Supporting Statement A For:

Accomplishments and Challenges of National Institutes of Health

International Bilateral Programs

(FIC, NCI, NIAAA, NIAID, NICHD, NIDA, NINDS, NIMH, OAR)

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Table of Contents

А.	JUSTIFICATIONIII
A.1	CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY1
A.2.	PURPOSE AND USE OF THE INFORMATION COLLECTION
A.3	Use of Improved Information Technology and Burden Reduction9
A.4	EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION9
A.5	IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES11
A.6	CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY
A.7	SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.512
A.8	Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
A.9	EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS
A.10	Assurance of Confidentiality Provided to Respondents
A.11	JUSTIFICATION FOR SENSITIVE QUESTIONS14
A.12	ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS14
A.13	ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS AND RECORD KEEPERS
A.14	ANNUALIZED COST TO THE FEDERAL GOVERNMENT15
A.15	EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS16
A.16	PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE16
A.17	REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE
A.18	EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS

LIST OF ATTACHMENTS

Attachment 1: Bilateral Surveys

1A. Survey for Administrative Supplements
1B. 1 Year Survey for all other awards (R01s, R21s, and U01s)
1C. Final Survey for all other awards (R01s, R21s, and U01s)

Attachment 2: International Bilateral Study Working Group Members

- Attachment 3: Privacy Act Memo
- Attachment 4: Office of Human Subjects Research Protection Exemption (OHSRP)

Attachment 5: Invitation to participate 5A. Email Invitation 5B. Follow-up Telephone Script for Non-Responders

ABSTRACT

This submission is a request for OMB to approve this survey of the accomplishments and challenges of National Institutes of Health (NIH) International Bilateral Programs for three years. The bilateral awards are made through the Funding Opportunity Announcement mechanism and administrative supplements, meaning they are funded by set-aside funds that are separate from the general pool of research program grant funds used to support investigator initiated research at NIH. The bilateral programs to be evaluated are the U.S.-China Program for Biomedical Research Cooperation, U.S. - India Bilateral Collaborative Research Partnerships on the Prevention of HIV/AIDS and Co-morbidities, U.S.-Russia Bilateral Collaborative Research Partnerships on the Prevention and Treatment of HIV/AIDS and Co-morbidities, and U.S.-South Africa Program for Collaborative Biomedical Research. These programs are funded and administered by various combinations of the following institutes: the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Cancer Institute (NCI), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute for Allergy and Infectious Diseases (NIAID), National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke (NINDS), and the Office of AIDS Research (OAR). While these programs differ, their underlying concept is the same; they require U.S. scientists to collaborate with scientists from other countries in order to conduct scientifically meritorious investigations of mutual interest to both countries. The proposed study requests information about 1) accomplishments of the awards, 2) unique findings or opportunities due to the international collaborations, and 3) successes and challenges of these collaborations. The information will be collected one year into the award and at the end of the award, when possible. This information is needed to evaluate the effectiveness of these programs across NIH.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

As has been true for decades, the United States remains the global leader in biomedical research, but it perhaps goes unnoticed that a number of key discoveries that have advanced the understanding of human health and disease have been the products of research conducted by U.S. investigators working abroad, often in low-income settings. In every field of medicine today, research partnerships in global health are extending the boundaries of knowledge of disease and strategies for diagnosis, treatment, or prevention. Many observers now appreciate that many of the future frontiers of biomedical discoveries may not be optimally pursued at home. Only by building partnerships with researchers overseas will the United States be able to maintain its

competitive edge and accelerate the expansion of knowledge for understanding and the cures desired by all. Indeed, U.S. researchers must take their science and innovation where the problems and opportunities exist. By collaborating internationally, U.S. researchers gain access to unique populations, can test drugs and devices where the burden of disease is most prevalent, benefit from other countries' biomedical research investments, work with outstanding investigators, and can study how to apply the low-cost yet effective solutions to problems abroad to address some health care needs in the United States.¹

