Medicine

521 Parnassus Avenue
Suite C-126, Box 0903
San Francisco, CA
94143-0903
tel: 415/476-6240
fax: 415/476-5020

Sharon Hrynkow, Ph.D.
Acting Director
Fogarty International Center
National Institutes of Health
Building 31, Room B2C02
31 Center Drive, MSC 2220
Bethesda, MD 20892-2220

Dear Dr. Hrynkow,

Attached please find the final report of the panel convened to review the Fogarty International Center's (FIC) International Bioethics Education and Career Development Award Program in May of this year. The report reflects the findings and recommendations made by the review panel, which I had the pleasure of chairing. I hope that the report will be helpful to FIC and its partners as they look to strengthen the program and as they fashion the next request for applications this fall.

During our three-day review meeting at NIH, we spoke to many persons connected with the program. We received many positive comments about the Bioethics program as well as comments about how the program could be modified to make it even more effective. We hope that FIC and its partners will give the suggestions, contained in the report, serious consideration as they go forward.

As you will see from the report, the review panel was impressed by the accomplishments of the bioethics program for pioneering curricula and research training in an area where none existed five years ago. This program will continue to be very important as the role of global health expands.

On a personal note, I should add I thoroughly enjoyed chairing the Bioethics review panel and working with the other panel members. My deep thanks to this very talented group, whose diverse background and expertise allowed us to look at the program from many different perspectives. I would like to thank the Abt team who helped staff the review, Alexis Wilson, Brian Zuckerman and Nate Towery as well as Linda Kupfer from FIC, who directed and conceptualized the review.

With best wishes,

Yours sincerely,

A handwritten signature in dark ink that reads "Bernard Lo". The signature is fluid and cursive, with the first name "Bernard" and the last name "Lo" clearly distinguishable.

Bernard Lo, M.D.

Executive Summary

The Fogarty International Center's (FIC) International Bioethics Education and Career Development Award Program (referred to hereinafter as the "Bioethics program"), addresses an important need in clinical research in developing countries and has already made important contributions in its first five years of existence. Clinical research in developing countries is essential to better understand and treat diseases whose burdens are disproportionately great in these regions. Ethical issues in research need to be resolved in order for scientists to gain the trust of the public and research participants.

FIC conducts qualitative process evaluations of its programs every five years. In May 2005, the Fogarty International Center convened a panel of six experts in research ethics and curriculum development to review progress of the first five years of the Bioethics program and to make suggestions regarding its future. This review served as the first formal evaluation of the Bioethics program.

With the program goals in mind, the panel spoke with Bioethics Principal Investigators (PIs), past and current program trainees, FIC program officer, National Institutes of Health (NIH) partners, and outside experts in bioethics and clinical research ethics. During these interviews, the panel explored the impact of the program with respect to FIC's mission and program goals as well as the impact on developing country researchers and institutions in order to suggest improvements and modifications to all areas of the Bioethics program. In accordance with the Fogarty Evaluation Framework, the panelists explored five aspects of the program: Program Planning, Program Management, Partnerships and Program Results with regard to Re-entry and Post-training Activities, and Program Results with regard to program Outcomes and Metrics of Success.

The panelists noted that even though it is relatively new, the trainee from the Bioethics program have published papers in high-impact journals, successfully obtained NIH funding, and established national ethics review committees. The panel strongly recommended the continuation and support of the Bioethics program, and suggested several modifications to strengthen its impact in the developing world and more closely align its objectives with the goals of FIC and the other NIH partners. The review panel made nine formal recommendations on modifications and improvements to the Bioethics program:

I. Strategic Planning

The broad objectives of the current program are to:

1. Improve the quality of international ethics training by supporting the development of courses that will provide the skills necessary for teaching and research related to bioethics and the conduct of ethical medical research in developing countries.
2. Support the advanced training of developing country professionals who will assume the roles and responsibilities of bioethicists involved in ethical review or clinical trial design in research and clinical investigations at their home institutions.

3. Develop and provide intensive short courses specifically designed for individuals directly involved in human subjects research, ethical review, and conduct of clinical trials in developing countries

The review team found that the program has made substantial progress in achieving these goals. In its first five years, the Bioethics program has trained 167 long-term and 1406 short- and medium- term trainees. Trainees have come from 38 developing countries and produced a total of 81 publications and 54 presentations. Almost all long-term trainees (98%) have returned to their country of origin following training. Sites have developed curricula for training in research ethics and designed popular short courses in research ethics. The full report and appendices provide details about the development of courses and the numbers of persons trained.

Since the inception of the program, new needs in research ethics have emerged that could be addressed. Moreover, the funding situation at NIH has changed dramatically; with current fiscal constraints, it is essential that the Program document how it has helped to achieve the objectives of NIH Institutes that have co-funded it. Thus the review committee recommends:

Recommendation 1: FIC should reassess the program objectives and modify them to take into account its accomplishments to date, current needs in developing countries, and the changing environment at NIH.

Specifically, the Bioethics program should assess the needs in developing countries for ethics training and infrastructure, actively seeking perspectives and input from the South. This could be accomplished by having grantees in their proposals describe the research bioethics needs in the regions they are targeting for training and how those needs fit into national or regional development goals. FIC should have objectives that allow flexibility for investigators to address the needs in their target regions. In addition, FIC should assess the needs of NIH partners, to ensure that the program helps other NIH Institutes carry out their missions.

The Program should remain focused on “research ethics” but strive to clarify the relationship between research ethics and broader bioethics issues. Bioethics is important as a core intellectual foundation of research ethics. However, the primary focus should be on research ethics, in keeping with the NIH mission. As the program is now, there is some discrepancy between the title of the program, its objectives, and the actual output; these should be aligned. The panel suggests that the program should be renamed the “Fogarty International Research Ethics Education and Career Development Award” to better reflect the true nature of the program.

II. Management

In the interviews, the review panel found consensus that the Bioethics program’s leadership is capable, enthusiastic, and committed. However, the review also identified several areas that should be addressed.

The Bioethics program should collect better information about the trainees and other NIH-sponsored grantees and share it with other stakeholders. This would amplify the impact of the program and facilitate collaborative linkages. Many trainees and alumni commented that they could not find out who else in their region had been trained in the Bioethics program and who in their home country had NIH grants.

Recommendation 2: FIC should develop and implement a comprehensive, centralized trainee tracking system.

A tracking system would be of great use to other NIH Institutes and programs, FIC's partners in the field, and principal investigators and trainees in other NIH-funded programs. These stakeholders could use this database to identify bioethics experts in locations where research is to be conducted, for example, to identify persons to serve on study review panels or data safety monitoring boards or to provide consultation and technical advice on bioethics to specific projects. In addition, such a database could also be used by the wider international bioethics community. It could be extended, in collaboration with other funders/relevant organizations, to provide a central resource for bioethics expertise in developing countries. The panel realizes that a trainee tracking system is currently under development at FIC; however, this system must include specific metrics (suggested below) for tracking progress under the Bioethics program.

Recommendation 3: FIC, in the review of proposals for the next Request for Applications (RFA), should work with the reviewing IC to substantially increase the number of peer reviewers from developing nations.

The panel notes that the previous proposal review panels had very few representatives from developing countries. The review process would be strengthened by substantially increasing the number of reviewers from developing countries, who could help ensure that the funded programs are capable of addressing the needs of countries and regions from which trainees are selected. A desirable goal would be to have 50% of reviewers from developing countries.

Recommendation 4: NIH should increase the flexibility of the current grants management mechanisms to better meet the needs of foreign awardees.

Several interviewees stated that NIH's current system for distributing funds does not meet the needs of grantees in developing countries, particularly those in institutions that have little experience with NIH grants. For example, mailing paper checks to institutions is not feasible in countries with unreliable mail service and in institutions that do not have a grants management office. NIH should consider revising their policies and procedures to allow alternative mechanisms of distributing funds, such as electronic wire transfer. Adoption of these methods, which are commonly used in the private sector, would reduce the burden on staff at FIC and staff in NIH grants management offices.

