

Supporting Statement A for

New Assessment of NHLBI's Global Health Initiative Collaborating Centers of Excellence

OMB# 0925-NEW

Date: 08/2015

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Table of Contents

A.	JUSTIFICATION.....	3
A.1	Circumstances Making the Collection of Information Necessary.....	3
A.2	Purpose and Use of the Information Collection.....	5
A.3	Use of Improved Information Technology and Burden Reduction.....	7
A.4	Efforts to Identify Duplication and Use of Similar Information.....	7
A.5	Impact on Small Businesses or Other Small Entities.....	7
A.6	Consequences of Collecting the Information Less Frequently.....	7
A.7	Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....	8
A.8	Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....	8
A.9	Explanation of Any Payment of Gift to Respondents.....	8
A.10	Assurance of Privacy Provided to Respondents.....	9
A.11	Justification for Sensitive Questions.....	10
A.12	Estimates of Hourly Burden Including Annualized Hourly Costs.....	10
A.13	Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....	11
A.14	Annualized Cost to the Federal Government.....	12
A.15	Explanation for Program Changes or Adjustments.....	12
A.16	Plans for Tabulation and Publication and Project Time Schedule.....	12
A.17	Reason(s) Display of OMB Expiration Date Is Inappropriate.....	13
A.18	Exceptions to Certification for Paperwork Reduction Act Submissions.....	13
Appendix A: Westat IRB Exemption Letter.....		14

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Center for Translation Research and Implementation Science (CTRIS) was established within the National Heart, Lung, and Blood Institute (NHLBI). In accordance with the legislative authority of NHLBI as stated in 42 U.S. Code § 285b, CTRIS plans, fosters, and supports integrated and coordinated research to understand multifactorial processes associated with translating evidence into practice. In particular, CTRIS focuses on late phases of translation research, known as the "T4" phase, for rapid and sustained adoption of effective interventions relating to heart, lung, and blood diseases in real world settings (<http://www.nhlbi.nih.gov/about/org/ctris>).

Within CTRIS, the Health Inequities and Global Health Branch serves as the NHLBI focal point for advice and guidance heart, lung, and blood research pertaining to health inequities, domestically and globally, including:

- identifying gaps and needs as well as research opportunities to address them;
- supporting the strategic development of "T4" translation research and implementation science in the global arena;
- representing the NHLBI to other governments, other Federal Departments and agencies, other NIH Institutes and Centers, international organizations, and the private sector on global health issues;
- developing strategy positions related to the determinants of health inequities and global health and facilitates the involvement of the Public Health Service in support of these positions and in collaboration with other agencies and organizations; and
- providing leadership and coordination for bilateral programs with selected countries, in support of Presidential and Vice Presidential initiatives within the Executive Branch.

The Health Inequities and Global Health Branch within CTRIS requests approval of a Paperwork Reduction Act (PRA) clearance to conduct an outcome evaluation of NHLBI's Global Health Initiative Collaborating Centers of Excellence (to be referred to as the NHLBI GHI COE program).

According to the World Health Organization (WHO), non-communicable diseases (NCDs) (e.g., cardiovascular diseases, cancers, diabetes, and chronic respiratory diseases) cause 35 million deaths each year—60% of all deaths globally — with 80% of deaths due to NCDs occurring in low- and middle income countries (http://www.who.int/chp/chronic_disease_report/media/impact/en/index.html). To

address the problem, the NHLBI collaborated with the UnitedHealth Group (UHG) to support a global network of centers of excellence (COE) to combat non-communicable chronic cardiovascular and pulmonary diseases (CVPD) in developing countries. Funded under a broad agency announcement from 2009-2014, each COE collaborated with research organizations in developed countries (developed country partners or DCPs) to build research and training infrastructures and to enhance capacity to conduct population-based or clinical research to monitor, prevent, or control CVPD.

