Supporting Statement A for

Assessing the Long-term impacts of research and training programs supported by the John E. Fogarty International Center (FIC)

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Contents

A.1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY.....2

A.2. PURPOSE AND USE OF THE INFORMATION.....2

A.3. USE OF INFORMATION TECHNOLOGY AND BURDEN REDUCTION.....2

A.4. EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION.....2

A.5 IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES.....2

A.6. CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY.....2

A.7. SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5.....2

A.8. COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE AGENCY.....2

A.9. EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS.....2

A.10. ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS.....2

A.11. JUSTIFICATION FOR SENSITIVE QUESTIONS.....2

A.12. ESTIMATES OF HOUR BURDEN INCLUDING ANNUALIZED HOURLY COSTS.....2

A.13. ESTIMATE OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORDKEEPERS 2

A.14. ANNUALIZED COST TO THE FEDERAL GOVERNMENT.....2

A.15. EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS.....2

A.16. PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE.....2

A.17. REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE.....2

A.18. EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS.....2

List of attachments

Attachment 1: Consent Form for Participants
Attachment 2: Estimate of hourly rate for foreign researchers
Attachment 3: Interview Guide for US-Based Principal Investigators
Attachment 4: Case Study Questionnaire for FIC Trainees
Attachment 5: Focus Group Discussion Guide for Trainees
Attachment 6: Interview Discussion Guide for Trainees (University-Based)
Attachment 7: Interview Discussion Guide for Trainees (Non University-Based)
Attachment 8: Interview Discussion Guide for University Leaders
Attachment 9: Interview Discussion Guide for Policy-Makers and Scientific Leaders
Attachment 10: Conceptual Framework
Attachment 11: Research Questions

A.1. Circumstances Making the Collection of Information Necessary

The John E. Fogarty International Center (FIC) at the National Institutes of Health (NIH) is dedicated to supporting and facilitating global health research conducted by U.S. and international investigators, building partnerships between health research organizations in the U.S. and abroad, and training the next generation of scientists to address global health needs. FIC currently administers 23 programs, 17 of which are research training programs intended to build research capacity in low and middle income countries by training researchers at organizations around the world. The oldest of these programs, the AIDS International Training and Research Program (AITRP), has trained approximately 1400 researchers since 1988.

While AITRP other FIC programs have been subject to periodic evaluation as individual programs (see for example Adedokun, Baytop et al. 2008), the cumulative impact of FIC support on research capacity building at educational institutions in low and middle income countries has not been evaluated. With a more than 20 year history of investment in international research capacity building, it is widely believed that impacts of FIC research training programs on collaborating organizations have been diverse and significant, but little evidence is currently available to substantiate this claim or to inform future investments by FIC in this area.

The authority to collect this information is under 42 USC 287b.

A.2. Purpose and Use of the Information

This study will use institution-based case studies to develop a comprehensive understanding of the long term impacts of FIC research training programs, including both proximate effects (e.g. professional development and career paths of individual trainees) and broader effects upon organizational capacity, knowledge production, and policy development. An additional goal is to develop and test a set of research methods for assessing long term impacts of research training

programs.

It is anticipated that this study will be used by FIC to inform its understanding of the potential long term impacts of its investments in research capacity building and the mechanisms through which these impacts occur. Such knowledge is essential to strategic planning at the Center level. The information will also be used by individual program staff members to improve planning and management of ongoing research training programs. It is also hoped that the results of the study will inform ongoing debates in the broader global health research community about the channels through which organizational research capacity development occurs and potential strategies for developing centers of research excellence.

A.3. Use of Information Technology and Burden Reduction

The nature of the information to be collected (detailed accounts of personal experiences with FIC programs and their impacts) requires personal interaction with informants via interviews and focus groups. In order to minimize communication barriers due to linguistic, cultural, or technological barriers, the interviews will be conducted in person. A brief written questionnaire will also be distributed to focus group participants. Under ordinary circumstances, information technology such as Computer Assisted Telephone Interviews could be used to facilitate this portion of the data collection, but the fact that the data collection will be conducted in low and middle income country settings with uncertain access to resources such internet access makes a paper-based approach more reliable.