Recommendation 5: NIH should provide adequate staffing for this important program.

Multiple interviewees described the particular challenges that are created by this unique, far-flung program, and the resulting burden on the FIC staff. Those interviewed praised the

helpfulness and capability of the Program Officer. However, there is not sufficient staff to carry out important tasks, such as integrating annual reports from individual sites and preparing an annual report for the entire program. The lack of staff to carry out these tasks hinders the ability of FIC to inform partners about the accomplishments of the program, to seek out new partnerships, to leverage funds, and to solidify current partnerships.

III. Partnerships and Communication

Interviews revealed that NIH partners were not as well informed as they should be about the program and its accomplishments. Better communication would heighten the impact of the Bioethics program and increase support for the program within NIH. FIC also needs to improve communication with other stakeholders outside NIH. These include extramural researchers from developed countries carrying out research in the developing world, investigators and research institutions in the developing world, Institutional Review Boards (IRBs) and bioethics networks in the developing world, such as the Latin American Forum of Ethics Committees in Health Research (FLACEIS), and organizations building research capacity in the developing world, such as the Wellcome Trust, and international agencies such as the World Health Organization (WHO). Again, these stakeholders offer opportunities for Bioethics grantees to start new projects in research ethics and to have a greater impact in developing nations.

Recommendation 6: FIC needs to better communicate with partners inside and outside NIH about the program and its accomplishments. Furthermore, Bioethics trainees and PIs need to be informed about other NIH programs and researchers whose needs overlap with their interests and skills and who offer opportunities to have a wider impact.

IV. Results: Re-entry/post-training activities

Fogarty Bioethics trainees have an extremely high rate of return to their home countries (98%), which compares very favorably with other programs. Other Fogarty programs boast 80% (AIDS International Training and Research Program) and 66% (International Training and Research Program in Population and Health) return rates. The U.S. National Science Board cites a 55% return for international Science & Engineering trainees in their publication, *Science and Engineering Indicators – 2004*. This is a major success of the program; however, additional steps should be taken to assure that trainees could continue to carry out work in research ethics after their return to their home countries.

The review panel identified barriers that graduates of the program faced after completing their training and returning to their home institutions. Difficulties include: lack of start-up funds, administrative support, and release time from teaching and administrative responsibilities. Thus the excellent training might be undone unless there are more intensive efforts to promote bridge support and re-entry. A modest amount of money for a short period of time would go a long way in helping graduates of the program launch careers at their home institutions. Several alternatives for bridge funding are described in the full report.

Recommendation 7: FIC should consider how to provide bridge funding and career development grants to trainees who successfully complete the Bioethics program.

V. Results: Outcomes and Metrics of Success

As with any NIH program, the FIC Bioethics Program needs to be carefully evaluated. The evaluation process of this program presents some unique challenges. First, like other training programs, the full effect of the program can only be assessed in the long run. Secondly, unlike other training programs, the FIC Bioethics program has multiple long-term goals. Hence, the usual metrics used to evaluate NIH training programs will not fully capture the impact of this program.

Traditional NIH training programs are intended to train independent investigators who will carry out innovative, rigorous research. Metrics used to evaluate these programs include publications in high-impact peer-reviewed publications, success in obtaining ongoing research support, degrees obtained, new positions achieved, and return rate to home countries. However, the FIC Bioethics program has broader objectives. The program is also intended to train individuals who will help build the capacity of IRBs or Ethics Review Committees (ERCs) in developing countries or who will educate investigators, staff, IRB members, and university and public officials about research ethics. Thus, the evaluation criteria for this program need to include appropriate metrics to assess these additional goals. Specific additional metrics are described in the full report. The progress of the program should be communicated to stakeholders in an annual report.

Recommendation 8: FIC and Bioethics PIs need to develop outcome metrics that will adequately describe the success and value of the accomplishments of their trainees, as well as the program accomplishments.

Recommendation 9: Bioethics PIs should make explicit links between the needs of the countries served, the needs of students from those countries, the objectives of the curriculum, the curricular elements, and measures of outcome.

VI. Conclusion

The Fogarty International Center's International Bioethics Education and Career Development Award Program has already made an outstanding contribution to developing capacity in research ethics in the developing world. It has demonstrated the innovation to fund in an area with no significant previous commitments. There continues to be a real and demonstrated need for such training worldwide. The Bioethics program strongly deserves continued support, and the Fogarty International Center needs to obtain funding so that the Bioethics program is able to carry out important additional activities. Despite the challenges of the current NIH financial situation, it is crucial to find the resources to carry out the important mission of this program. The Panel recommends certain changes to the Bioethics program in order to better meet the changing needs of research ethics capacity in the developing world.

Background on the International Bioethics Education and Career Development Award Program

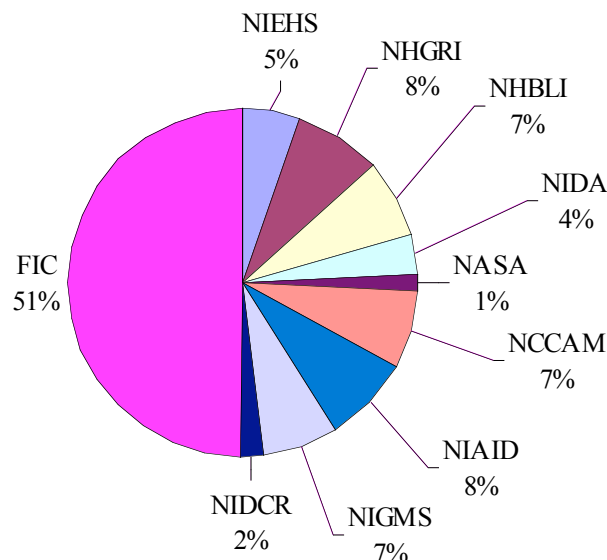
A. Background

Launched in March 2000 with the publication of the first RFA, the International Bioethics Education and Career Development Award program is an institutional curriculum development and training grant that enables both United States and foreign institutions to develop or expand current graduate curricula and training opportunities in international bioethics and research ethics. In accordance with the Fogarty International Center's strategic plan to strengthen research bioethics expertise in low- and middle-income nations, this initiative aims to increase the number of developing country professionals and academics with knowledge and experience in bioethics. Funded programs recruit biomedical and behavioral scientists, clinical investigators, nurses and other health professionals, and relevant academics, training them with state-of-the-art knowledge of ethical considerations, concepts and methods in research involving human subjects. It is expected that such advanced training will enhance the career development of individuals from developing countries as well as strengthen bioethics knowledge and experience at the trainees' host institutions.