The long term goal of the NHLBI GHI COE program was to contribute to a reduction in the incidence and prevalence of chronic CVPDs in low- and middle-income countries (LMICs) by 2030, by catalyzing and supporting a global network of biomedical research centers that conduct collaborative research and train researchers. In total, the program comprised 11 COEs and primary DCPs with activities in more than 20 LMICs. Additional information about the COEs can be found here:

<http://www.nhlbi.nih.gov/about/globalhealth/centers/index.htm>.

The specific program objectives of the NHLBI GHI COE include:

- Train LMIC researchers capable of independent research in CVPDs during the award period;
- Develop sustainable research and research training capacity of LMIC institutions in CVPD research during the award period;
- Advance information about the prevention and treatment of chronic CVPDs in LMIC populations during the award period; and
- Understand sustainability within and across NHLBI COEs. Note: Sustainability is an overall implicit objective of the program.

NHLBI has contracted with Westat to conduct an **outcome evaluation** of the NHLBI GHI COE program to examine the extent to which the program achieved its intended objectives in developing sustainable research and research training capacity, and advancing information about the prevention and treatment of chronic non-communicable CVPD in LMIC populations. The outcome evaluation will utilize a mixed-methods approach to comprehend each COE's processes, short term outcomes, and sustainability outcomes/efforts. Specifically, the evaluation will involve triangulating quantitative data sources (e.g., archived systematic reporting data), and qualitative data sources (e.g., archival data and key informant interview data). Data collected will be used to develop a Case Study report for each COE outlining their experience with implementing their program as well as a comprehensive cross-site Lessons Learned Report describing knowledge and experiences from the overall program, including similarities and differences across a variety of project settings and conditions.

Data collection efforts relevant to this PRA application will be limited to one-time telephone interviews with key informants from COEs and DCPs (i.e., COE principal investigators, COE trainees, COE training directors, and DCP staff) to solicit contextual information pertaining to outcome attainment across the four program objectives. This clearance will enable the evaluators to conduct in-depth qualitative interviews with key informants from COEs. Information regarding the status of research studies, dissemination activities, and training and mentoring activities will be collected through archival data (e.g., status reports, meeting minutes). Interview data, however, will allow the study team to identify contextual themes that cannot be obtained through archival data sources, such as synergies between program partners, facilitators and barriers to implementation and sustainability, perceptions of the value added of the NHLBI GHI COE program, and information regarding achievements and challenges across the four program objectives. Findings from interviews will be incorporated into the Case Studies report and Lessons Learned report, which will be used by CTRIS to inform NHLBI and NIH stakeholders about structural issues relevant to planning both global and domestic biomedical research and training programs with diverse operational conditions and challenges. Additionally, COEs may utilize the Case Studies report as a marketing tool to attract additional funding and media coverage.

A.2 Purpose and Use of the Information Collection

The proposed one-time telephone interviews with key informants is fundamental to the evaluation of the NHLBI GHI COE program, as it will provide information needed to provide a comprehensive assessment of the extent to which the program achieved its intended objectives in developing sustainable research and research training capacity, and advancing information about the prevention and treatment of chronic non-communicable CVPD in LMIC populations. Specifically, a total of 36 interviews will be conducted (i.e., 9 COE PIs, 9 COE Training Directors, 9 COE Trainees, 9 DCP staff). The information domains collected from interviewees will include:

- Adoption of NIH research policies
- Ability to secure additional funding
- Global health research collaborations
- New or improved approaches to the prevention and treatment of chronic CVPDs
- Research dissemination activities
- Contributions to health policy changes
- Barriers/facilitators to implementing the program
- Barriers/facilitators to promoting sustainability of the program
- Ability to recruit and retain trainees
- Training programs available
- Mentoring programs available

- Satisfaction of training program
- Career accomplishments

Findings from this qualitative data collection will be used to develop two final reports. The Case Studies report will be designed to achieve a “vertical,” in-depth understanding of the achievements, challenges, lessons learned, and programmatic and contextual factors that influence performance standards at each COE. Findings will also be incorporated into a Lessons Learned report, which will assess a “horizontal,” cross-case analysis of similarities and differences across project settings and conditions. This report will synthesize common and unique themes that emerge across COEs, as well as the contextual factors and mediators that influence greater or lesser program success.