With this in mind, various institutes across the NIH, in conjunction with the Office of AIDS Research, have come together to create bilateral programs to advance global biomedical research; build expertise and leverage resources across borders; and reduce deaths worldwide. The U.S.-China Program for Biomedical Research Cooperation (U.S.-China), the U.S. - India Bilateral Collaborative Research Partnerships on the Prevention of HIV/AIDS and Comorbidities (U.S.-India), the U.S.-Russia Bilateral Collaborative Research Partnerships on the Prevention and Treatment of HIV/AIDS and Co-morbidities (U.S. Russia), and the U.S.-South Africa Program for Collaborative Biomedical Research (U.S.-South Africa) are trans-NIH programs to support international collaborative biomedical research to advance science and expand biomedical knowledge. These bilateral programs are unique in that they require U.S. scientists and scientists from China, South Africa, Russia, and India to propose and establish collaborations to conduct high quality research of mutual interest and benefit to both countries while developing the basis for future institutional and individual scientific collaborations. These collaborations utilize the research capacities of the institutions and scientists in both countries to advance biomedical research. Another unique feature of these programs is that they all receive matching or complementary funds from their respective partner countries, which maximizes the

¹ Glass RI. What the United States Has to Gain From Global Health Research. JAMA. 2013;310(9):903-904. doi:10.1001/jama.2013.276558. RI.

benefits for both countries without requiring additional U.S. investment. Finally, these four programs represent an opportunity to contribute to the research capacity of other countries. They incentivize U.S. scientists to form partnerships with new investigators who are not as well established in the field of biomedical research and incentivize countries to invest in their own research infrastructure.

These four programs were established by issuing Notices of Availability of Administrative Supplements and Funding Opportunity Announcements (FOAs). These awards are funded and administered by various combinations of the following institutes: the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Cancer Institute (NCI), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute for Allergy and Infectious Diseases (NIAID), National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke (NINDS), Fogarty International Center (FIC), and the Office of AIDS Research (OAR) (Table 1).

Notice/FOA	Date Issued	Type	# of	Length	Participating I/Cs and Offices			
			Investi-					
			gators**					
U.SChina								
NOT-CA-11-003	2/4/2011	AS*	30	1 yr	NCI, NIAID, OAR			
NOT-CA-12-002	12/2/2011	AS*	32	1 yr	NCI, NIAID, NIMH, OAR			
RFA-AI-12-021	4/4/2012	R01	25		NCI, NIAID, NIMH, OAR,			
			25		NINDS			
	U.SIndia							
RFA-AI-12-033	6/13/2012	R21 9 2 vrs		2 yrs	NCI, NIAAA, NIAID, NICHD,			
KI ^A -AI-12-055	0/13/2012	N21	3	2 y15	NIDA, NIMH, OAR			
			U.SRus	sia				
NOT-MH-12-001	10/12/2011	AS*	10	1 yr	FIC, NCI, NIAAA, NIAID,			
1101-111-12-001	10/12/2011	ЛЗ	10	I yi	NICHD, NIDA, NIMH, OAR			
RFA-DA-14-001	11/16/2012	R21	8	2 yrs	NCI, NIAAA, NIAID, NICHD,			
	11/10/2012	1121	0	2 y15	NIDA, NIMH, OAR			

Table 1. International Bilateral Programs

TBD	2014	R01	8	3 yrs	TBD		
U.SSouth Africa							
RFA-AI-14-010	12/13/2013	R21	50	2 yrs	FIC, NCI, NIAID, NICHD, NIMH, OAR		
RFA-AI-14-009	12/13/2013	R01	50	5 yrs	FIC, NCI, NIAID, NICHD, NIMH, OAR		
RFA-AI-14-018	2014	U01	6	2-5 yrs	NCI, NIAID, NICHD, OAR		

*AS= Administrative Supplement

** This is the number of principal investigators that will be invited to participate in the study and does not include the 41 NIH intramural investigators who were awarded funds through these programs and who will be asked to evaluate the program as part of their job duties.

Only those grantees who receive funding from the NIH under these programs are required to submit annual progress reports and other post-award documents associated with the monitoring, oversight, and closeout of an award. In the U.S.-China, U.S.-Russia and U.S.-India programs, the international investigators applied for and received funding through partner organizations (National Natural Science Foundation of China, Russian Foundation for Basic Research, and Indian Council for Medical Research), and thus are not required to report their accomplishments to the NIH.²

Those grantees who did receive funding from the NIH under these programs (U.S. investigators in U.S.-China, U.S.-Russia, and U.S.-India, as well as all investigators in U.S.-South Africa) are required to submit annual progress reports to the NIH, but the information collected in these reports is limited and dependent upon the funding mechanism.