The Fogarty International Center (FIC), in partnership with the National Center for Complementary and Alternative Medicine (NCCAM), the National Heart, Lung, and Blood Institute (NHLBI), the National Human Genome Research Institute (NHGRI), the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Dental and Craniofacial Research (NIDCR), the National Institute on Drug Abuse (NIDA), the National Institute of Environmental Health Sciences (NIEHS), the National Institute of General Medical Sciences (NIGMS), and the National Aeronautics and Space Administration (NASA) currently support sixteen, four-year International Bioethics Education and Career Development awards and two, two-year planning grants for developing country institutions (Figure 1). FIC issued a request for applications (RFA) for the program in FY 2000, FY 2002 and FY 2004. The first programs funded under the 2000 RFA provided training for participants from the Asian, Anglophone Africa and Latin American regions; the most recent RFA encouraged applications focusing on participants from the Middle East, Western (Francophone) Africa, Eastern Europe and the former Soviet Union. FIC expects to issue a revised version of the RFA in FY 2006. This focused program review occurred in preparation for this revised RFA.¹

¹ Sources: *Abt Associates Inc. summary of International Bioethics Education and Career Development Award RFAs.* Also, program website at: <http://www.fic.nih.gov/programs/bioethics/bioethicsaward.html>

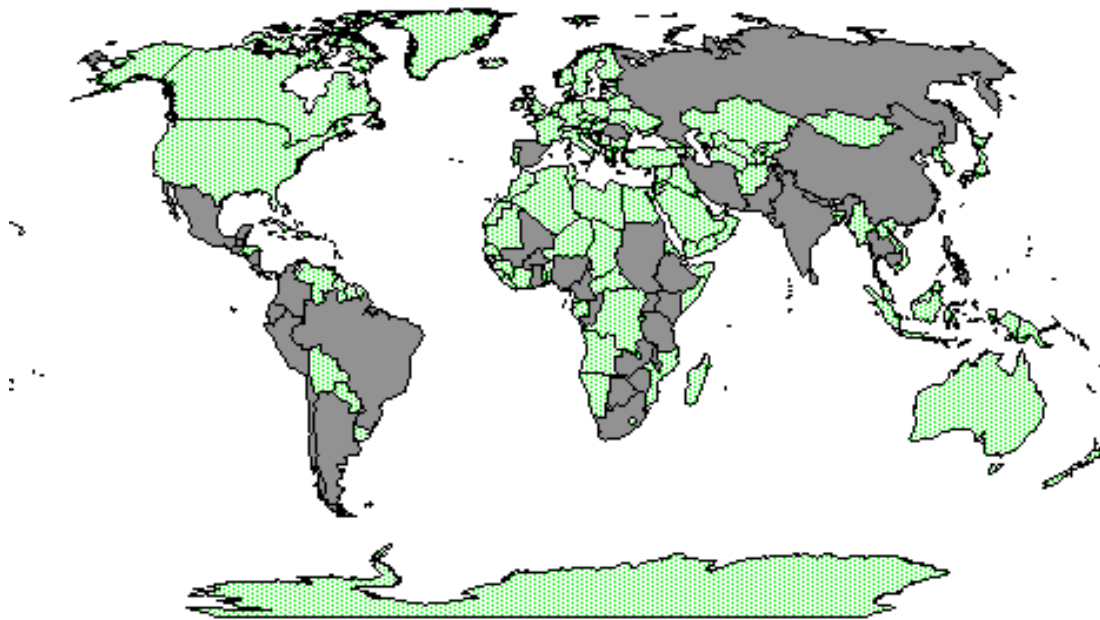
Figure 1: FY 2004-2005 Funding Sources for the Bioethics Program (Total: \$3,407,340)



Source: Abt Associates Inc. analysis of program data for review panel

As of April 2005, the International Bioethics Education and Career Development Award program has enrolled a total of 167 long-term trainees (102 have graduated; 65 are in-progress).² Trainees hail from 38 countries worldwide, though the majority (53%) are from Anglophone and Francophone Sub-Saharan Africa (Figure 2a and 2b).

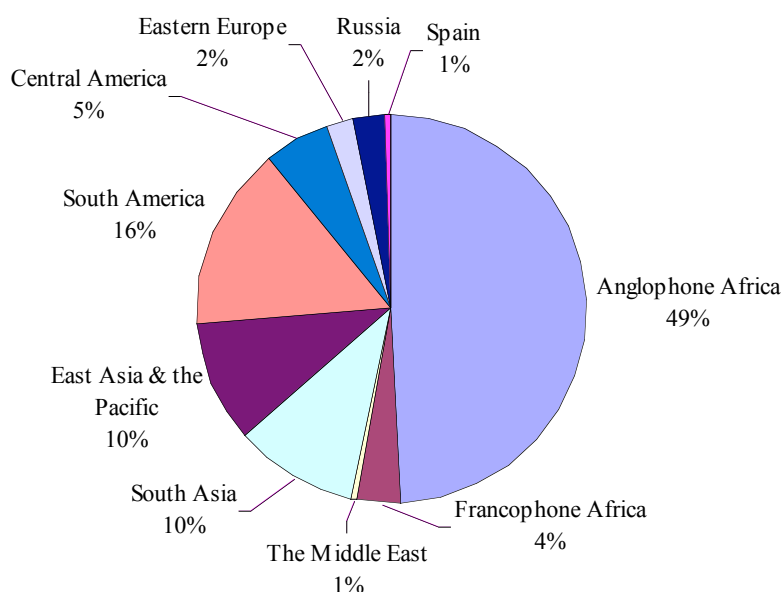
Figure 2a: Geographic Representation of Bioethics Long-Term Trainees (n=167)



Source: Abt Associates Inc. analysis of program data for review panel

² For the purpose of this review, a “long-term” trainee receives a minimum of 6 months of training.

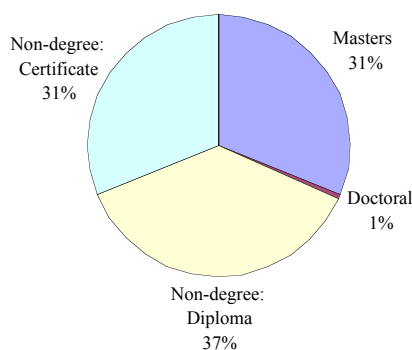
Figure 2b: Regional Distribution of Bioethics Long-Term Trainees (n=167)



Source: Abt Associates analysis of program data for review panel

The majority of the long-term training is non-degree Certificate and Diploma training, though some institutions offer Masters degree training (Figure 3). In addition to the long-term training programs, numerous short courses and intensive workshops in research ethics have created an ever-growing world-wide list of trainees with basic knowledge of research bioethics. The Bioethics program trainees have presented and published a total of 135 papers on research ethics-related topics and have spread knowledge in their home countries about the importance of ethics in health research and professional practice (Appendix D and E).

Figure 3: Training Conferred to Bioethics Long-Term Trainees (n=167)



Note: Though the RFA does not support doctoral training, there is one trainee affiliated with and partially funded by the SARETI program who is completing doctoral work.

Source: Abt Associates Inc. analysis of program data for review panel

B. Program Mission

As stated in the 2003 RFA, the Bioethics program goals are threefold:

1. To improve the quality of international ethics training by supporting the development of courses that will provide the skills necessary for teaching and research related to bioethics and the conduct of ethical medical research in developing countries.
2. To support the advanced training of developing country professionals who will assume the roles and responsibilities of bioethicists involved in ethical review or clinical trial design in research and clinical investigations at their home institutions.
3. To develop and provide intensive short courses specifically designed for individuals directly involved in human subjects research, ethical review, and conduct of clinical trials in developing countries

C. Bioethics Review Process

From May 2 to 4, 2005 a group of six experts in the areas of bioethics, health research ethics, and curriculum development gathered at the Fogarty International Center at the NIH in Bethesda, MD to assess the progress and achievements of the International Bioethics Education and Career Development Award over the last five years. The letter to the panel chair can be found in Appendix A and the biographical sketches of the review panel can be found in Appendix B. The review was conducted following the FIC Framework for Evaluation which can be found at: http://www.fic.nih.gov/about/eval_framework.pdf. The six panelists conducted in-person interviews and conference calls with key program stakeholders: nine Principal Investigators, thirteen long-term program trainees, six NIH partners, the FIC Program Officer, as well as four outside bioethics and health research ethics experts with knowledge of the Bioethics program (interviewees listed in Appendix C).

I. Program Planning

After speaking with key program stakeholders, the review panel found that the Bioethics program has made substantial progress towards achieving all of the program goals. Many courses have been developed and a talented cadre of individuals has been trained by enthusiastic PIs. Bioethics program trainees are making strides towards improving the bioethics communities within their home countries and institutions.

Goal 1: To improve the quality of international ethics training by supporting the development of courses that will provide the skills necessary for teaching and research related to bioethics and the conduct of ethical medical research in developing countries.

