Supporting Statement A for

**Feedback Survey for the Brain Disorders in the Developing World Program of the John E. Fogarty International Center (FIC)**

 Date: May 31, 2013

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**List of attachments**

Attachment 1: Text of welcome page and informed consent statement for awardee survey

Attachment 2: Estimate of hourly rate for foreign researchers

Attachment 3: Invitation to participate in the awardee survey

Attachment 4: Awardee survey instrument (US/HIC version)

Attachment 5: Awardee survey instrument (LMIC version)

Attachment 6: Reminder email for survey non-respondents

# 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 issued the first call for proposals for the Brain Disorders in the Developing World: Research Across the Lifespan program (referred to throughout this statement as “Brain Disorders program”) in November 2002. The purpose of the Brain Disorders program is to develop collaborative research and capacity building projects on brain disorders throughout life relevant to low- and middle-income countries. Applicants are expected to develop innovative, collaborative research programs that would contribute to the long-term goal of building sustainable research capacity in nervous system function and impairment throughout life. Between FY 2003 and 2012, a total of 148 awards were made under the Brain Disorders program, and the total investment by FIC and its partners at NIH has been approximately $75 million.

There are several features of the Brain Disorders program that make it a unique and important component of FIC’s extramural award portfolio:

* In support of FIC’s current strategic priorities, the Brain Disorders program focuses on strengthening capacity for chronic disease research in the developing world in an area that many experts believe is particularly underdeveloped relative to its contribution to morbidity and mortality;[[1]](#footnote-1)
* The Brain Disorders program relies on a funding model that is unusual at FIC, making a relatively large number of awards using the Exploratory/Developmental Research Grant Award (R21) mechanism and then offering awardees an opportunity to compete for larger Research Project Grant Program (R01) awards under a dedicated solicitation;
* The program has successfully leveraged an a large amount of co-funding from partner Institutes and Centers at NIH, greatly increasing its potential impact from what would be possible using FIC funds alone.

Investigation is warranted to further understand whether and how the Brain Disorders program has contributed to furthering FIC’s strategic goals as well as whether and how the models and strategies employed by this program could be applied in other contexts. Furthermore, it is FIC policy to review each of its programs for effectiveness at the five year mark and to conduct a more in-depth evaluation after 10 years; Brain Disorders is currently approaching its 10 year anniversary.

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

# A.2. Purpose and Use of the Information

The findings of this evaluation study will provide valuable information concerning: (1) whether and how the program has met its goal of supporting research and research capacity-building on brain disorders in low- and middle-income countries; (2) the extent to which the program as implemented functions efficiently and effectively; (3) opportunities to improve upon the current implementation of the program; (4) the extent to which the program is consistent with the strategic priorities of Fogarty and its partners at NIH; and (5) models, best practices, and lessons learned that may be applicable to other FIC programs, now and in the future.

It is anticipated that the results of this study will be used by FIC in planning for the future of the Brain Disorders program and to determine whether the Brain Disorders funding model could potentially be applied in other contexts. The information will also be used by individual program staff members to improve planning and management of the Brain Disorders program.

# A.3. Use of Information Technology and Burden Reduction

In order to minimize burden, web-based surveys will be employed to collect information from awardees and program participants in a standardized fashion.

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

Every effort has been made to identify other sources of information about the Brain Disorders program that can be mined for information rather than collected via the proposed survey. Such sources include NIH enterprise databases (for publications, award details, and the funding history of participants), applications for funding (for details about the awardees and the proposed project), and the annual and final progress reports submitted annually to FIC (for research and capacity-building outputs). Where feasible, survey respondents will be asked to review and verify or elaborate on partial information available from other sources rather than reproducing it from scratch.

# 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.

# 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 April 2, 2013 (78 FR 19723). No comments were received.

Since the proposed data collection is a feedback survey for a specific FIC program, there are few individuals outside of the agency with relevant knowledge. However, FIC has consulted extensively with a contractor with ample experience conducting program evaluations for NIH. FIC is also creating 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 study will be identifiable by the name of the respondent. Records of individual responses will be maintained by the contractor and destroyed once the feedback survey is complete. Survey participants will be asked to review and acknowledge a statement of informed consent as the initial page of the web-based survey form (see Attachment 1 for relevant text only; also included in Attachments 4 and 5). Briefly, the consent statement will inform participants that any 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 in the study 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

The data collection instruments for this study do not contain questions of a sensitive nature or regarding matters that are commonly considered private.