All NIH grantees with R01s, R21s, or U01s are required to report progress and accomplishments in these annual progress reports, but are not required to distinguish between the domestic and international accomplishments of the project or include the accomplishments of

² The South African Medical Research Council gifted matching funds to the NIH under the U.S.-South Africa program so both U.S. and South African investigators applied and received funding through the NIH. Thus both U.S. and South African investigators will be required to submit annual progress reports.

their international collaborators or information on the effectiveness and appropriateness of the international collaborations created under these bilateral programs.

All NIH grantees with administrative supplements can choose to include information on the progress of the work funded by administrative supplements in the annual progress reports required by the parent grant, but are not required to include anything about the work performed under the supplement or the effectiveness or appropriateness of the international collaborations.

The proposed study requests information about: the accomplishments of the awards (for those awards that are not required to submit this information), unique findings or opportunities due to the international nature of the collaborations formed under the programs, and the successes and challenges of these collaborations. The information collected in this study will be used for program study and performance analysis. Although no formal study components currently exist, program performance, including success of the international collaborations and scientific accomplishments, will be assessed as part of deliberations across participating institutes on the continuation of the special set-asides for bilateral programs. This study will aid in the analysis of program effectiveness and efficiency in achieving its objectives. For example, it may aid in the identification of areas that could benefit from increased efficiencies or shared activities, as well as inform other aspects of future programs (including award mechanisms, and partner countries).

The International Bilateral Evaluation Working Group was formed to design and implement the study of these four international bilateral programs. The group consists of representatives from each of the participating institutes and the Office of AIDS Research (**Attachment 2**). All participants in this working group had multiple opportunities to offer input and edit all relevant materials. Once this working group finalized their materials, they were then

distributed to the larger group of program officers and program directors who oversee the four programs for approval.

Section 402 of the Public Health Service Act (42 USC § 241), authorizes collection of this information, as outlined in the Appointment and Authorities of the Director – Sec. 402e-2-4. Section 402e authorizes the Director of the NIH to collect and disseminate (including through publications) to the health care community and other entities, information on the study of research conducted by or through the national research institutes.

A.2 Purpose and Use of the Information

The current proposal is to administer a survey **(Attachments 1A-1C)** to evaluate the effectiveness of awards funded through the U.S.-China Program for Biomedical Research Cooperation, the U.S.-South Africa Program for Collaborative Biomedical Research, the U.S.-Russia Bilateral Collaborative Research Partnerships on the Prevention and Treatment of HIV/AIDS and Co-morbidities, and the U.S. – India Bilateral Collaborative Research Partnerships on the Prevention and Treatment of the bilateral awards who receive funding from the NIH will be invited to complete the study. The report consists 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 requirement of international collaborations of these programs (e.g., advantages of international collaborations, etc.).

Information to be collected:

• Unique scientific findings/opportunities due to the international nature of the collaborations

- Advantages and challenges of collaborating internationally
- Description of plans to continue collaboration
- Key domestic and international achievements including findings, publications, and presentations when these are not collected in progress reports (e.g., administrative supplements)
- Practical applications of findings when not collected in progress reports
- Training Activities
- How they identified their collaborator
- Other feedback on program activities

Review and Use of Submitted Information

Completion of the proposed study is a unique requirement to these programs and is of great importance in building and sustaining international partnerships in biomedical research. The study is intended to answer three questions:

- What did the projects funded under these programs accomplish?
- Which of the accomplishments of these projects were results of the unique opportunities presented by collaborating internationally?
- Were there common elements (e.g., challenges, advantages, etc.) across programs or specific to a program that could be used to inform programming in the future?

What did the projects funded under these programs accomplish?

This study will help us to identify the accomplishments of these awards that are not captured in the progress reports (e.g., those of administrative supplements and Chinese investigators), which will allow program staff to have a complete understanding of effectiveness of the awards. Additionally, the study will distinguish the achievements of U.S. investigators from their international collaborators, allowing both the U.S. and international governments to understand the value that each program brings to their country. In addition, it can serve as evidence to inform decisions by institutes across the NIH as well as international governments, as to whether they should contribute to similar programs in the future.