- A total of 167 long-term trainees, and 1406 short- and medium-term trainees have graduated from the Bioethics program (Appendix D, Table 1).
- Individuals from 38 countries have been trained (Appendix D, Table 2).
- Diverse curricula have been created related to bioethics and research ethics in developing countries.
- In many countries, the Bioethics program is the only opportunity for training in bioethics or research ethics.

Goal 2: To support the advanced training of developing country professionals who will assume the roles and responsibilities of bioethicists involved in ethical review or clinical trial design in research and clinical investigations at their home institutions.

- Trainees of the program are returning to their countries, and in many cases, are the leaders in bioethics and research ethics in their countries (Appendix D, Table 3).
- One graduate has set up a national ethics review board in his home country, Nigeria, for which he received a Presidential medal.
- One graduate is first author of publications on bioethics in prestigious scientific journals including *The Lancet*, *Nature*, and *Science*.
- One graduate is now the principal investigator on her own Bioethics program in India, and another graduate is a faculty member on a Bioethics program training grant in Nigeria.
- In India, the Bioethics program has trained every bioethicist working in the country.
- In South Africa, one graduate is now the leader in ethics and law for the regional Fogarty AIDS International Training and Research Program (AITRP) and ensures that all material that passes through his institution is in accordance with NIH ethical guidelines.

Goal 3: To develop and provide intensive short courses specifically designed for individuals directly involved in human subject research, ethical review, and conduct of clinical trials in developing countries

- A total of 27 short-term and 28 medium-term workshops have been held in all regions of the world (Appendix D, Table 4).
- Graduates of these workshops are now better equipped to serve on their national IRB and ERCs. For example, one trainee served on the national ERC in Zambia prior to her training; however, she had much difficulty as neither she, nor any of her colleagues, had any specific training. After graduating from the Bioethics program, she has become a leader and a resource for other members of the Zambian ERC.

While the Bioethics program is adequately meeting its three goals, new needs in research ethics have emerged since the inception of the program in 2000 that the program could address. Moreover, the funding situation at NIH has changed dramatically; with current fiscal constraints, it is essential that the Bioethics program document how its grantees have helped to achieve the objectives of NIH Institutes that have co-funded it. Thus the panel recommends:

Recommendation 1: FIC should reassess the program objectives and modify them to take into account its accomplishments to date, current needs in developing countries, and the changing environment at NIH.

Specifically, FIC should assess the needs in developing countries for ethics training and infrastructure, actively seeking perspectives and input from the developing countries. This could be accomplished by having grantees describe in their proposals the research bioethics needs in the regions they are targeting for training and how those needs fit into national or regional development goals. FIC should set objectives that allow flexibility for investigators to address the needs in their target regions. For example, the panel heard evidence that in some regions short courses in bioethics no longer serve an important need; hence those sites should not plan to carry out those courses.

In addition, FIC should consider the needs of NIH partners, to ensure that the program helps other NIH Institutes carry out their research missions. The panel found that there are missed opportunities for FIC to enhance the activities of other Institutes at multiple levels by providing consultation and technical advice to individual R01 grants, or to large-scale clinical trials and center grants. FIC could set this as a general objective for the Bioethics program and encourage PIs to determine if this is relevant to the needs of the region they are targeting and if so how to carry out this objective. FIC should also determine which specific research ethics problems other NIH Institutes are facing in the research projects they sponsor in developing countries and consider how the FIC might help address those specific issues. This would not only gain more “buy-in” from the partner institutes, but would potentially help to open up new funding sources for trainee recruitment, education and re-entry.

Additionally, the review panel recognized that the Bioethics program should continue to focus on “research ethics” but strive to clarify the relationship between research ethics and broader bioethics issues. Bioethics is important as a core intellectual foundation of research ethics. In keeping with the mission of the NIH, the primary focus of the Bioethics program should be on research ethics. As the program is currently designed, discrepancies exist between the title of the program (The International Bioethics Education and Career Development Award), its objectives, and actual program outputs; the panel recommends that these aspects be aligned to eliminate the discrepancies. The panel suggests that the Bioethics program should be renamed the “Fogarty International Research Ethics Education and Career Development Award” to better reflect the true nature of the program.

II. Program Management

Through interviews with current and former trainees, principal investigators, and FIC staff, the review panel found the program's leadership capable, enthusiastic, and committed. Bioethics program PIs unanimously described the Program Officer as helpful and supportive of their programs and trainees. The panel did identify several areas for improvement in the management of the program, however, and these are addressed in the following discussion.

First, the Bioethics program needs to collect better information about its trainees and to share it with other stakeholders. The NIH should also collect and make available information about other NIH-sponsored grantees working in related fields or on collaborative projects requiring advanced research ethics knowledge. Collecting, organizing, and distributing this information would amplify the impact of the program and facilitate collaborative linkages both among Bioethics program trainees as well as between Bioethics program trainees and projects run by NIH Institutes. Many current and former trainees commented that they could not identify others in their region who had been trained in a Bioethics program. The current program management system does not track former trainees across programs, and the lack of a comprehensive tracking system presents a barrier to FIC's effort to document the impact of the Bioethics program.

Recommendation 2: FIC should develop and implement a comprehensive, centralized trainee tracking system.

A tracking system would be of great use to other NIH Institutes and programs, Fogarty's partners in the field, and principal investigators and trainees in other NIH-funded programs. These stakeholders, especially at the NIH level, could use this database to identify bioethics experts in locations where research is to be conducted, for example to identify persons to serve on study review panels or data safety monitoring boards or to provide consultation and technical advice on bioethics to specific projects. Trainees expressed that their fellow trainees are a valuable resource of information and networking opportunities to not only the NIH partners and NIH projects, but also to each other when questions arise or help is needed. Such a database could not only be used by NIH and its associates, but by the wider international bioethics community. Indeed, such a database could be extended, in collaboration with other funders/relevant organizations, to provide a central resource for bioethics expertise in developing countries.

The panel heard from PIs that the current forms provided by FIC for trainee tracking are inadequate; FIC is in the process of initializing an online trainee tracking system for all of its programs, and the panel expressed hope that this new system would catalyze more accurate data on training program outcomes. Additionally, PIs commented that the standard FIC/NIH tracking forms do not match the bioethics program needs and outcomes. For example, the accomplishments and skill sets of trainees of this program are not well captured by standard NIH measures of success such as new grants received and numbers of papers published. A graduate who has successfully set up a national IRB or national research ethics guidelines would not fall within these categories but would be an invaluable resource for other countries and NIH programs. The metrics needed to determine success of the Bioethics program should be incorporated into the tracking system.

Recommendation 3: FIC, in the review of proposals for the next RFA, should work with the reviewing IC to substantially increase the number of peer reviewers from developing nations.

From interviews with FIC program staff and other IC staff the panelists learned that the previous proposal review panels had very few representatives from the South – that is, from developing countries like those whose research ethics capacity the Bioethics program aims to increase. The review process would be strengthened by substantially increasing the number of reviewers from developing countries, who could help ensure that the funded programs are capable of addressing the needs of countries and regions from which trainees are selected. While previous proposal review panels have included individuals with professional experience working in developing country settings, the panelists concluded that it would be preferable to have reviewers who have an “insider’s” perspective on the needs of developing countries and the feasibility of proposed activities. Suggestions for proposal review panelists include:

- Former Bioethics program trainees
- Principal investigators who are not competing during the current RFA cycle
- Bioethics and research ethics experts (such as the panelists for this review) currently working in developing countries

The panel suggested that FIC work with the reviewing IC to set a goal of recruiting 50% of proposal review panelists from developing countries. The Center for Scientific Review could use conference calls and online discussions to make such review panels feasible.

Recommendation 4: NIH should increase the flexibility of the current grants management mechanisms to better meet the needs of foreign awardees.

