Supporting Statement A for

Recruitment and Screening for the Insight into Determination of Exceptional Aging and Longevity (IDEAL) Study (NIA) - OMB # 0925-0631

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Abstract

Longevity combined with good health and functionality at the end of life represents a common goal. Although research has examined correlates of long life and functional decline, we still know relatively little about why certain individuals live in excellent health into their eighties while others succumb to failing health at much younger ages. Understanding the mechanisms important to ideal aging may provide new opportunity for health promotion and disability prevention is this rapidly growing segment of the population.

The purpose of IDEAL (Insight into the Determinants of Exceptional Aging and Longevity) is to recruit into the Baltimore Longitudinal Study on Aging (BLSA) exceptionally long lived and healthy individuals and to learn what makes them so resilient and resistant to disease and disability, and to identify potential interventions that may contribute to the IDEAL condition. By enrolling the IDEAL cohort in the BLSA their biologic, physiologic, behavioral and functional characteristics will be evaluated using the same methods used with the current cohort who will serve as a type of control group. The first aim is to identify factors and characteristics that distinguish IDEAL from non-IDEAL individuals. We intend to compare the two groups to identify factors that discriminate IDEAL aging from non-IDEAL aging individuals. The second aim is to identify physiological, environmental and behavioral characteristics that are risk factors for losing the IDEAL condition over several years or longer. We postulate that the mechanisms of extreme longevity probably differ from those associated with delay or escape from disease and disability. As is customary in the BLSA, we plan to follow this cohort for life with yearly visits. This is a request for OMB to approve a reinstatement with change to the Recruitment and Screening for the Insight into Determination of Exceptional Aging and Longevity (IDEAL) Study for 3 years.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Baltimore Longitudinal Study of Aging (BLSA) is the National Institute on Aging's (NIA) major clinical research program in human aging that has been conducted in Baltimore since 1958, and it is by far the oldest longitudinal study of aging in the world. The BLSA study population is a series of volunteers who join the study at different ages, and are followed indefinitely with serial evaluations over time. A consortium of scientists collects and analyzes data from this study population with the aim of characterizing normal and pathological aging. Thus, the BLSA can be envisioned as longitudinal study oriented toward:

1. The description of the anatomical, physiological and functional changes that occur over the aging process;
2. The identification of the biological and physiological pathways that lead to frailty in older persons;
3. The development of hypotheses concerning possible targets for interventions that may positively affect several aspects of the aging process and prevent age-related diseases.

BLSA was established prior to the Paperwork Reduction Act of 1995. When the NIA decided to begin offering the home visit option to BLSA participants, a clinical exemption was sought and granted (CE 08-01-01).

The BLSA began under the Gerontology Branch of the National Heart Institute in 1958 and then moved under the Gerontology Branch of the newly-created National Institute of Child Health and Human Development (NICHD) in 1965. When the Research on Aging Act of 1974 (Public Law 93-296) established a National Institute on Aging (NIA), the BLSA was still part of

the NICHD Gerontology Research Center (GRC), but in the following year, 1975, the GRC separated from NICHD to become the core of the NIA, bringing the BLSA to the NIA. The NIA seeks to understand the nature of aging and the aging process, and diseases and conditions associated with growing older, in order to extend the healthy, active years of life. The Research on Aging Act has undergone several amendments, the last being P.L. 101-557 in 1990, which reasserts NIA's leading role for the federal government in the conduct and support of research on aging and the health and well-being of older people. This study is in keeping with NIA's mission to: foster the development of research and clinician scientists in aging; communicate information regarding aging and advances in research on aging to the scientific community, health care providers, and the public; and to support and conduct biological, genetic, clinical, behavioral, social, and economic research related to the aging process, conditions and diseases associated with aging, and other special needs and problems of older Americans.

Longevity combined with good health and functioning at the end of life is the goal of most individuals and finding ways of promoting this condition is an important goal of NIA. Although research has been done on the correlates of long life and functional decline, we still know relatively little about why certain individuals live in excellent health into their 80's while others fail much sooner. We proposed to enroll in the BLSA individuals who have already reached the goal of healthy longevity (IDEAL cohort) using as eligibility criteria the same very strict criteria for "Healthy" used for the universal BLSA enrollment. In practice, at the time of study entry BLSA participants should be free of any major medical condition, taking no chronic medication (with few exceptions), and have no functional (ability to walk 400 m. without stopping and without developing symptoms) or cognitive problems (MMSE score >27 and Blessed Mental <3). The IDEAL cohort will be compared with BLSA participants who met the

same strict criteria for health at the study entry when they were younger, but later on developed chronic diseases and physical and cognitive impairments. There are currently already 480 individuals age 80 and older who match such description of IDEAL "controls". In summary, IDEAL and non-IDEAL individuals will be age and sex matched and discriminated by their IDEAL or non-IDEAL status.