A.4. Efforts to Identify Duplication and Use of Similar Information

Every effort has been made to identify information that can be collected by the contractor rather than from the survey respondents. For example, details such as publication records and NIH funding history will be gathered by the contractor from NIH databases in lieu of requesting this information from the survey respondents. To the extent that it is possible to do so, relevant information will also be

extracted from previous evaluations of the research training programs in question, although it is anticipated that this information will be out of date in most cases.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A.6. Consequences of Collecting the Information Less Frequently

Information will only be collected once per collaborating institution using a case study approach, so frequency of data collection is not a concern. If information is collected for fewer cases than anticipated, the study will still have value for strategic planning and program management. No technical or legal obstacles are anticipated.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The proposed data collection fully complies with all guidelines of 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

As required by 5 CFR 1320.8(d), comments on the information collection activities as part of this study were solicited through publication of a 60 Day Notice in the Federal Register on May 27, 2010 (volume 75, number 102, page 29763). One comment was received from a member of the public. The commenter raised objections to the study on the grounds that: a) in the present economy, tax dollars should not be spent wastefully; and b) tax dollars should not be spent outside the US. The commenter did not address cost and hour burden specifically, and the objections raised appeared to apply more generally to FIC's mission than to the proposed case studies. As such, FIC does not believe the objections can reasonably be accommodated within the context of this study design.

FIC has created an external advisory group for the study, and members are actively being recruited. The advisory group will be consulted on matters related to study design, data collection, analysis, and reporting.

A.9. Explanation of Any Payment or Gift to Respondents

No payment or gift will be made to respondents as a part of this study.

A.10. Assurance of Confidentiality Provided to Respondents

Data gathered as part of this survey will be identifiable by the name of the respondent, but records of individual responses (in the form of interview notes) will be maintained by the contractor and destroyed as soon as each case report is completed. Participants will review and sign a written notice of informed consent (Attachment 1) prior to participation. Participants will be informed that the information they provide will not be disclosed to anyone but the researchers conducting this study except as otherwise required by law, that data collected from them will only be reported by the contractor in an aggregate form, and that their participation is completely voluntary.

This data collection activity is exempt from 45 CFR 46 Regulations for Protection of Human Subjects because: a) the data will be reported in aggregate and therefore participants will not be identifiable directly or through identifiers linked to the subjects; and b) because any disclosure of the human subjects' responses outside the research would not place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Nevertheless, review and approval will be sought from the contractor's Institutional Review Board.

A.11. Justification for Sensitive Questions

This survey does not contain questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Personally Identifiable Information gathers as part of this study will be limited to the names of respondents. As described in A.10, records of individual responses (in the form of interview notes) will be maintained by the contractor and destroyed as soon as each case report is completed. Participants will review and sign a written notice of informed consent (Attachment 1) prior to participation. Participants will be informed that the information they provide will not be disclosed to anyone but the researchers conducting this study except as otherwise required by law, that data collected from them will only be reported by the contractor in an aggregate form, and that their participation is completely voluntary.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

As summarized in Table A.12.1, the estimated number of participants per case study is 105. Data will be collected only once per participant. The expected burden will be one hour per participant for interviewees and two hours for focus group participants. Two case studies will be completed per year for a total annual burden to respondents of 290 hours; FIC is planning a total of 10 case studies over five years for a total of 1450 hours.

An average hourly rate for the foreign researchers was estimated at $13/hr (US). This rate was estimated by obtaining the mid-range salaries for scientists in six low- to middle-income countries where FIC has investments (two countries each in Africa, Asia, and South America) from an internet resource for international salary data (Please see Attachment 2 for more information). For US-based researchers, we estimated an hourly rate of $38.94 (based on an average annual salary of $81,000). As summarized in Table A.12.2, the annualized cost to respondents is estimated at: $4,807.60, and the total cost over five years is $24,038. There are no Capital Costs to report.