Several PIs stated in interviews with the Bioethics program review panel that NIH’s current system for distributing grant funds does not meet the needs of grantees in developing countries, particularly those working in institutions with little experience with the NIH grants system. NIH grants funding distribution practices assume that all awardee institutions have robust grants management offices equivalent to those of American institutions, where there is often an entire office set up for compliance with the NIH grants management system. The Bioethics program review panel encourages FIC and NIH to consider revising their policies and procedures to allow alternative funds management mechanisms, especially for developing country institutions, such as:

- Disbursement of funds electronically through wire transfer. In the current system, the NIH mails paper checks via the United States Postal Service to foreign countries with unreliable and occasionally corrupt postal delivery services.
- Use of courier services (e.g., DHL / FedEx) to ensure tracking of parcels and certification of delivery. This option could be used in lieu of electronic disbursement, as a more secure option for paper check delivery than the United States Postal Service offers for developing country institutions.

- Prospective provision of funds rather than “draw down” accounts. In the current NIH system, yearly program funding is set aside in accounts for each grantee, who invoices against the account throughout the year, drawing down the account. PIs expressed that it would save them significant amounts of time and energy to receive their yearly funding as an upfront payment at the beginning of the year, rather than complete constant invoices against an account not under their control. The NIH grants management officer echoed this possibility in his conversation with the review panel, and stated that FIC was working to meet these requests.
- Indicating on each check the intended use of the funds (e.g., the name of the project or grant) would be most helpful. Both NIH staff and several Bioethics program PIs noted that too often their yearly checks had arrived at the grantees’ home institutions with only a grant or project number on them, leaving the institution’s staff confused as to how to proceed with distribution of the funds.

Adoption of such methods as the four described above would reduce the burden on the Bioethics program staff at FIC, the NIH grants management staff, and the grantee PIs in developing country institutions.

Recommendation 5: NIH should provide adequate staffing for this important program.

Multiple interviewees articulated to the review panel the particular challenges faced by this unique, far-reaching program and the resulting burden it places on the FIC Program Officer. All interviewees praised the helpfulness and capability of the Program Officer; they expressed dismay that the program is not sufficiently staffed to carry out important tasks such as: tracking program outcomes; organizing program data collected from individual sites; distributing program information to all Bioethics program stakeholders (including both NIH partners and Bioethics program trainees); and preparing an annual report for the entire program in order to maximize dissemination of program accomplishments and advocate for continued financial support by NIH partners. The lack of staff to carry out these tasks hinders the ability of FIC to inform partners about the accomplishments of the Bioethics program, which in turn will limit the growth or even sustainability of the program due to the upcoming funding constraints anticipated by all NIH Institutes. The panel suggested that the FIC staff search for interns and volunteers, as well as additional paid program staff, to address outstanding program tasks.

III. Partnerships and Communication

The review panelists spoke with a panel of representatives of six NIH partner institutes: the National Center for Complementary and Alternative Medicine (NCCAM), the National Heart, Lung, and Blood Institute (NHLBI), the National Human Genome Research Institute (NHGRI), the National Institute of Dental and Craniofacial Research (NIDCR), the National Institute on Drug Abuse (NIDA), the National Institute of Environmental Health Sciences (NIEHS), and the National Institute of General Medical Sciences (NIGMS).

The panel's interview with the partner institutes revealed that the NIH partners could be better informed about the Bioethics program and its accomplishments as they provide almost half of the program's yearly funding. As discussed in the Strategic Planning Section, the NIH partners were not fully aware of how this FIC program might help them carry out their institute's research mission, and without such evidence, their institutes may be hard pressed to continue funding the Bioethics program. As such, FIC needs to better inform its NIH partner institutes about the program, the accomplishments of its trainees, and its impact as related to the needs and missions of individual institutes. Representatives from the partner institutes expressed to the review panel a recognition by their Institutes that there is a lack of bioethics expertise in the developing world. They agreed that the Bioethics is a cross-cutting and valuable program at the NIH; however, they need to see valid and measurable outcomes from the Bioethics program if they are to continue to support it financially. While this is a young program, it is important to justify and communicate its impact on the developing world to the funding partners. As one partner stated, "there is some value in decentralized programs such as this one, but there needs to be some point of integration at the NIH level. There needs to be more coordination and communication at the NIH level and someone must act as a spokesperson for the cause."

Conversely, Bioethics PIs and trainees were not aware of other NIH programs that were pertinent to their interests and expertise. Better communication would heighten the impact of the Bioethics program, especially in developing countries, and increase support for the program within NIH. For example, alumni of the Bioethics program might collaborate with graduates of other FIC training programs to start new projects in their home countries and regions. One former trainee is already engaged in such an effort, recruiting graduates of the University of KwaZulu-Natal/University of Pretoria program to apply their bioethics training to the work of the Center for the AIDS Program of Research in South Africa (CAPRISA – funded by the NIH's NIAID), where he is the director of the ethics review group. Despite his connections to other Bioethics programs in South Africa, he still discovered other graduates of the Bioethics programs at the most recent Global Forum for Bioethics in Malawi in April 2005. This need for increased communication between FIC and its NIH partners, between PIs, and between Bioethics trainees led the panel to suggest recommendation six:

Recommendation 6: FIC needs to better communicate with partners inside and outside NIH about the program and its accomplishments. Furthermore, Bioethics trainees and PIs need to be informed about other NIH programs and researchers whose needs overlap with their interests and skills and who offer opportunities to have a wider impact.

The panel noted that this communication could come in many forms. Communication between Bioethics trainees and PIs about the program and its accomplishments, including data about the current work and location of past and current trainees, could simply take the form of a master list of all trainees distributed by PIs to each graduate of a Bioethics program. This information would allow trainees to identify collaboration opportunities, provide contacts for building bioethics and research ethics networks, and provide trainees access to the bioethics knowledge of their fellow graduates in times of questions or crises. Communication at the NIH level could take the form of annual reports, annual program meetings, or short seminars featuring Bioethics PIs or past trainees, which would serve to highlight the bioethics and research ethics skills and knowledge provided by Bioethics training that would be useful to the mission and programs of the NIH partner institutes. The panel also noted that this communication would be much more effective if the FIC Director plays a lead role in discussions with other NIH Institutes.

FIC also needs to improve communication with other stakeholders outside NIH and the Bioethics program. These stakeholders include extramural researchers from developed countries carrying out research in the developing world, investigators and research institutions in the developing world, IRBs and bioethics networks in the developing world (such as the Forum for Ethical Research in Asia and the Western Pacific (FERCAP), the Latin American Forum of Ethics Committees in Health Research (FLACEIS), the Forum for Ethics Committees in the Confederation of Independent States (FECCIS) and the Pan-African Bioethics Initiative (PABIN)), organizations building research capacity in the developing world such as the Wellcome Trust, and international agencies such as the World Health Organization. In addition, FIC should support networking events such as the Global Forum for Bioethics. These stakeholders offer opportunities for Bioethics program trainees to start new projects in research ethics and to have a greater impact in developing nations.

IV. Results: Re-entry and Post-Training Activities

Bioethics program trainees have an extremely high rate of return to their home countries (98%), which compares very favorably with other FIC programs.³ This metric is one aspect of measurable success for the program; additional steps should be taken to assure that trainees can continue to carry out work in research ethics after their return to their home countries. As mentioned by one long-term trainee, “this program served as a gateway into the world of Bioethics for me – I will always be working in this field; but, I am early in my career and I need additional support.” The panel felt that it was extremely beneficial for FIC trainees to have the support of their home institution, for re-entry purposes. However, required home institution support should not be made a condition of acceptance into a Bioethics training program, as it might disadvantage certain trainees.

