Supporting Statement A For:

Progress Reports for Center for Global Health's Low and Mid - Income Countries (LMICs) Global Health Collaborations

(NCI)

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Paul C. Pearlman, Ph.D.
Center for Global Health
National Cancer Institute

9609 Medical Center Dr.
RM 3W550
Rockville MD, 20850

Telephone: 240-276-5354
Email: paul.pearlman@nih.gov

Table of Contents

LIST OF ATTACHMENTS

Attachment 1: Progress Report Forms
1A. 6 Month Report
1B 12 Month Report

Attachment 2: Privacy Act Memo

Attachment 3: Notification Letters for Scientific Progress Reports
3A. Notification Letter 6 Month
3B. Notification Letter 12 Month

ABSTRACT

This is a request for a new clearance for the Center for Global Health's (CGH) Low and Mid - Income Countries (LMICs) Global Health Collaborations. The CGH LMIC Global Health Collaborations are part of a pilot initiative and partnership, between the National Cancer Institute CGH and the Office of Cancer Centers (OCC), to promote collaborations between the NCI designated Cancer Centers and foreign institutions from Low and Middle Income Countries (LMICs). This collaboration is designed to develop and implement mutually beneficial global cancer research programs by increasing the capability of these countries to participate and partner in cancer research. The proposed guidelines, as outlined in the Request for Proposals for Pilot collaborations with LMICs in Global Cancer Research or Global Health Research at NCI-Designated Cancer Centers announcement, request information about award performance related to objectives, accomplishments, barriers and challenges, collaborators, and findings. The information is gathered six months into the award and 12 months after the award (upon expiry). This information is needed to monitor the performance of this special program within NCI, funded through three Requests for Proposals (RFPs); the first was released April 18, 2013 and CGH expects to release another in 2014 and the final one in 2015. The respondents are the Principal Investigators of the awards. The information will be used to monitor individual award performance and the effectiveness of the program as a whole. Since these projects are funded through the contract mechanism, the PIs will not be required to submit interim and final progress reports like other National Institutes of Health grantees must.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

Cancer is a leading cause of death worldwide with a disproportionate burden occurring in low- to moderate-income countries (LMIC). It is estimated by 2020, new cancer cases will reach more than 16 million globally and the majority of this burden will be borne by residents of LMICs. There is a clear need for research that draws from diverse regions of the world to better address global cancer burden. Evidence from this research will help populations not only in LMICs but also in the US.

The Center for Global Health (CGH) LMIC Global Health Collaborations are part of a pilot initiative and partnership, between CGH and Office of Cancer Centers (OCC) to promote collaborations between the National Cancer Institute (NCI) designated Cancer Centers and foreign institutions from LMICs. This collaboration is designed to develop and implement

mutually beneficial global cancer research programs by increasing the capability of these countries to participate and partner in cancer research. This includes the critical development of clinical trials networks and advanced technology centers, and increasing the number of trained personnel to deliver state of the art prevention, treatment, and cancer care to patients. By enhancing cancer research efforts in these countries, it is expected that the NCI-designated Cancer Centers would strengthen their collaborations that would lead to further enhancement of the foreign programs. It is also expected that this initiative could improve prevention and treatment strategies for all cancer patients, based on new findings and discoveries, both in the US and abroad. CGH has a programmatic and research subcontracting support from Leidos Biomedical Research, Inc. to support the first Request For Proposal (RFP) and may employ them for the second two RFPs.

The CGH LMIC Global Health Collaborations awards are made in response to three Request for Proposals (RFPs) using the contract mechanism. The first RFP was released April 18, 2013 and CGH expects to release the second in 2014 and the third in 2015. The use of the contract mechanism means that the CGH LMIC Global Health Collaborations are funded by set-aside funds that are separate from the general pool of research program grant (RPG) funds used to support investigator initiated research at NIH. The use of the set-aside funds indicates that the area is a programmatic priority for CGH/NCI and reflects programmatic interest beyond that for a typical RPG award, as does the use of contract mechanism. The CGH LMIC Global Health Collaborations awarded under the first RFP are administered by Leidos Biomedical Research, Inc. on behalf of CGH and OCC. Leidos Biomedical Research, Inc. will review the reports, share them with CGH staff, and create summary reports and recommendations. The awards made under the second and third RFPs may also be administered by Leidos Biomedical Research, Inc.,

or they may be directly administered by CGH and/or OCC. Whoever is responsible for the administration of the awards under the second and third RFPs will also be responsible for reviewing the reports, ensuring that CGH staff has access to these reports, and creating summary reports and recommendations.