The Insight into the Determination of Exceptional Aging and Longevity (IDEAL) Study is an extension of the Baltimore Longitudinal Study of Aging (BLSA). NIA's goal for the recruitment effort was to enroll 500 healthy individuals aged 80 or older over the course of five years. Including these new individuals, the BLSA will be able to utilize fully the extensive set of measures that have been recently introduced in the study for pursuing the original mission of the BLSA which is the study of healthy aging, independent of the effect of disease. Members of the IDEAL Study cohort will be compared to current BLSA participants who are no longer healthy or fully functional when they reached the age of 80. As is done with current BLSA participants, IDEAL subjects will be followed for life with yearly visits. A secondary objective of the IDEAL Study is to identify physiological, environmental and behavioral characteristics that are risk factors for loss of a person's healthy aging status over time. This is based on the hypothesis that mechanisms of extreme longevity are different from those associated with delay or avoidance of disease or disability. This is a request for OMB to approve a reinstatement with changes of Recruitment and Screening for the Insight into Determination of Exceptional Aging and Longevity (IDEAL) for 3 years. Note that since the submission of this request beyond the current OMB clearance of April 30, 2014; all IDEAL study data collection has stopped until clearance is secured. The purpose of the project is to conduct continued recruitment and screening for the IDEAL Study.

Over the years, more than 500 manuscripts have been published based on data collected in the BLSA. We could easily argue that most of what we know about aging and its relationship with age-related diseases was first discovered in the BLSA. The IDEAL Study will add to the literature by providing information regarding the factors associated with exceptionally healthy aging.

A.2 Purpose and Use of the Information Collected

We are seeking OMB approval for reinstatement with changes, for the purpose of continuing recruitment and screening for the IDEAL Study. The changes included in this submission are: two new recruitment components (a more expanded recruitment presentation and a recruitment mailing to CMS beneficiaries); the use of a two-stage telephone screening protocol conducted in place of a single telephone screening contact; minor changes to both the screening interview and screening exam protocols; and a new consent form created under the direction of the NIEHS IRB.

A multifaceted recruitment approach is being used to reach the target audience in a wide variety of ways. Those who are interested in participating in the IDEAL study are asked to complete a two stage recruitment process consisting of a two-part telephone interview and a physical exam.

Recruitment plan

Given the study's target population, face-to-face presentations, relationship building with senior organizations, networking with state and local providers for seniors and material sharing have proven to be effective recruitment approaches. The recruitment audience has been extremely diverse with varying levels of scientific interest. We have adapted our recruitment

presentations accordingly. Please see Attachment 1 for the two standard recruitment presentations used to address this diversity in our audiences – one is a more general overview whereas the other provides more scientific information. We believe a multi-faceted recruitment approach is critical and we are seeking to reach the target audience in a wide variety of ways. Our recruitment methods are also based on an assessment that ***word-of-mouth*** may well be the most effective way of identifying potential eligible persons. The process of asking those with whom we interact if they know a potential candidate for the study is highlighted in project conversations and presentations. As participants are identified, both at the presentation phase and during screening, we utilize a "snowball" sampling approach and ask that recruits share with us any family, friends, or acquaintances who might meet the criteria for participation. We will continue to work closely with the IRB to identify acceptable approaches for contacting additional subjects identified in this manner. The initial contact will be made via presentations to various organizations that cater to or involve large numbers of seniors. Organizations that have been targeted include:

- Senior Centers
- Senior residences
- Veterans of Foreign Wars (VFW) and other Veteran Senior Communities
- Programs Faith-based organizations
- Maryland, Virginia, Delaware, and Pennsylvania chapters of the Senior Olympics
- State, County, and Local agencies sponsoring Senior Expo events
- American Geriatrics Society
- Senior Friendly Neighborhoods
- Centers for Medicare and Medicaid Services

- Administration on Aging
- Senior Corps of the Corporation for National and Community Service
- Local Chapters and Associations for Nationwide Non-Governmental Organizations for Seniors [i.e. American Association of Retired Persons (AARP) and National Active and Retired Federal Employees Association (NARFE)].
- Fraternal Organizations

Please see Attachment 2 for the recruitment letters that are sent to targeted organizations. There are two versions for the recruitment letters. The first is used with organizations whose members or patrons are primarily seniors, such as senior centers and residences, whereas the second is used with organizations whose scope of membership is broader, but may include seniors, such as volunteer organizations, athletics, and arts groups.