Former and current Bioethics trainees spoke to the panel of a need for various forms of re-entry support: travel grants to present their work abroad, funding for portable computers and Internet connections at their home institutions, scientific journal subscriptions to keep current with the research ethics field, and most importantly unallocated funding to free them from part of their institutional duties in order to complete their Bioethics practica and to apply their knowledge of research ethics in their home country and institution. The panel identified the potential problem that after being trained in the Bioethics program, graduates would be unable to continue their work in research ethics because they lacked start-up funds, administrative support, or release time from teaching and administrative responsibilities. Because of these obstacles, their ethics training might be undone unless FIC makes intensive efforts to promote bridge support or other types of re-entry funding. In many cases, the panel thought that providing qualified trainees with modest amounts of funding for a short period of time would go a long way in launching their careers and building on the successes of the Bioethics program.

Recommendation 7: FIC should consider how to provide bridge funding and career development grants to trainees who successfully complete the Bioethics program.

Although some funding opportunities for re-entry work do currently exist – for example, the Wellcome Trust provides funding for both small and large-scale projects through its Biomedical Ethics Program – the panel identified a serious gap in funding between the end of training and gaining enough practical experience toward applying for support for research or other bioethics activities. Other potential funding organizations are the Bioethics division of the World Health Organization and possibly the Gates Foundation.

The panel suggested that FIC and Bioethics program PIs could provide this support for re-entry in several ways. First, trainees should be directed towards other opportunities for bridge funding, such as one of the organizations mentioned above. Second, individual program PIs should be encouraged or required to develop plans for providing graduates with re-entry or

³ Other FIC programs boast 80% (AIDS International Training and Research Program) and 66% (International Training and Research Program in Population and Health) return rates. The National Science Board, in its publication *Science and Engineering Indicators*, 2004, cites a 55% return for international Science and Engineering trainees.

bridge funding. FIC could assist PIs by providing additional training on how to write grant applications that include a mechanism for re-entry funding and by creating an FIC-sponsored bridge-funding award for which trainees could apply. Third, FIC should consider setting up its own career development program and partnering with other Institutes to do so. This suggestion will probably require FIC efforts toward modifying existing programs such as K01 awards, FIRCA or GRIP awards, and program and center grants.

With the difficulty in modifying existing NIH/FIC programs in mind, the panel spoke with NIH staff. They recognized that this and other programs need mechanisms directed toward re-entry funding, and expressed a willingness to work with the panel's recommendations to create solutions to the problem of inadequate re-entry and bridge support for trainees.

In their conversation with representatives of FIC's six NIH partners that provide funding to the Bioethics program, the panel heard suggestions from several representatives that their Institutes would consider funding fellowship awards for the Bioethics program trainees to work on projects specific to the missions of their institutes and related directly to research ethics. Short- or medium-term fellowships directed exclusively to recent graduated trainees of the Bioethics or other NIH training programs with a strong international training component would be another possible mechanism for the re-entry or bridge funding requested by many Bioethics trainees.

A long-term career development program such as the Bioethics program will only be as successful as the weakest link in each of its trainees' career trajectories. Other NIH training grants, such as the T32 awards, recognize that graduates will need additional support before they can become independent investigators, especially when the trainees come from developing country institutions. As such, the NIH already has in place the K23, Roadmap K12, and other career development awards that work to bridge the gap between completion of initial training and the launching of an independent career. The panel expressed hope that the FIC program staff and Bioethics program PIs will steer trainees to these and other sources of bridge and re-entry funding as well as work to develop additional sources of funding for re-entry practicum projects specific to the Bioethics program in order to maximize the impact of the program at every level.

V. Results: Outcomes and Metrics of Success

As with any NIH program, the Fogarty International Center's Bioethics program needs to be carefully evaluated. However, because of the crosscutting nature and unique goals of the program, the usual metrics for evaluating other NIH training programs will not fully capture the impact of this program. Traditional NIH training programs transfer state-of-the-art knowledge to independent investigators who carry out innovative, rigorous research as judged by publications in high-impact peer-reviewed publications and success in obtaining ongoing research support from NIH and similar organizations. However, the Bioethics program has broader objectives. While aiming to provide advanced knowledge of research ethics to developing country investigators who will go on to carry out research in the model described above, the program is also intended to train individuals who will help build the capacity of IRBs or ERCs in developing countries or who will educate investigators, staff, IRB members, and university and public officials about research ethics. As such, metrics such as publications and ongoing grant support do not apply to trainees building IRB or ERC capacity or providing research ethics training to others in their home countries. The evaluation criteria for this program need to include appropriate metrics to assess these additional goals.

Recommendation 8: FIC and Bioethics PIs need to develop outcome metrics that will adequately describe the success and value of the accomplishments of their trainees, as well as the program accomplishments.

The panel suggested several additional metrics that could help FIC staff assess the Bioethics program's progress towards achieving these additional goals. These suggestions include:

- Consultations and technical advice provided by Bioethics trainees to clinical research projects being carried out in the home country.
- Establishment of local, regional, or national IRBs in the trainee's home country, recommending policies and procedures for these IRBs, and improving their performance.
- Creating new programs to teach research ethics to a variety of stakeholders, including home-country researchers, IRB members and staff, research participants, the public, and university and government leaders.
- Providing information about research ethics to home-country stakeholders through such media as the lay press or local or regional medical publications.
- Invitation to participate in a workshop or a conference presentation – including both first-time and repeat invitations.

FIC and PIs need to collect and present data from their programs in sufficient detail so as to convince people outside the Bioethics program of their value. Thus, a mere listing of consultations to researchers, new research ethics courses or articles in local publications may not be sufficient. Additional information about the impact of these activities is needed to put them in

context. In addition to quantitative measures of accomplishments, PIs and the trainees themselves need to provide qualitative information on the impact of the home-country activities.

The panel emphasized that all stakeholders in the Bioethics program need to recognize that long-term tracking is vital to the program in order to provide timely and thorough information on program outcomes to any interested party. An improved tracking system such as the one described in the management section of this report will assist FIC staff in meeting the Recommendation Eight. The panel noted that an annual report – especially containing data on the impacts made by program trainees in their countries as relating to the projects and missions of the program’s NIH partners – would help build support for the Bioethics program at other NIH Institutes and also catalyze collaborative projects with stakeholders within and outside NIH.

In addition to training, education, and ethics capacity building, curriculum development is another primary goal of the Bioethics program. The panel found evidence from the Bioethics curricula that the courses and experiences developed and implemented by each grantee institution meets the curriculum development goals of the program. In all cases, grantee institutions have developed clearly defined courses, practica, and projects designed to provide state-of-the-art research ethics knowledge to their trainees. The practica offer trainees opportunities to participate in local IRBs, to practice teaching research ethics, or to write a journal article in a mentored setting (Appendix D, Table 5). The practica have been well-received by trainees, and have led to some of the program’s most positive outcomes. Each grantee training program offers trainees multiple chances to evaluate the curricula and experience of the program, and most programs report that they are constantly rated four out of five or higher, and are constantly adapting their curricula to account for comments and suggestions by trainees. The panel looked favorably on these efforts for self-evaluation, and noted that evaluation efforts within individual programs can only strengthen the impact of the programs.

Beyond these general comments, the panel had difficulty evaluating the quality of curricula on paper for a number of reasons. First, instructors describe courses on paper in one way and may teach it in another. Second, what teachers believe they teach does not necessarily correspond to what is learned by students. Third, there are many important experiences that do not fit neatly into the framework of a "curriculum," such as informal networking among participants.

To more fully evaluate curricula, the panel attempted to establish for each program a clear connection between the needs of students, objectives of the courses, formal curricular elements, and measures of outcome. The panel acknowledged that evidence or absence of such a connection does not demonstrate a need to praise or rework a program’s curriculum, as the only accurate measure of curricular success is a thorough outcome assessment with program-specific metrics such as the suggest metrics discussed earlier. Since an outcome assessment was beyond the charge of the panel, panelists made the following recommendation with an eye to a future assessment as well as the continued success of the Bioethics program.