The design of the data collection ensures that the information will have “practical utility.” The NHLBI GHI COE program represented a major investment of more than \$34 million to develop a worldwide network of research and training centers to ensure institutional and community capacity. Additionally, as each COE was led by a research institution in an LMIC paired with at least one academic institution in a developed country to enhance research and training opportunities, this mechanism significantly differs from the prevailing models of NHLBI and NIH funding. Thus, reports detailing the implementation, progress, lessons learned and outcomes of the program will be beneficial for NHLBI and NIH stakeholders to understand the impact of this major investment and novel model. CTRIS will review case studies and use findings to inform NHLBI and NIH stakeholders’ decision-making on the implementation and planning of global and domestic biomedical research and training programs. Case studies may also be used as guidelines for those interested in establishing programs within similar institutions and operating conditions. The Case Studies report may also be used by COEs to attract additional funding and media coverage. The Lessons Learned report will be useful to NHLBI and NIH leadership who are planning and evaluating the results of grant programs with diverse operating conditions and challenges.

Additionally, CTRIS intends to utilize program findings to develop future global health initiative ideas to be presented at NHLBI Idea Forum meetings, where NHLBI leadership and staff from all divisions extensively discuss and refine ideas. Following the Idea Forum, ideas are reviewed and prioritized by the NHLBI Board of Extramural Experts (BEE) and then by the NHLBI Advisory Council (NHLBAC), both of which review the proposed ideas and advise the NHLBI director about specific initiatives to consider.

If interviews with COE and DCP staff are not collected, it will be extremely difficult to determine whether the NHLBI GHI COE program reached its objectives or to fully understand the contextual factors influencing outcomes from the perspectives of different stakeholders. Additionally, valuable information on lessons learned in terms of the programmatic aspects of developing, implementing and

maintaining similar programs would not be captured and used to inform NHLBI and NIH's direction-making processes when considering global health initiatives.

A.3 Use of Improved Information Technology and Burden Reduction

Data collection is limited to individual, one-hour, pre-planned telephone interviews. Thus, the collection of information will not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology to reduce respondent burden.

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

In 2012, NHLBI engaged Humanitas, Inc., to conduct a feasibility study for an outcome evaluation of the GHI COE program. One goal of this feasibility study was to identify programs that are comparable in purpose, structure and participants to the GHI COE program, to be used as comparison groups for the outcome evaluation. After conducting a literature review and collecting input from NIH personnel, Humanitas, Inc. determined that given the unique and diverse centers involved in the project, no ideal comparison group could be identified. Thus, there are no evaluations of comparable programs that could serve the purpose and need to assess the outcomes specific to the GHI COE program. Additionally, assessments of program outputs and infrastructure have not always been a priority for global health research programs to date (Humanitas, Inc., 2013). Thus, the proposed data collection will not duplicate similar efforts.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this effort; therefore, there is no impact on small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time study based on a single time period for data collection. As stated in A.2, if key informant interviews are not conducted, it will be extremely difficult to determine whether the NHLBI GHI COE program reached its objectives. Valuable information on lessons learned will not be captured and used to inform NHLBI and NIH's leadership regarding future global health initiatives.

The proposed data collection for this PRA application will be conducted once. Interviewees will not be expected to participate more than once during this data collection and will not be re-contacted.

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 (d) (2). All guidelines of 5 CFR 1320.5 are met; therefore, there are no special circumstances relating to these guidelines.

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

Federal Register:

The 60-day Notice was published in the Federal Register on 3/13/2015, document number 2015-05722, pages 13396-13397. One comment was received.