Personally Identifiable Information gathered as part of this study will be limited to the names of respondents and their educational and employment history as relevant to research capacity-building by the Brain Disorders program. 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 the feedback survey is completed. All participants will review and acknowledge a statement of informed consent (Attachment 1) prior to participation.

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

As summarized in Table A.12.1, assuming an 80% response rate, the estimated number of survey responses will be 211. The frequency of response is once. The total annual burden to respondents (and total burden of the study, since data will be collected only once) will be 123 hours, and the study will be complete in one year.

An average hourly rate of $38.94 was used to calculate cost for researchers in the US or other high-income countries (based on an average annual salary of $81,000). An average rate of $13/hr (US) was used for researchers in low and middle income countries. 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 (see Attachment 2 for details). As summarized in Table A.12.2, the annual (and total) cost to respondents is estimated at $3,098.12. 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 $62,328.12.

**Table A.12.1.Annualized Estimate of Hour Burden**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Type of Respondent** | **Number of Responses (Invited)** | **Response Rate (Expected)** | **Number of Responses (Expected)** | **Frequency of Response** | **Average Time per Response** | **Annual Hour Burden** |
| Awardee Survey (LMIC) | 139 | 8/10 | 112 | 1 | 35/60 | 65 |
| Awardee Survey (US and HIC) | 123 | 8/10 | 99 | 1 | 35/60 | 58 |
| **Total** |   |   | **211** |   |   | **123** |

**Table A.12.2. Annualized Cost to Respondents**

|  |  |  |  |
| --- | --- | --- | --- |
|   | **Estimated total annual burden hours requested** | **Estimated hourly wage** | **Estimated annual cost to respondents** |
| Awardee Survey (LMIC) | 65 | $13.00  | $849.33  |
| Awardee Survey (US and HIC) | 58 | $38.94  | $2,248.79  |
| **Total** | **123** |   | **$3,098.12**  |

# 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 $50,000. 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 $62,328.12 (Table A.14.1).

|  |
| --- |
| **Table A.14.1. Total Cost Burden of Information Collection** |
| Annualized Cost to Respondents (from A.12.2) | $3,098.12 |
| Annual Cost of Contractor’s Services | $50,000  |
| NIH Staff Time | $9,230  |
| **Total** | $62,328.12  |

# 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

The results of this feedback survey will be written up as a narrative report with FIC and other NIH stakeholders as the primary target audience. A version of the report deemed suitable for public release will eventually be published on the FIC website.

Quantitative and semi-quantitative responses to the survey questions will be tabulated and cross-tabulated. Descriptive statistics will be calculated to characterize response patterns. Analytic statistics may be calculated as appropriate to answer specific questions about whether and how responses differed between subgroups (especially between HIC and LMIC respondents). Data from open-ended survey questions will be coded and analyzed using standard qualitative methods.

Planning for this study began in September 2012. Review and analysis of administrative data is ongoing. Survey data collection will begin immediately after OMB approval (expected in August 2013, Table A.16.1). The data collection phase is expected to last approximately two months, followed by one month of analysis and an additional month to develop a final report. The entire feedback survey will be complete by the end of the 2013 calendar year.

|  |
| --- |
| **Table A.16.1: Estimated Project Schedule** |
| **Activity** | **Time Schedule** |
| Review and analyze data from administrative sources; Conduct interviews with NIH employees | March-May 2013 |
| Field survey and conduct awardee/trainee interviews | Immediately after OMB approval (estimated: August 2013) |
| Complete data collection | 2 months after OMB approval (estimated: September 2013) |
| Complete data analysis | 3 months after OMB approval (estimated: October 2013) |
| Complete final report | 5 months after OMB approval (estimated: December 2013) |

# 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.

1. For example, see Disease Control Priorities in Developing Countries (2nd edition), published April 2006, available online at: <http://www.dcp2.org/pubs/DCP> (accessed May 31, 2013). [↑](#footnote-ref-1)