Which of the accomplishments of these projects were results of the unique opportunities presented by collaborating internationally?

There are many advantages unique to international collaborations including: access to unique populations and data, the ability to test drugs and devices where conditions are most prevalent, the ability to benefit from other countries' biomedical research investments, the ability to work with outstanding investigators, the ability to increase research capacity (both in the United States and internationally), and the ability to study how the low-cost yet effective solutions to problems abroad can be applied to address some health care needs in the United States. This study will allow us to identify those projects that could not have been funded through more traditional programs and the unique value that they bring. For example, U.S. investigators could partner with South African investigators to study a cancer that is rare in the U.S., but more prevalent in South Africa, and without this opportunity for collaboration, they would not have access to South African specimens.

Were there common elements (e.g., challenges, advantages, etc.) across programs or specific to a program that could be used to inform programming in the future?

Investigator experiences with the bilateral collaborations (e.g., the ease with which they were able to form collaborations, the strength of research results from these projects, challenges due to these collaborations) will provide important information on ways that the NIH can most effectively encourage international collaborations. For example, if the most successful collaborations were those that had a communications plan that they followed, then future programs could require and assist in the creation of communications plans. Comparing responses

across these four programs will provide insight into the advantages and disadvantages of partnering with each country and may help to identify characteristics of partner countries that are particularly important for successful collaborations. These insights may be applied to improve future programming. For example, it is possible that there may have been legislation in China that made it difficult for U.S. investigators to gain access to Chinese specimens, and this may have significantly delayed work. Future programs could limit the types of awards that allow for specimen research to longer awards or require U.S. investigators to show documentation stating that they have approval to access Chinese specimens before the award is made.

A.3 Use of Improved Information Technology and Burden Reduction

The survey will be completed and sent as PDFs by the principal investigators via e-mail, to the NCI program office who will save them as PDFs on an internal NIH drive. No automated or dedicated IT system will be used for these reports.

A Privacy Impact Assessment (PIA) is currently underway.

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

The study proposed here will not duplicate any existing information collection, since this information is not currently collected. There will be three versions of the survey; the first version (**Attachment 1A**) will be distributed to those awardees who received funding under an administrative supplement and will ask respondents to list all publications, presentations and patents associated with the supplement. Principal investigators who received funding under an administrative supplement will only be asked to evaluate the program once, since administrative supplements are only one year in duration.

The second two versions (Attachments 1B and 1C) will be distributed to all awardees who received funding through an R01, R21 or U01 mechanism and will not request this list of publications, presentations and patents, because this information is already collected in the annual progress reports. There are two versions of the survey for awardees who received funding through an R01, R21 or U01 mechanism, because these awardees will be asked to evaluate the program at two different time points since these awards have durations ranging from 2-5 years. One will be distributed one year into the award (Attachment 1B) and one will be distributed at the end of the award (Attachment 1C). The version that will be distributed one year into the award will request information on the number of years the investigator had been working in the area of research and how they identified their international collaborator (Attachments 1B). The survey that will be distributed at the end of the award (Attachments 1C) will not ask about the number of years working in the area of research or how they identified their international collaborator because this information should not change over time and will already have been collected in the survey that is completed one year into the award.

All surveys will collect the same information on the unique opportunities, the advantages and the challenges associated with the international collaborations under the awards. This information is not publicly available and cannot be gathered from other sources. We have consulted the PHS 2590 (OMB No.: 0925-0002 Expiry Date: 8/31/2015) and the PRA liaison office at NCI, and the information to be gathered through the proposed guidelines is not collected in existing reports. We have also consulted with the program officers in all participating institutes and have confirmed that they do not currently collect any of these data. In those questions that refer to "international" investigators or "international" components **(Attachments**

1B and 1C), we will replace the word "international" with South African, when we distribute the survey to South African principle investigators.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in this information collection.