These collaborations are expected to leverage the scientific expertise and leadership in cancer control, prevention or treatment of the NCI-designated cancer centers in order to promote cancer research and increase research capacity in LMICs. In keeping with CGH's emphasis on follow-up and sustainability, progress in these areas (sustainability, training, and collaborations) in addition to scientific achievement as measured by progress towards specific aims, is monitored through the use of program specific progress report guidelines.

NCI typically dispenses funds to awardees on a yearly basis, following programmatic and administrative review and approval of annual progress reports submitted by awardees. NIH uses PHS 2590 form for progress reports and now has transitioned to the Research Performance Progress Report (RPPR) (OMB No. 0925-0002, Expiration Date 8/31/2015). The CGH LMIC Global Health Collaborations were not awarded through the grants mechanism, rather they were awarded using the contract mechanism and therefore do not use this yearly reporting system. Additionally, the CGH LMIC Global Health Collaborations require progress reports to be filed every six months, and the RPPR system does not currently support reporting filed with frequency greater than once a year. This necessitates the use of the attached program specific progress report guideline to collect information on award performance, including the program specific information outlined above.

Section 410 of the Public Health Service Act (42 USC *§* 285), authorizes collection of this information, as outlined in Special Authorities of the Director – Sec. 413. [285a-2]. Section

413 authorizes the NCI Director to collect and disseminate (including through publications) to clinicians and the general public information on cancer research, diagnosis, prevention and treatment.

Monitoring progress and achievements is necessary to ensure that awardees are on track to reach program goals and that the intent and requirements of the RFP are being met. Evidence that program goals are not being met (e.g., missed objectives or a lack of collaboration) are used by Leidos Biomedical Research, Inc. (or CGH or OCC, depending on who is administering the awards) to open discussions with investigators on how to adjust their research or collaboration plans to improve performance in these areas. Reporting every six months allows these adjustments to be made quickly enough to prevent serious shortcomings. Strong performance by awardees is used to inform best practices and identify areas that could benefit from shared activities. Close scientific engagement with awardees is a feature of contracts and enables program staff to identify research areas or issues of shared difficulty or high potential reward. Program staff can then organize discussions or projects to confront or exploit these areas. Up-to-date knowledge of challenges in the development of cancer research collaborations in LMICs is also crucial to fulfilling the programmatic goal of promoting cancer research and increasing research capacity in LMICs.

The information collected in the progress report guideline can also be used for program evaluation and performance analysis. Although no formal evaluation components currently exist, program performance, including success of the development of collaborations and scientific findings, will be assessed prior to the end of the program, as part of institute deliberations on the continuation of the CGH LMIC Global Health Collaborations.

A.2 Purpose and Use of the Information

The current proposal is for the collection of information to monitor progress by investigators funded through the CGH's Request for Proposals for Pilot collaborations with LMICs in Global Cancer Research or Global Health Research at NCI-Designated Cancer Centers. Notification letters, (**Attachment 3A-3B),** will be sent by a Leidos Biomedical Research, Inc. representative containing Scientific Progress Reports at 6 and 12 months, respectively. Each report will be prepared by the principal investigator of the award. The 6- and 12-Month Scientific Progress Reports consist of information already known to the investigator, which has not previously been gathered and submitted to the program office or made public. Much of the information is specific to the requirements of this program. Information to be collected includes:

- Collaborators
- Brief description of project topic
- Accomplishments
- Barriers and challenges
- Budget utilization justification
- Other feedback
- Resources generated*
- Patient/specimen accrual*
- Benefits of infrastructure development*
- Publications*
- Future plans*
- New collaborations*

*This information will only be collected in the 12 month report.

Review and Use of Submitted Information

The currently proposed progress report guidelines are intended to monitor performance in those areas that CGH considers to be of greatest importance in building and sustaining successful collaborations in LMICs. The reports will help CGH understand investigators progress and experiences with these awards (e.g., the ease with which they were able to form collaborations to pursue these projects, the strength of research results from these projects), so that CGH can better design programs in the future to effectively encourage collaborations. Promotion of successful collaborations with LMICs is a particular priority for CGH research programs.