Consultations:

Humanitas, Inc. was contracted by NHLBI between September 2012-March 2013 to conduct a feasibility study. The purpose of this contract was to assess the resources needed to conduct an outcome evaluation and to inform the NHLBI about whether and how to move forward with planning and conducting an outcome evaluation. A major focus of the study was also to develop measures to determine whether the GHI COE program met its goals. Although they were not directly consulted for the outcome evaluation or this PRA submission, their feasibility study was reviewed and informed the design of the outcome evaluation. The feasibility study had 4 objectives:

- Develop study questions for an outcome evaluation of the NHLBI GHI COE program
- Develop appropriate performance measures for an outcome evaluation, after considering populations and variables to study and the availability of prospective comparison groups
- Assess the availability of archival data that could be used for the outcome evaluation, and identify the potential data sources and methods for collecting the data
- Develop a plan for an outcome evaluation of the NHLBI GHI COE program

For the feasibility study, Humanitas, Inc. reviewed the availability of archival sources of data, including the COE performance database, progress reports, a COE process evaluation, and various records. Based on the findings, Humanitas, Inc. strongly recommended that interviews be conducted to identify lessons learned from COE staff. Additionally, interview data provide a more fully informed and comprehensive assessment of the content and context for training, capacity building, and policy changes, complementing what can be captured through analysis of archival data.

A.9 Explanation of Any Payment of Gift to Respondents

Incentives are necessary to compensate individuals for their time and lost opportunity costs (e.g. time lost that could have been spent working). We expect to provide each interviewee a \$25 payment for participating in the data collection. As the NHLBI GHI COE funding period has ended, incentives will be provided to interviewees to encourage participation. This payment is also similar in value to respondents' hourly wages, as reported in Table A-12 B.

A.10 Assurance of Privacy Provided to Respondents

Participation in all data collection activities is entirely voluntary. Individuals will be assured of the privacy of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). Participants will be told the purposes for which the information is being collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose. These activities are not part of a clinical trial, but they do involve human subjects research through obtaining data for research purposes under 45 CFR 46.102. Westat IRB has assessed this data collection activity and determined that it is exempt from IRB review. An IRB exemption letter for this activity can be found in Appendix A. No identifiable information about the participants will be collected, as they will already be known from their participation in the NHLBI GHI COE program.

All personnel involved in any aspect of this evaluation will be trained on the relevance and the procedures of maintaining privacy of the participants. Specifically, all personnel are required to be certified in International Conference on Harmonisation - Good Clinical Practice (ICH-GCP) Human Subjects Protection training, sign a non-disclosure agreement, and participate in security awareness training on an annual basis.

Privacy of all respondents will be strictly maintained. Standard systems will be implemented to avoid breaches in privacy. No data in the study database will contain Personally Identifiable Information (PII). All reports, study data collection, processing, and administrative forms will be identified by a unique code. All computer entry, database, and analysis programs will be done with coded numbers only.

Interviews will be audio-recorded. Participants will be asked to consent to interviews as well as to be audio-recorded. Participants may decline at any time to participate in the interviews or to be audio-recorded. All hardcopy and electronic notes and audio-recorded data will be kept in a locked file drawer or in password-protected electronic files in the study database, accessible only to authorized study team members. Once the interviews have been summarized or transcribed, the audio recordings will be destroyed. Data will only be reported to NHLBI and will not contain any PII. The Privacy Act will apply.

A.11 Justification for Sensitive Questions

The majority of questions are not of a sensitive nature. However, some participants may feel uncomfortable answering particular questions about their COE, its achievements, or levels of support provided by their colleagues or funder. Such questions are necessary to understand how the program was implemented, sustained, and how lessons learned from this initiative can assist with planning for future programs.