A.6 Consequences of Collecting the Information Less Frequently

The proposed information collection will occur twice in the lifecycle of each award when possible. The first collection, when possible, will be one year after the award has been made. This collection is important because it will allow program directors to make informed decisions about continuing, extending and forming similar programs, as soon as possible. For all those awards who have a duration greater than one year (all awards other than those made through the administrative supplement), there will also be a second collection, which will be completed at the end of the award. This collection is important because it will allow the program offices to compare responses across the two different time points. This will allow program officers to identify trends and differences between types of awards and programs as the collaborations mature. For example, it is possible that the challenges identified in the first collection, one year after the award has been made, may be overcome by the end of the award, but it is still very important to identify those challenges in order to minimize them in future programming. Similarly, some of the same challenges may be identified at both time points, which will indicate the scope and importance of these challenges for awardees to program staff, which, in turn will help program staff to prioritize changes for future programs. In the absence of the information

provided by these surveys, the program officers will not be able to judge the effectiveness of the programs and make informed decisions regarding funding future programs.

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 apply 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 <u>Federal Register</u> notice soliciting comments on this study prior to initial submission to OMB was published on March 13, 2014 (Vol. 79, P. 14256). No public comments were received.

Multiple institutes and the Office of AIDS Research have collaborated to provide input into this project and PRA/OMB submission. These entities are mentioned in Section A.1. Additionally, the International Bilateral Evaluation Working Group (**Attachment 2**) has provided feedback about all relevant documents including the survey and submission package for OMB. Additionally, the international collaborators (program leads of the National Natural Science Foundation of China, South African Medical Research Council, Russian Foundation for Basic Research, and Indian Council for Medical Research) have been informed of our intention to evaluate these programs. Additionally, the National Natural Science Foundation of China is conducting a similar study of the Chinese principal investigators under the U.S.-China program.

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 (PII) will be collected in the form of grantee names and their affiliated institution. Information related to awardees' name, institution, and collaborating principal investigators will be linked to scientific progress, interactions with their international collaborators, and plans to raise additional funds. Information will be collected by and seen only by members of the program offices. Personally identifiable information in reports will not be shared with anyone outside of NIH, and physical copies of reports will be kept in NIH secured storage areas. Electronic files will be kept on password protected government computers and secure NIH servers. Any future publications that arise from this study will feature either an analysis of anonymized or aggregate data.

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" (**Attachment 3**). This SORN was published in Federal Register on 9/26/2002, Vol. 67, p. 60742.

Since this is not considered research, the Office of Human Subjects Research Protection (OHSRP) has reviewed this proposal and determined that it is exempt for IRB (**Attachment 4**).

A.11 Justification for Sensitive Questions

There are no sensitive questions being asked in the survey.

A.12 Estimates of Annualized Burden Hours and Costs

The one hour per report estimate includes time to gather information, most of which should already exist (e.g., publication lists kept by investigators for their Curriculum Vitae) but some of which they may need to think about (e.g., challenges encountered during collaborations). This may vary slightly as the second version does not request a list of publications, presentations and patents, but this is only one additional question and the investigators should already have this information. In many cases we expect the time to prepare to be significantly shorter, since investigators will have prepared narratives for grant applications, research group homepages and internal reports that include some of this information, but the estimate given should be sufficient even for a report that does not copy narrative from other sources. Depending on the type of notice/FOA and when it was granted, some grantees may be asked to respond twice.

A total of 72 investigators will be asked to complete the Survey for Administrative Supplements (Attachment 1A) over the three year period. An additional 156 investigators will be asked to complete both the 1 year and the final surveys over a three-year information period (Attachments 1B and 1C) which amounts to a total of 228 investigators over three years. It is estimated that there will be non-responders and these non-responders will be contacted and read a script. It is roughly estimated that there will be 47 over the three year period. The estimated annual burden is 129 hours, which works out to be 387 burden hours over the course of the threeyear information collection request (Table A.12-1). This does not include the 41 NIH intramural investigators who received funding through these programs. These intramural investigators will be asked to evaluate the programs as part of their job duties, and thus have not been included in the burden or cost calculations.

Type of Respondents	Forms	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
	Administrative Supplements	24	1	1	24
	Year 1 Survey	52	1	1	52
Principal Investigators	Final Year Survey	52	1	1	52
	Telephone Script for Non- Responders	16	1	3/60	1
Total		76			129

Table 12-1. Estimated Annualized Burden Hours

The total cost to the respondents is \$17,530, and using an estimated value of the principal

investigators' time of \$45.65 per hour, this works out to be an annualized cost of \$5,889.00

(Table A.12-2). This wage rate was obtained from the "Physical Scientists, All Other"

occupation, occupation code 19-2099 at the Bureau of Labor Statistics

(http://www.bls.gov/oes/current/oes_nat.htm#19-0000).