Progress reports are reviewed by Leidos Biomedical Research, Inc. staff, or CGH or OCC depending on who is administering the awards. Once they have reviewed the reports, staff may contact investigators with questions or comments regarding scientific details or programmatic matters. Examples include asking investigators about specific objectives that have not been met, providing help to an investigator to address challenges to patient recruitment, and having discussions on amendments to specific aims or milestones in response to unexpected scientific developments or difficulties in performing experiments. These interactions between staff and investigators also allow investigators to better leverage the shared body of knowledge existing in the CGH LMIC Global Health Collaborations program. For example, reported difficulties in developing a platform to share electronic training may allow staff to share platforms being used by other awardees, or even a potential collaboration between different awardees to combine and share their materials on a single platform.

The 6 Month report **(Attachment 1A)** and the 12 Month report **(Attachment 1B)** are fundamentally identical, except for the fact that the 12 month report also requests an overview of the partnership and the project including all resources, status of patient/specimen accrual,

description of the benefits and impacts of all infrastructure, publications, future plans and new collaborations. This additional question was not included at the 6 month report because the projects will not have been completed at that point. The responses will be used to evaluate the outcomes of the program in order to ensure that participants are utilizing the resources being provided to them and that the goals of the program are being met. Evidence that program goals are not being met (e.g., lack of new partnerships or failure to meet objectives) may be used by program staff to initiate discussions on how to adjust the RFPs to improve performance. Strong performance by participants is used to inform best practices and identify areas that could benefit from shared activities.

A.3 Use of Improved Information Technology and Burden Reduction

The interim reports are completed and saved as a PDF by the principal investigators then sent, via e-mail, to Leidos or the administering office for review and eventual submission to CGH (if not directly submitted to CGH). As mentioned in Section A.1, no system for regular reporting for contracts exists. No automated or dedicated IT system will be used for these reports.

A consultation with the NCI Privacy Act Coordinator is being conducted to determine whether a Privacy Impact Assessment (PIA) is necessary for this project. If so, then a PIA will be completed.

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

Typically awards made through contracts do not require any regular reports. The interim and final report proposed here will not duplicate any existing information collection, since this collection doesn't occur now. The information proposed here is not publicly available and cannot be gathered from other sources. CGH has consulted the PHS 2590 and the PRA liaison

office at NIH, and the information to be gathered through the proposed guidelines is not collected in existing reports and cannot be collected in a twice-yearly basis using the currently existing NIH reporting tools.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

A.6 Consequences of Collecting the Information Less Frequently

The proposed information collection will occur 6 months into the award and at the end of the award (12 months post award). Information is collected on that time table to allow the Leidos and CGH to monitor and adequately manage performance in individual awards and interactions between awards. In particular, these awards include objectives in addition to specific aims, and progress towards objectives is monitored closely. In the absence of the information provided by the reports, Leidos and CGH will not be able to judge progress towards objectives or assist in overcoming difficulties in meeting them. Inability to collect this information will also hamper the program office's ability to make informed decisions regarding funding similar programs in the future.

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

None of the special circumstances relating to the guidelines of 5 CFR 1320.5 applies to this information collection, and the proposed guidelines fully comply with 5 CFR 1320.5.

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

The 60-Day Federal Register Notice soliciting comments on this study prior to initial submission to OMB was published on July 28, 2014, Vol. 79, P. 43755. No public comments were received.

There have been no efforts to consult outside the agency.

A.9 Explanation of Any Payment or Gift to Respondents

There will be no payments or gifts to respondents.

A.10 Assurance of Confidentiality Provided to Respondents

Personally identifiable information will be collected. Information related to awardees' scientific progress, interactions with partner organizations and collaborators, and success in leveraging their awards to raise additional funds will be included in the report. Information will be collected by and seen by Leidos Biomedical Research, Inc. and OCC and CGH staff members. Information in reports will not be shared with anyone outside of Leidos Biomedical Research, Inc. and NIH. Electronic files will be kept on password protected Leidos computers and government computers. The data collection is covered by NIH Privacy Act Systems of Record Notice (SORN) #09-25-0036, "Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH". This SORN was published in Federal Register on 9/26/2002, Vol. 67, p. 60742.

A.11 Justification for Sensitive Questions

There are no sensitive questions included in the proposed guidelines.