Recommendation 9: Bioethics PIs should make explicit links between the needs of the countries served, the needs of students from those countries, the objectives of the curriculum, the curricular elements, and measures of outcome.

VI. Conclusion

The Fogarty International Center's International Bioethics Education and Career Development Award Program has already made an outstanding contribution to developing capacity in research ethics in the developing world. It has demonstrated the innovation to fund in an area with no significant previous commitments. There continues to be a real and demonstrated need for such training worldwide. The Bioethics program strongly deserves continued support, and the Fogarty International Center needs to obtain funding so that the Bioethics program is able to carry out important additional activities. Despite the challenges of the current NIH financial situation, it is important to find the resources to carry out the important mission of this program. The Panel recommends certain changes to the Bioethics program in order to assist it in meeting the changing needs of research ethics capacity strengthening in the developing world.

Appendix A – Letter to the Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

June 15, 2005

Bernard Lo, M.D.
University of California, San Francisco
Program in Medical Ethics
School of Medicine
521 Parnassus Avenue
Suite C-126, Box 0903
San Francisco, CA 94143-0903

Dear Dr. Lo:

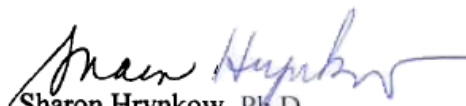
On behalf of the Fogarty International Center (FIC) and our National Institutes of Health (NIH) partners, thank you for your leadership on the panel you recently chaired that reviewed the International Bioethics Education and Career Development Award Program. The report of the panel you have forwarded to me is comprehensive and the recommendations substantive.

It is clear that you and the team gave enormous effort to this task and we are extremely grateful. Be assured that FIC will carefully consider the information and suggestions in the report as we, with our NIH partners, direct the future of the program. Let me add also that your comments and suggestions may also be instructive for other FIC research training programs as well.

I know that these reviews require much time and effort on your part. We depend on outside reviews to help us to strengthen and shape our programs as we go forward. This report will clearly assist us in that undertaking.

Again, thank you and your team for all of your work!

Sincerely,


Sharon Hryn timer, Ph.D.
Acting Director
Fogarty International Center

Appendix B – Review Panelist Profiles

David A. Borasky, Jr., CIP

Mr. Borasky is Immediate Past President of the Applied Research Ethics National Association (ARENA) and serves on the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R). He received his Bachelor of Arts degree from LeMoyne College. A Certified IRB Professional, he is responsible for the management of Family Health International's (FHI) Institutional Review Board. In addition, Mr. Borasky facilitates basic research ethics training for FHI staff collaborators in the field. He helped develop FHI's *Research Ethics Training Curriculum* and *Research Ethics Training Curriculum for Community Representatives*. He has also authored or coauthored articles and book chapters on international research ethics and IRB management and functions. Mr. Borasky is currently leading the implementation of the NIH-funded Collaborative IRB Mentoring Project, which provides support to the IRBs at the University of Zambia and the University of Malawi.

Dr. Dafna Feinholz Klip, MA, PhD

Dr. Feinholz Klip is Planning and Academic Director of the National Commission of Bioethics in Mexico. She is also President and Chairperson of FLACEIS (Latin American Forum of Ethics Committees in Health Research). She received her PhD in research psychology in 1997 from Universidad Iberoamericana in Mexico. She has served as Research and Planning Director of the Women and Health Program, and Academic Coordinator of the National Commission of Human Genome at the Ministry of Health in Mexico. She has been the chairperson of the Latin American Forum for Ethics Committees for Health Research since 2000. Dr. Klip currently teaches in the PhD program at the Psychoanalytic Association in Mexico, as well as at the Medical School at the Universidad Nacional Autónoma de México (UNAM). Her current research interests include gender and health, ethics in research, and reproductive health (especially abortion and unexpected pregnancy).

Bernard Lo, MD (chair)

Dr. Lo is Professor of Medicine and Director of the Program in Medical Ethics at University of California, San Francisco. He is also the Director of the Center for AIDS Prevention Studies Ethics Core. Early in the AIDS/HIV epidemic, his team proposed clinical guidelines for voluntary HIV testing and suggested how advance directives can improve decisions about life-sustaining treatment for incompetent persons with HIV infection. More recently, his group recommended policies on HIV-infected health care workers and on informing physicians about promising new treatments for severe illnesses. His new book, *Resolving Ethical Dilemmas: A Guide for Clinicians*, contains chapters on issues arising in the care of HIV-infected patients, including confidentiality and partner notification, decisions about life-sustaining interventions, assisted suicide, patient requests for interventions, refusal by physicians to care for patients, and transmission of HIV in health care settings. Currently he is working on projects concerning post-exposure prophylaxis in the non-occupational setting and standards for clinical trials in developing countries. Dr. Lo is a member of the Board of Health Sciences Policy of the Institute of Medicine of the Board of Directors of the American Society of Law, Medicine, and Ethics. Dr. Lo will serve as chair of this review panel.

Bella Starling, PhD

Dr. Starling is Senior Project Manager for the Biomedical Ethics Programme of the Wellcome Trust, which funds research in the ethical, social, legal and public policy implications of biomedical science. She coordinates the grant application processes for the Wellcome Trust, including peer-review. She also organizes workshops and meetings to stimulate research areas and encourage debate. Recent events have included ethics in mental health research; pharmacogenetics and ethics; post-trial access to interventions proven to be effective in research in developing countries; and how to get research into policy and practice. In addition, she liaises with the Biomedical Ethics Programme policy unit to put together recommendations on international research ethics policy, bioterrorism and mental health.

Before commencing at the Wellcome Trust, Dr. Starling pursued a career in science publishing, as editor of *Current Opinion in Neurobiology* and *BioMedNet Magazine* - a web-based publication featuring articles on science and society, science policy and careers. Previous to her work in science publishing, she completed postdoctoral research on the genetic differentiation of neural stem cells (a topic she pursued while earning her PhD in Neuroscience from Edinburgh University). Dr. Starling has attended several of the most recent Global Forums on Bioethics, the most recent of which was held in March 2005 in Malawi.

David Thomas Stern, MD, PhD

Dr. Stern is an Associate Professor in the Departments of Internal Medicine and Medical Education at the University of Michigan and Director of Global REACH (Global Research, Education, and Collaboration in Health). Dr. Stern's research interests include international health and medical education, physician professionalism, patient-physician communication, and methods for assessing physician behavior. As Director of Global REACH, he is currently leading the assessment for a project funded by the Institute for International Medical Education to develop and implement an assessment of core competencies of physicians-in-training at the top 8 medical schools in China. He also is actively engaged in developing international collaborations and facilitating rotations for the medical school's faculty, residents, and students.

Angela Amondi Wasunna, LLB, LLM

Ms. Wasunna is the Associate for International Programs at The Hastings Center, New York. She is an Advocate of the High Court of Kenya and received a Bachelor of Laws (LL.B.) degree from the University of Nairobi Kenya in 1996, a Master of Laws (LL.M.) degree with a bioethics specialization from McGill University, Montreal, Canada, and a Master of Laws (LL.M.) degree from Harvard Law School in 2000. Her research and writing interests include health and human rights issues, reproductive law and policy, intellectual property rights, financing of health care in developing countries, ethical issues raised by international research, as well as ethical-legal issues arising from HIV/AIDS. She is a member of the International Bar Association, the Pan African Bioethics Initiative, the Law Society of Kenya, and she is an elected member of the Board of Directors of the International Association of Bioethics.

Ms. Wasunna is currently the principal investigator of a project in East Africa that addresses legal, ethical, and human rights challenges faced by health care workers involved in HIV/AIDS care. She is involved in a Fogarty Institute funded project to build research ethics capacity among medical researchers in Haiti. She is also a principal investigator of an international research project that explores the impact of intellectual property rights (patents) on access to essential drugs in developing countries.