Attachment 3 is the recruitment poster and Attachment 4 is the double-sided study brochure with a corresponding postcard with condensed brochure content. Westat has successfully worked with NIA to develop a website that contains information regarding both the BLSA and the IDEAL Study; this site draws interested individuals who can obtain information about the study, its purpose and recruitment criteria. The site address is www.nia.nih.gov/ideal.

In addition, Westat has subcontracted media strategy and buying services to Boscobel Marketing Communication, Inc. Boscobel is a full service marketing communication firm and woman-owned small business with broad capabilities in media planning, buying and placement. Boscobel will be responsible for radio and television promotion for the recruitment effort.

Finally, we have received approval from Centers for Medicare and Medicaid Services (CMS) to send a direct mailing containing study information to selected CMS beneficiaries who meet the age and geographic eligibility criteria, were alive as of June 2013, and whose claims

data in 2011 did not include exclusionary chronic conditions (e.g., stroke, heart disease, cancer, diabetes, chronic kidney disease, Alzheimer's, etc.). Westat worked with the CMS to determine criteria for pre-screening beneficiaries and a resulting file of 282,745 beneficiary IDs was delivered. Following standard CMS protocol for research studies, all beneficiaries are sent an advanced notice by the Beneficiary Contact Service (BCS), and are offered the opportunity to opt out of receiving the IDEAL mailing. If they do not opt out, Westat mails a letter and study brochure inviting recipients to review the listed eligibility criteria and either call the 800 number or return a postcard requesting a follow-up contact. Please see Attachment 9 for copies of the BCS advanced letter and the IDEAL mailing materials.

Recruitment continues to be directed towards seniors who reside within a 150 mile radius of Baltimore, MD. We have carried out the recruitment effort in waves. The first wave focused on areas immediately around Baltimore, including Baltimore City and Baltimore County, followed by Anne Arundel, Calvert, Carroll, Frederick, Howard, and Harford Counties, and, more recently, Montgomery County, Maryland, Northern Virginia, and Washington, D.C. The second wave has included farther reaching counties in Maryland, Virginia, and areas of Delaware. The third wave will include New Castle, Delaware, and counties in the states of New Jersey and Pennsylvania that fall within the 150 mile radius catchment area of Baltimore.

Telephone Interviews

As previously mentioned, seniors who are interested in the IDEAL Study are asked to complete a two stage screening process to determine their eligibility. The first stage of the process consists of a telephone interview; the interview is conducted in two parts, and only the callers who pass the first part are asked to complete the second. During recruitment

presentations and other recruitment activities, and in the written recruitment materials, seniors are given an 800 number to call to complete the telephone interview. The Stage One interview consists of questions concerning demographics, physical ability, health status, and medical conditions. Please see Attachments 5a and 5b (Phone Screener Interviews).

We recognize that the screening interview questions do not match those used in the standardized instruments. Rather, they are based on the physical function section of the BLSA Interview, which is administered to BLSA participants at each visit. Since existing BLSA participants comprise the comparison group for IDEAL, and the IDEAL eligibility criteria are the exact same criteria used for determining eligibility for all BLSA participants, we are using questions from this instrument rather than the standardized disability set. Note that the screening data will not be used for any analyses -- they are strictly for the establishment of eligibility for the IDEAL and BLSA – therefore the comparability of the screening data to other survey data is not relevant.

Physical Exam

Those who are eligible after completing the telephone interview are asked to complete the second stage of the screening process. The physical examination is a modified version of the full BLSA assessment protocol consisting of the following components:

- General appearance
- Vital signs
- Chest and heart auscultation
- Sensory systems including vision, hearing, sensory proprioception, neuropathy and balance

- Movement and strength of the upper and lower extremities.

In addition the potential participant will also be asked to complete physical performance tests, cognitive exams, an electrocardiogram and a blood draw. The results of the examination are recorded on the Physical Examination Form. Please see Attachment 7 for a copy of the Physical Exam Form.