A.12 Estimates of Annualized Burden Hours and Costs

The 6 month report is estimated to take 1.5 hours per report **(Attachment 1A)** and the 12 month report **(Attachment 1B)** is estimated to take four hours per report since it requires an additional overview that is not required by the 6 month report. These estimates include time to gather information, most of which should already exists (e.g., records of patient recruitment, accomplishments, publications, etc.) but some of which may be collected from other members of the collaborations (e.g., progress on specific objectives). The estimate is based on the time

necessary to complete the reports (**Attachments 1A-1B)**. In many cases, we expect the time to prepare to be significantly shorter, since similar narratives will be prepared by the investigators for grant applications, research group homepages and internal reports, but the estimates given should be sufficient even for a report that does not copy narrative from other sources. The annualized estimate of respondent burden is 83 hours to complete each report once a year for 15 respondents (Table A.12-1). This amounts to 83 hours annually and 249 hours over three years of information collection.

The annualized cost to the respondents is $3,578.85 using an estimated value of the principal investigators' time of $43.38/hr, which amounts to a total of $10,736.55 over three years (Table A.12-2). The mean hourly wage rate was calculated using the occupation "medical scientists except epidemiologists", occupation code 19-1042, from the Bureau of Labor Statistics most recent data at http://www.bls.gov/oes/current/oes_nat.htm#19-0000.

A.12 - 1 Estimates of Annual Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Time per Response (in minutes)	Total Burden Hours
Principal Investigators	6 Month Report	15	1	90/60	23
Principal Investigators	12 Month Report	15	1	240/60	60
Total		**15**			**83**

A.12 - 2 Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Total Annual Burden Hours	Hourly Wage Rate*	Total Annual Respondent Cost
Principal Investigators	15	83	$43.38	$3,600.54

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs to respondents other than their time to participate.

A.14 Annualized Cost to the Federal Government

The cost of this information collection to the federal government arises entirely from the labor of program staff and contractors spent on the development of the reports and then on the review of the reports. Review includes time spent reading the report and possible follow up contact with investigators for clarification on answers provided in the report. Although data from the reports will be used in program evaluations, program evaluation will occur whether or not this information is collected, and use of the reports in evaluation studies will not result in additional costs to the government. In fact, the collation of information in reports will decrease the cost of gathering data for use in evaluations. There will be a small amount of additional labor arising from curation of the report data into databases (e.g., training, recruitment, etc.) for use by Leidos staff to monitor and evaluate program activities.

We estimate that all work on the review and storage of reports submitted in response to the proposed guidelines will require approximately 100 contractor hours annually, spread between 5-6 contractors, at an average hourly rate of $72.00, for a total of $7,200/year for both years that we expect to gather this information. Federal costs are based on labor. NCI personnel are needed to review the reports provided by the contractors to program staff requiring 40 hours/year, of a program official, at a GS13 step 1 level ($89,924 or hourly wage of approximately $43.23), for a total of $1,729.20 per year for both years that we expect to gather this information. The total cost of this collection, review, and analysis is estimated to be $8,929.20/year for each of the two years we expect to gather the information.

Table 14-1 Annual Cost to the Federal Government*				
	HOURS	**HOURLY WAGE RATE**	**ANNUAL COST**	**TOTAL COST**
Contractor Costs	100	$72.00	$7,200.00	$14,400.00
NCI Personnel Program Official GS 13/1 ($89,924)	40	$43.23	$1,729.20	$3,458.40
Total			$8,929.20	$17,858.40

A.15 Explanation for Program Changes or Adjustments

This is a new information collection.

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

Information on collaborators, accomplishments, publications, etc. will be tabulated and basic descriptive statistics will be calculated (e.g. number of persons trained, percentage of objectives met, etc.) for use in program evaluations. Informal review of the information will be done after each information collection, to monitor program progress in real time, with a formal program evaluation planned during the year following initial collection of the data. The small size of the dataset for this information precludes statistical analysis of these data. However, the information will be analyzed qualitatively to compare program outcomes with goals.

Although the primary purpose of this information collection is to understand why these programs have or have not been successful, data from these evaluations may be used for publications. These publications would not generalize findings to other programs.

The interim report is filed 6 months after the award and final report 6 months after the interim. The project time schedule (Table A.16-1) represents a 6-month time frame and then is repeated 6 months later for the final report.

Table A.16-1 Project Time Schedule

	Months after OMB approval			
	Month 1	Month 2	Month 3	Month 4
Obtain responses from investigators				
Review of responses				
Tabulation and analysis of responses				
Summarize results				

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

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

The proposed guidelines for program specific progress reports for CGH LMIC Global Health Collaborations reports do not require any exceptions to the Certification for Paperwork Reduction Act Submissions (5 CFR 1320.9)