Appendix C – Interviewees

NIH Partners:

- Barbara Sina (Current Program Officer)
- Karen Hofman (FIC)
- Andy Jones (NIH Grants Management Officer)
- Donald Schneider (NIH Center for Scientific Review)
- Richard Anderson (NIGMS)
- Lois Cohen (NIDCR)
- Steve Gust (NIDA)
- Jack Killen (NCCAM)
- Shoba Shrinivasen (NIEHS)
- Susan Schafer (NIAID)
- Ellen Werner (NHLBI)
- Kenneth Bridbord (FIC)

Principal Investigators:

- Richard Cash (Harvard School of Public Health)
- Nancy Kass (Johns Hopkins School of Public Health)
- Nandini Kumar (PI, Indian Council for Medical Research / former trainee, UTJCB)
- Jim Lavery (University of Toronto Joint Centre for Bioethics, Assistant PI)
- Fernando Lolas (Universidad de Chile)
- Ruth Macklin (Albert Einstein College of Medicine)
- Harun-Ar-Rashid (Bangladesh Medical Research Council)
- Peter Singer (University of Toronto Joint Centre for Bioethics)
- Douglas Wassenaar (University of KwaZulu-Natal/University of Pretoria)

Other Experts:

- Zeke Emanuel (Magnuson Clinical Center, NIH)
- Michael Parker (University of Oxford)
- Udo Schuklenk (Glasgow Caledonian University)
- Fabio Zicker (WHO/TDR)

Long-term Trainees:

- Mayra Achio (AECM-former trainee from Costa Rica)
- Anant Bhan (UTJCB-current trainee from India)
- Eduardo Duro (AECM-current trainee from Argentina)
- Julius Ecuru (IRENSA-former trainee from Uganda)
- Aamir Jafarey (HSPH-former trainee from Pakistan)
- Simon Langat (IRENSA-former trainee from Kenya)
- Mantoa Mokhachane (JHSPH-former trainee from South Africa)
- Mohan Nair (UTJCB-former trainee from India)
- Paul Ndebele (SARETI-current trainee from Zimbabwe)
- Esther Nkandu (IRENSA-former trainee from Zambia)
- Wellington Oyibo (SARETI-former trainee from Ethiopia)
- Jerome Singh (UTJCB-former trainee from South Africa)
- Paulina Onvomaha Tindana (JHSPH-former trainee from Ghana)

Appendix D – Supplementary Program Data

Table 1: Number of Short, Medium, and Long-Term Program Trainees

Funding Cycle	Program number	Short-Term	Medium-Term	Long-Term
Funding from 2000 - current	1	197	0	16
	2	575	0	15
	3	63	0	20
	4	0	2	13
	5	0	0	15
	6	35	20	19
Funding from 2002 - current	7	168	38	6
	8	20	1	19
	9	151	0	37
	10	56	80	0
	11	0	0	5
Funding from 2004 - current	12	0	0	0
	13	0	0	2
	14	0	0	0
	15	0	0	0
	16	0	0	0
2004 – 2006 Planning Grants	17	0	0	0
	18	0	0	0
	TOTAL	1265	141	167

Note: Short-term training is defined for the purposes of this table and overall award evaluation as any class, workshop, or training session with duration of equal to or less than one week. Medium-term training is defined as any training with duration greater than one week and less than six months. Long-term training is defined as training with duration greater than six months.

Source: Abt Associates analysis of program data for review panel

Table 2: Geographic Distribution of Trainees by Program.

Program number	Latin America	Africa	Asia	Europe	Total by Program
1	16				16
2		7		8	15
3	1	8	11		20
4			13		13
5		15			15
6		19			19
7			6		6
8	18			1	19
9		37			37
10	0	0	0	0	0
11			5		5
13		2			2
Total by Region	35	88	35	9	167

Note: Program #10 has no long-term trainees. None of the programs with 2004 as their first year of funding other than program #13 has any long-term trainees.

Source: Abt Associates Inc analysis of program data for review panel

Table 3: Examples of Post-Training Bioethics Experiences of Long-Term Trainees.

- A Bioethics program Masters graduate from India, has applied for a Fogarty curriculum development grant under the International Bioethics Education and Career Development award and is currently Program Director of the Indian Center for Medical Research's program, which is funded until 2008.
- An MPH student and certificate program graduate from Nigeria has been appointed as a fellow with the WHO special program for research and training in tropical diseases (TDR). She has been active in setting up and improving standard operating procedures at the IRB in her home university in Nigeria. She is training other research fellows there in research ethics. She is also involved in the review of research proposals regarding ethics research.
- A graduate of a Bioethics certificate program is now a consultant to the National Commission on Bioethics in Ecuador, and is also participating with other Universidad de Chile program graduates in writing an ethics of research handbook.
- A Masters graduate from Romania has developed an ethics course for use in Romania; coordinated an international conference on ethics in April of 2004, and writes and reviews for the Romanian Journal of Bioethics.
- A Masters graduate of the Bioethics program from India is a Steering Committee member of the Asia Pacific Bioethics Network and is part of a team in Mumbai, India including other Fogarty graduates whose focus is the promotion of bioethics and the development of bioethics curricula.
- A graduate of a Bioethics certificate program from Nigeria has participated in IRB meetings at the Federal Ministry of Health in Nigeria, and been involved in the institutional IRB at the National Institute for Pharmacology Research and Development. He was awarded a presidential gold medal for setting up a National Ethics Review Committee in Nigeria.

Source: Abt Associates Inc. analysis of program data for review panel

Table 4: Number of Workshops by Program.

Program Number	Number of ST Workshops	ST Workshop Trainees	Number of MT Workshops	MT Workshop Trainees
1	5	197	0	0
2	7	575	0	0
3	2	63	0	0
4	0	0	1	2
5	0	0	0	0
6	1	35	17	20
7	5	168	1	38
8	1	20	1	1
9	2	151	0	0
10	4	56	8	80
11	0	0	0	0
13	0	0	0	0
TOTAL	27	1265	28	141

Note: Program numbers 5, 11, and 13 hold no short or medium-term training workshops. With the exception of program 13, none of the 2004 programs have published their final workshop curricula or plans and consequently are not included in the table.

Source: Abt Associates Inc analysis of program data for review panel

Table 5: Examples of Practicum Projects by Country of Long-Term Trainees.

Country	Title and project period
Russia	Development and teaching of a course on bioethics, May-June 2002, for St. Petersburg State University
Nigeria	Development of ethical guidelines for research, May-June 2002
Nigeria	Development and teaching of medical humanities course focusing on bioethics, May-July 2003
Romania	Organ transplantation; development of ethics course, May-July 2003
Russia	Development of course in bioethics and psychology, May-July 2004
Romania	Ethical issues in conducting substance abuse research, May-June 2004
Nepal	Interrelationship between household culture, women's autonomy and informed consent
Thailand	Reasoning in decision making to participate in a new anti-HIV drug trial: a hypothetical scenario for HIV positive patients in Thailand.
China	Informed consent issues in clinical research in China
China	The informed consent for medical care of schizophrenic patients in China
China	The influence of Japanese criminal human experiments 1932-45 and the American cover-up on postwar research ethics
China	Stakeholders Perceptions of IRBs in China
India	Stakeholders Perceptions of IRBs in India
China	Assess the Attitudes of Chinese Research Community on Ethical Issues in Collection and Usage of Human Genetic Databases
China	Ethical Review of Research that Might Harm Non-participants in China – The Case of Xenotransplantation
China	Research Ethics Survey and Application of International Ethical Principles and Guidelines for Human Subject Research in Cambodia
Pakistan	Informed Consent: a Perspective from Pakistan

Note: The examples above are representative of the practicum projects undertaken by long-term trainees of each training program. Several projects have applied for and been granted IRB approval by both their host and home institutions.

Source: Abt Associates Inc. analysis of program data for review panel

Appendix E – List of Publications by Program

(Program Trainee names in **bold**)

Program 1

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