To minimize any potential distress, participants will be informed during the consent process and reminded by the interviewer or data collection instrument instructions that they have the right to refuse to respond to any questions they do not want to answer and that they may stop participating at any time. Furthermore, participants will be reminded that a PIN will be used to track data. All identifying personal information will be removed from transcripts of audio-recorded data, and audio recordings will be destroyed once data have been analyzed. Electronic data, including web surveys and audio recordings, will be stored on a secure, password-protected network, accessible only to authorized staff. Hardcopy data will be stored in locked files and rooms for storage of documents.

A.12 Estimates of Hourly Burden Including Annualized Hourly Costs

Table A.12-A represents the hourly burden for each respondent group for this data collection. Interviews will be conducted one time and will be completed in one hour. Interview guides for each of these groups have been submitted with this request.

Table A.12-A: Estimated Annualized Hourly Burden to Respondents

Type of Respondent	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Total Annualized Burden (in hours)
Principal Investigators	9	1	1	9
Training Directors	9	1	1	9
Developed Country Partners	9	1	1	9
Trainees	9	1	1	9
TOTAL				36

Respondents will be pre-selected, per their role in the NHLBI GHI COE program.

Table A.12-B represents the calculations for the cost of interviewees' time to participate in 1 hour interviews. The total cost to the respondents is \$855 for the information request.

Estimates for Developed Country Partners (medical scientists) were calculated from the Bureau of Labor Statistics:

Medical Scientists - 19-1040 \$42.95 http://www.bls.gov/oes/current/oes_nat.htm#19-0000

As Principal Investigators and Training Directors are located in international settings, their salaries were not calculated from the Bureau of Labor Statistics. Rather, salaries were calculated from COE budget documents submitted to NHLBI at the start of the program. Annual percent salary increases for 5 years were included to estimate the annual salary for 2014 for each Principal Investigator and Training Director. Per hour rates were then calculated from these annual salaries and then averaged across the COEs. As the majority of Trainees were graduate students and did not receive a salary, their hourly wage rates are calculated as \$0.

Table A.12-B: Estimated Annualized Cost to Respondents

Type of Respondent	Number of Respondents	Average Burden Per Response (in hours)	Total Annual Burden Hours	Hourly Wage Rate (US Dollars)	Respondent Cost (US Dollars)
Principal Investigators	9	1	9	\$40	\$360
Training Directors	9	1	9	\$25	\$225
Developed Country Partners	9	1	9	\$30	\$270
Trainees	9	1	9	\$0	\$0
TOTAL	36	1	36	--	\$855

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

Cost to respondents will be limited to their time to respond to recruitment emails, schedule the interview, provide the requested information. There are no costs to respondents other than their time to participate in the research activities.

A.14 Annualized Cost to the Federal Government

Table A.14: Annualized Cost to the Federal Government

The annualized cost to the federal government is \$110,470.00

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Scientific Program Specialist	GS 13-3	\$97,000	1%	N/A	\$970
Program Official	GS 15-10	\$158,000	1%	N/A	\$1,500
Contractor (X5)	N/A	\$21,600	100%	N/A	\$108,000

A.15 Explanation for Program Changes or Adjustments

This is a new request for information collection.

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

The study team is requesting an 18 month clearance for this data collection. As this data collection involves interviews, there are no plans for statistical analysis. Qualitative analysis will be conducted with interview data. As disseminating results in conferences and journal articles is part of CTRIS's mission, findings from this data collection may be presented at professional conferences and in peer-reviewed journals. An example timeline for data collection activities is presented below.

Table A.16: Example of Project Time Schedule after OMB Approval

Activity	Time Period
Send recruitment emails to interviewees	1 month after OMB approval
Conduct interviews	1 ½ - 6 months after OMB approval

A.17	Reason(s) Display of OMB Expiration Date Is Inappropriate
Conduct analysis	Ongoing as data are collected
Submit study reports	18 months after OMB approval

All written and electronic material will display the expiration date for the OMB approval of the information collection.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in item 19 “Certification for Paperwork Reduction Act Submissions,” of OMB Form 83-I.