When the study was initiated, the majority of screening interviews and examinations were carried out by Westat telephone and field staff, and screening examinations were done in the home. In August 2013, these activities were transferred to the NIA's BLSA clinic at MedStar Harbor Hospital in Baltimore. The NIA staff onsite at MedStar Harbor Hospital have assumed all screening duties. The screening process, instruments, and communication materials remain largely the same. The blood analysis is carried out by the NIA Research Laboratory. This has been an extremely valuable shift as it allows the lab results to be available while the participant is on site, thereby allowing for the suspension of further testing of any participant should those results render the participant ineligible. With the transfer of the physical screening exam to the more formal hospital facilities, participants are subject to brief wait times between testing which has increased the physical screening exam from 90 minutes to 120 minutes. Prior to the physical assessment appointment potential participants receive a cover letter (see Attachment 6), and a copy of the consent booklet and form (see Attachment 8). Note that since IDEAL is part of the BLSA, and participants are familiarized with the relationship between the two studies starting at recruitment, the consent materials used with screening exam participants are the BLSA materials, and separate IDEAL-specific consent materials are not used.

Each phase of the recruitment is conducted by staff with special skills relevant to their task. The first part of the telephone interview is conducted by a recruitment specialist, whereas

the second part is conducted by a licensed nurse practitioner; the physical examination also is conducted by a nurse practitioner.

The information collected during the screening process is used solely for the purposes of determining the eligibility of potential participants in the IDEAL Study. The study cannot be conducted without this information.

A.3 Use of Information Technology and Burden Reduction

The first part of the telephone screening interview is administered using a paper form. The information is then keyed into a database. The second part is administered using a paper form that has been programmed using Teleform which removes the need for data entry. The telephone screeners (both recruiters and nurse practitioners) are trained to administer the interview in a standardized fashion using well-established interviewing techniques.

Telephone interviewers are available Monday through Friday, excepting holidays to receive screener calls. The 800 number is equipped to accept messages. To the extent possible, the NIA's goal is to have someone available to administer the telephone interview whenever calls are received during normal office hours, thus ensuring that they occur at a time that is convenient for the participant. The 800 number has a message if staff are unable to answer that indicates someone will call back during normal office hours. Only participants that are eligible following the second part of the screening interview will be asked to participate in the screening exam, which will be conducted at the BLSA clinic at MedStar Harbor Hospital. These visits are scheduled during normal business hours, on a date that is convenient to the participant. Examiners follow a structured exam form designed to optimize efficiency of procedures and minimize the burden on respondents. Additionally, the exam includes break-off points so that

the visit can be shortened in the event that a test result indicates the participant is ineligible. Specifically, if a participant is found to be ineligible during the physical exam, the examiner concludes the visit at a suitable break-off point.

This study was covered under the Privacy Impact Assessment for BLSA that was approved in 2003 and is annually reviewed and updated by NIA. In 2011, the NIA Information Systems Security Office (ISSO) confirmed the applicability of the current BLSA PIA to the IDEAL study, that no modifications to the BLSA PIA were necessary, and that a separate IDEAL PIA submission was not needed. The ISSO has again confirmed that the IDEAL contract is with the BLSA PIA and has confirmed that the last BLSA PIA review was performed in 2011. Please see Attachment 10 (BLSA PIA).

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

The types of information being collected by this project have been collected in previous studies; however that information cannot be used to screen potential participants for the IDEAL Study. A new recruitment effort and information collection was undertaken to identify participants specifically eligible for and willing to participate in the IDEAL study.

A.5 Impact on Small Business or Other Small Entities

This study will not have any impact on small business or other small entities.

A.6 Consequences of Collecting Information Less Frequently

The potential participant will be required to complete a two-part telephone interview and, if eligible, one physical exam, during the screening process. The interviewer may find it

necessary to re-contact the participant to clarify a response given during the telephone interview. These clarifications are necessary to insure the accuracy of the information being used to determine the respondent's eligibility for the study. If necessary, any re-contact will be made only after the entire interview has been carefully reviewed by study staff to avoid multiple contacts for the purpose of collecting information.

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

This project complies fully with all guidelines of 5 CFR 1320.5.

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

The 60-Day Federal Register Notice for this information collection was published on April 2, 2014 in Vol. 79, page 18569. The purpose of the publication was to provide an opportunity for public comment regarding this information collection. No public comments or requests for information were received.