As described in A.14, the expected total annual cost to the federal government, inclusive of contractor costs, NIH costs, and expected burden to the public, is $39,037.60**.**

Table A.12.1.Annualized Estimate of Hour Burden

Category of Participant	Expected number of participants per case study	Number of cases per year	Number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
US-based principal investigators (Interviews)	20	2	1	1	40
Case institution trainees (Focus groups and survey)	40	2	1	2	160
Case institution leaders (Interviews)	4	2	1	1	8
Case institution trainees (Interviews)	13	2	1	1	26
FIC grantees at case institutions (Interviews)	20	2	1	1	40
Policy-makers/ scientific leaders in case institution country (Interviews)	8	2	1	1	16
Total	105 per case study*				290

* Because there will be two case studies per year, the total number of participants expected annually will be 210.

Table A.12.2. Annualized Cost to Respondents

	Estimated total annual burden hours requested (based on two case studies per year)	Estimated hourly wage	Estimated annual cost to respondents
US-based principal investigators (Interviews)	40	$38.94	$1,557.60
Case institution trainees (Focus groups and survey)	160	**$13.00**	$2,080.00
Case institution leaders (Interviews)	8	**$13.00**	$104.00
Case institution trainees (Interviews)	26	**$13.00**	$338.00
FIC grantees at case institutions (Interviews)	40	**$13.00**	$520.00
Policy-makers/scientific leaders in case institution country (Interviews)	16	**$13.00**	$208.00
Annual Total	290		$4,807.60

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no Operating or Maintenance Costs to report.

A.14. Annualized Cost to the Federal Government

Total annual cost to the Federal Government for this data collection includes the services of a contractor to collect the data, government staff time to manage and support the contractor, and the cost to respondents described in A.12.

The annual cost for the contractor, including travel costs and the contractor's fixed fee, will be $25,000. This does not include analyses of collected data or preparation of reports.

It is estimated that approximately six weeks of NIH staff time will be associated with the conduct of this study. Using an average salary of $80,000 for NIH staff, this adds $9230 in costs.

Thus, total annual cost to the Federal Government is estimated at $34,037.60 (Table A.14.1).

Table A.14.1. Total Cost Burden of Information Collection

Annualized Cost to Respondents (from A.12.2)	$4,807.60
Annual Cost of Contractor's Services	$25,000
NIH Staff Time	$9230
Total	**$39,037.60**

A.15. Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Planning for this study began in September 2009. Data collection for the first case is expected to begin immediately after OMB approval (expected in November 2010, Table 4). It is expected that approximately six months will be required to complete data collection and qualitative analysis for each case, so the second case will begin approximately six months after OMB approval (May 2011). A

report detailing results from the first two case studies will be due one year after the start of data collection (November 2011). This report will be disseminated to stakeholders within FIC and to the public via the Center's website. It is also hoped that the report will be suitable for publication in a peer-reviewed journal. Two additional case studies will be completed per year for the next four years, with an annual report submitted at the end of each year. The final report, expected in October 2015, will summarize cumulative results.

Table 4: Estimated Project Schedule

Activity	**Time Schedule**
Begin first case study	Immediately after OMB approval (November 2010)
Begin second case study	Six months after OMB approval (May 2011)
Reporting on first year's cases	12 months after OMB approval (October 2011)
Case studies 3 and 4	13-24 months after OMB approval (November 2011- October 2012)
Reporting on second year's cases	24 months after OMB approval (October 2012)
Case studies 5 and 6	25-36 months after OMB approval (November 2012- October 2013)
Reporting on third year's cases	36 months after OMB approval (October 2013)
Case studies 7 and 8	37-48 months after OMB approval (November 2013- October 2014)
Reporting on fourth year's cases	48 months after OMB approval (October 2014)
Case studies 9 and 10	49-60 months after OMB approval (November 2014- October 2015)
Reporting on fifth year's cases and final summary reporting	60 months after OMB approval (October 2015)

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exceptions are sought; the OMB Expiration Date will be displayed on the survey instruments.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are sought from the Paperwork Reduction Act or from form 83-I.