Table 12-2. Annualized Cost to Respondents

Type of	Number of	Total Annual	Hourly Wage	Total Annual
Respondents	Respondents	Burden Hours	Rate	Respondent Cost
Principal Investigators	76	131	\$45.00	\$5,889

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 federal program staff spent on the development of the study, the review of the responses, and the program study. There are no contractors contributing time, energy or effort to this project.

We estimate that all work on the review and storage of surveys will require the effort of 0.06 FTE, spread over about 6 program directors/program officials. The bulk of this effort will be by the program officials, at a GS12 level or above, so that this data collection will result in an estimated cost of \$5,764/year for each of the three years we expect to gather the information.

We also estimate that all work on the analysis of the surveys will require the effort of 0.12 FTE, spread over about 6 program officials. The bulk of this effort will be by the program officials, at a GS12 level or above, so that the data analysis will result in an estimated cost of \$12,383/year for each of the three years we expect to gather the information. The total annual cost to the Federal government is estimated to be \$18,146 (Table A. 14-1).

Table A.14-1. Annual Cost to the Federal Government

	Tasks	Title	Grade/ Step	Staffing (Salary x % of time)	Annual Cost
NIH	R&D, Data	Program	12/1	\$75,621 x 1%	\$756.21
Personnel	Collection,	Director			

	Report		12/3	\$80,662 x 1%	\$806.62
			13/1	\$89,924 x 1%	\$899.24
			13/4	\$98,916 x 1%	\$989.16
			14/1	\$106,263 x 1%	\$1,062.63
			15/1	\$124,995 x 1%	\$1,249.95
	Data Analysis	Program Director	12/1	\$75,621 x 2%	\$1,512.42
			12/3	\$80,662 x 2%	\$1,613.24
			13/1	\$89,924 x 2%	\$1,798.48
			14/1	\$106,263 x 2%	\$2,125.26
			15/1	\$124,995 x 2%	\$2,499.90
			15/5	\$141,660 x 2%	\$2,833.20
Total					\$18,146.31

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

The information will be analyzed qualitatively to compare program outcomes with goals. Very basic descriptive statistics will be calculated from the information collected like percentage of new and existing collaborations in each program, number of publications, number of new collaborations, number of persons trained, etc. The majority of the data being collected is qualitative data, which will be analyzed for common themes and compared across programs. The qualitative data will be read and annotated to identify core themes from which inductive and deductive codes will be developed and defined. The research team will code the data, which means that each time the data include information that one of the codes applies to, the information will be tagged by the research team using qualitative data analysis software (e.g., Maxqda or NVivo). For example, one of the codes that may be developed may be "unique populations." The definition of the code "unique populations" will be developed by the research team (e.g., any reference to collection or analysis of sample, specimens, data, or populations that would be unavailable to the U.S. investigator without a collaborating international investigator). Then, if one respondent discussed how they were able to analyze the results of the latest Chinese national health survey, the research team could identify that as a "unique population" and tag the relevant part of the response with the code "unique population." Once the data are coded, they will be searched by topical themes and a description encompassing the context, depth and breadth of core themes in the data will be developed. Themes will be compared by program and by type of collaboration (e.g., new vs. existing) to identify differences. Although the primary purpose of this information collection is to understand why the collaborations funded under these programs have or have not been successful in order to evaluate the programs, data from these reports may be used for publications. These publications would most likely take the form of commentaries and would not generalize findings to other programs.

The project time schedule (Table 16-1) represents a 6-month time frame which begins once clearance is received and a grant is funded. This table would be repeated every year through the three year information collection phase, so that each administrative supplement is surveyed at the end of the supplement and each R01, R21 and U01 is surveyed one year into the award and at the end of the award.

Table 16-1. Project Time Schedule

	Months after OMB approval		
	Months 1-2	Months 3-4	Months 4-6
Contact Principal Investigators			
Obtain responses from Principal Investigators			
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 project does not require any exceptions to the Certification for Paperwork

Reduction Act Submissions (5 CFR 1320.9).