The recruitment plan was developed by Westat and is based on years of experience recruiting elderly participants for studies concerning health issues. These studies include but are not limited to the BLSA-Home Visit Program (National Institute on Aging), Women's Health and Aging Study (Johns Hopkins University, OMB No. 0925-0376, expiration 8/31/97) and NIH-AARP Cohort Study (National Cancer Institute, OMB No. 0925-0423, expiration 9/30/98). Westat has subcontracted media strategies and buying services to Boscobel Marketing Communications Inc. The information collection protocol was developed by the Luigi Ferrucci based on his expertise.

A.9 Explanation of Any Payment of Gift to Respondents

Any payment given to participants will be in the form of inexpensive tokens such as refrigerator magnets.

A.10 Assurance of Confidentiality Provided to Respondents

This project has been reviewed by the Westat IRB, the MedStar IRB, and the NIEHS IRB. NIA staff and contracted staff onsite at MedStar Harbor Hospital are responsible for obtaining informed consent from all individuals who participate in the screening. Verbal consent is implied by subject agreement to complete the two part telephone interview. For Stage Two screening, written informed consent is obtained at the time of the visit and before any component of the exam or blood collection is done. The consent includes a thorough and complete explanation of all components of the exam, the risks and benefits involved, any untoward effects one might expect, and who to contact with additional questions or problems. For a copy of the written consent booklet and form used during the physical exam, see Attachment 8.

The data collection staff are trained in the informed consent process by the NIA. They are trained to provide the subject with the time to carefully read the form, or read it to them, answer any questions that the subject may have and request that the subject sign the form if he or she is willing to participate. A copy of the consent form is given to the subject for his/her records. For a description of the procedures used to maintain the respondent's privacy and confidentiality please see Section A.11.

A.11 Justification for Sensitive Questions

Personally Identifiable Information (PII) and (PHI) is collected, including name, date of birth, education, and medical history. In addition, the interview contains questions regarding the potential participant's HIV status and whether or not he or she has ever been diagnosed with a psychological or psychiatric condition. The information concerning medical history and current medical conditions is necessary to determine the eligibility of potential participants.

The IDEAL recruitment staff of the NIA recognize the importance of maintaining the confidentiality of the PII and PHI. All identifying data are stored in separate, encrypted tables with password protection access limited to authorized personnel. We also comply with the Federal Information Processing Standards (FIPS PUB 41) and Computer Security Guidelines for Implementation of the Privacy Act of 1974. Westat, the NIA, and MedStar Harbor Hospital have well established procedures to protect the confidentiality of identifying information both for hardcopy forms and electronic data files. All Westat, NIA, and contracted staff onsite at MedStar Harbor Hospital sign a pledge of confidentiality. The pledge is re-signed on an annual basis for staff to reaffirm this commitment. All paper forms with identifiers are kept under carefully controlled conditions and locked in file cabinets when not in use. Access to the paper forms is limited to authorized personnel. Electronic files are password protected and identifying information is encrypted and separated from the research data.

During the recruitment process, Westat, NIA, and NIA-contracted staff onsite at MedStar Harbor Hospital will ensure that all potential participants understand that their participation is voluntary, that there is no penalty for withdrawal, and that the data obtained will be used for research purposes only. Subjects will also be reminded of the benefits of participation in the IDEAL Study which include free medical screening and assessments and the opportunity to contribute significantly to knowledge about how humans age.

IDEAL is part of the BLSA system, for which Privacy Act System of Records Notice (SORN) 09-25-0200, Clinical, Basic and Population-based Research Studies, was published in the Federal Register, Volume 67, No. 187, September 26, 2002. The System Name is NIH NIA Baltimore Longitudinal Study of Aging (BLSA).

A.12 Estimate of Hour Burden Including Annualized Hourly Costs

The recruitment goal was to enroll a total of 500 participants over a five year period or 100 participants per year. As previously identified, enrollment is the result of recruitment staff identifying target-rich segments within the 150 mile radius of Baltimore which is the geographic area available for recruitment. We plan to continue recruitment efforts in a manner that is both time-and resource efficient. These efforts include: conducting presentations where potentially eligible participants or their family and friends frequent, and advertising via local government, senior, and religious publication outlets. In addition, staff attend and exhibit at senior expos, retirement and fraternal organizations, religious forums, health aging forums and senior events. The estimated annual hour burden required for potential participants to complete the two stage screening process has been reduced and is based on projections that 500 individuals will complete the first stage consisting of part 1 of the telephone interview, which requires 10 minutes, and of that 500 who completed part 1 of the telephone interview, 200 individuals will complete part 2 of the telephone interview. Part two of the telephone interview also requires 10 minutes. Of the 500 Stage One Telephone interviews (Part 1 and 2) participants, only 100 are expected to complete Stage Two of the screening process, the physical exam, which requires 2 hours to complete. Of the 100 people who participate in Stage Two of the screening process

only 65 are expected to qualify to participate in the study. The annual hour burden is shown in the table below. The total number of annual burden hours is 333.

Table A.12-1. Estimate of Hour Burden

Type of Respondent	Instrument	Estimated Annual Number of Respondents	Number of Responses per Respondent	Average Time per Response (in hours)	Total Annual Burden Hours
Individuals	Recruitment Phone Screen Part 1 (Attachment 5a)	500	1	10/60	83
Individuals	Recruitment Phone Screen Part 2 (Attachment 5b)	200*	1	10/60	33
Individuals	Consent (Attachment 8)	100*	1	10/60	17
Individuals	Screening Exam Visit (Attachment 7)	100*	1	2	200
Totals		500			333

*These individuals are included in the 500.

Potential participants must be at least 80 years of age. It is expected that most 80 year olds are no longer working therefore there is no annualized cost to respondents. Nevertheless, in order to estimate a respondent cost, the project has used the figure of $28,798 for annual median family total income for all persons (i.e., male and female) ages 80 or older, as reported in the Social Security Administration's *Income of the Aged Chartbook, 2012* (SSA Publication No. 13-11727, Released: April 2014). The hourly wage rate has been calculated by dividing the Social Security Administration figure by a "year-round, full-time" hours figure of 2,080 hours. Based on a median hourly wage rate of $13.84, the total annualized cost to respondents will be $4609.

Table A.12-2 ESTIMATES OF ANNUALIZED BURDEN HOURS				
Type of Respondent	**Instrument**	**Total Annual Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Individuals	Recruitment Phone Screen Part 1 (Attachment 5a)	83	$13.84	$1149
Individuals	Recruitment Phone Screen Part 2 (Attachment 5b)	33	$13.84	$457
Individuals	Consent (Attachment 8)	17	$13.84	$235
Individuals	Screening Exam Visit (Attachment 7)	200	$13.84	$2768
Totals		333		$4609

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

There are no other annual costs to potential participants during the screening process.

A.14 Annualized Cost to the Federal Government

This is a request for a three year approval period. During this time the total cost to the Federal Government will be $138,723. This includes the contract cost, telephone charges for interviews, equipment used to conduct the physical exam, and lab analysis of the blood specimens. The specific staff identified in Table A.14-1 are employees of NIA. The annual cost to the Federal government is $46,241.

TABLE A.14-1. ANNUALIZED COSTS TO THE FEDERAL GOVERNMENT

	Total Cost
Contract Cost	$21,065
Oversight by COR, GS 14-9 ($113,904) (3.5% effort)	$4,711
Clinical Recruiter, GS 9-1 ($52,146) (7.5% effort)	$3,911
Registered Nurse, GS 12-1 ($75,621) (10% effort)	$7,562
Two Nurse Practitioners NP 1=GS 13-1 ($89,924) (5% effort) NP 2 = GS 13-1 ($89,924) (5% effort)	$8,992 $4,496 $4,496
TOTAL	$46,241

A.15 Explanation for Program Changes or Adjustments

This is a request for reinstatement with changes for an established project. The changes included in this submission are: two new recruitment components (a more expanded recruitment presentation and a recruitment mailing to CMS beneficiaries); the use of a two-stage telephone

screening protocol conducted in place of a single telephone screening contact; minor changes to both the screening interview and screening exam protocols; and a new consent form created under the direction of the NIEHS IRB.

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

The data collected by this information collection will not be used for analysis. We are requesting a three year approval period for this project. The table below describes the project time schedule.

Table A.16-1. Project Time Schedule

Project Activity	Time schedule
Beginning of Recruitment Wave 3	1 week after approval for 12 months
Reconnection throughout Catchment and Continued recruitment	12-36 months after approval

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

There is no reason not to display the expiration date for OMB approval of the data collection instruments used for this study.

A.18 Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the Certification for Paperwork Reduction Act Submission being sought for this study.