

Supporting Statement A for

Recruitment and Screening for the Insight into Determination of Exceptional Aging and Longevity (IDEAL) Study (NIA)

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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 Research on Aging Act of 1974 (Public Law 93-296) established a National Institute on Aging (NIA). 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 propose to enroll in the BLSA individuals who have already reached the goal of healthy longevity (IDEAL cohort) using as eligibility criteria ~~exactly~~ the same very strict criteria for "Healthy" used for the 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) and cognitive problems (MMSE score >27 and Blessed Mental <3). These individuals 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~~IDEAL and non-~~ideal~~IDEAL individuals will be age and sex matched and discriminated by their IDEAL or non-IDEAL status.

~~More recently, the BLSA has begun to focus on factors associated with exceptionally healthy aging.~~ **— 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 is 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. The IDEAL Study cohort will be compared to current BLSA participants who were 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. The purpose of the project for which we are seeking OMB approval is to conduct 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

The purpose of the project for which we are seeking OMB approval is to conduct recruitment and screening for the IDEAL Study. A multifaceted recruitment approach will be used to reach the target audience in a wide variety of ways. Those who are

interested in participating in the IDEAL study will be asked to complete a two stage recruitment process consisting of a telephone interview and a physical exam.

Recruitment plan

Given the study's target population, we anticipate that face-to-face presentations, relationship building with senior organizations, and material sharing will likely be the most effective recruitment approaches. Please see Attachment 1 for a draft of the recruitment presentation. However, we believe a multi-faceted recruitment approach is critical and we will seek 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 will be highlighted in project conversations and presentations. As participants are identified, both at the presentation phase and during screening, we will 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 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 to be targeted include:

- Senior Centers
- Senior residences
- Faith-based organizations

- Maryland, Delaware, and Pennsylvania chapters of the Senior Olympics
- 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
- Nationwide Non-Governmental Organizations for Seniors (AARP)

Please see Attachment 2 for a draft of the recruitment letter that will be sent to the targeted organizations.

In addition, Westat will subcontract media strategy and buying services to Boscobel Marketing Communication, Inc. Boscobel is a full service marketing communication firm with broad capabilities in media planning, buying and placement. Boscobel will be responsible for newspaper, radio and television promotion for the recruitment effort. Please see Attachment 3 for draft copy of a recruitment poster and Attachment 4 for a draft copy of the study brochure. Westat will work with NIA to develop a website that contains information regarding both the BLSA and the IDEAL Study; a site where interested individuals can obtain information about the study, its purpose and recruitment criteria.

Recruitment will be directed towards seniors who reside within a 150 mile radius of Baltimore, MD. We propose to launch the recruitment effort in waves. The first wave will focus on areas immediately around Baltimore, including Baltimore City, Baltimore County, Montgomery County, Maryland, Northern Virginia, and Washington, D.C. The second wave will include the remaining counties in Maryland and Philadelphia,

Pennsylvania. The third wave will include New Castle, Delaware, and counties in New Jersey and Pennsylvania.

Telephone Interview

As previously mentioned, seniors who are interested in the IDEAL Study will be asked to complete a two stage screening process to determine their eligibility. The first stage of the process consists of a telephone interview. During the recruitment presentation seniors will receive 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 Attachment 5 for a copy of the telephone interview.

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 will be 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 majority of the physical exams will be conducted in the home of the potential participant. However, we will be prepared to conduct these exams in other settings as appropriate, for example, in a room provided at a senior living community. Prior to the home visit potential participants will receive a packet of information including a cover letter (see Attachment 6), a consent form, and a list of pre-visit instructions(see Attachment 7). The physical examination will be conducted by nurses with current licensures in the state of Maryland who will be hired specifically for this project. The results of the examination will be recorded on the Physical Examination Form. Please see Attachment 8 for a copy of the Physical Exam Form.

The information collected during the screening process will be 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

We plan to use a web version of the interview, programmed using Teleform. When a prospective participant calls in to complete the screening interview, the telephone interviewer will be able to call up a blank interview and administer it. The telephone interviewers will be trained to administer the interview in a standardized fashion using well-established interviewing techniques.

With our multi-faceted recruitment approach, we anticipate that there may be times when the recruitment coordinator (perhaps accompanied by an elite interviewer) will visit a senior living community or health fair and carry out the in-person Stage One screening interviews. We will provide the staff with a laptop computer and internet access so that they can also use the web version of the interview.

To provide for maximum coverage to accommodate incoming calls, we plan to train a group of interviewers who can be available to receive calls on evenings and weekends in addition to weekdays and administer the telephone interview. To the extent possible, our goal will be to have someone available to administer the telephone interview whenever calls are received, thus ensuring that they occur at a time that is convenient for the participant. The 800 number will have a message if we are unable to answer that indicates someone will call back shortly, but we want to limit the number of callbacks.

Only participants that are eligible following the screening interview will be asked to participate in the screening exam, which will be conducted at participants' homes. These visits will be scheduled at a time that is convenient to the participant. Examiners

will follow a structured exam form and script designed to optimize efficiency of procedures and minimize the burden on respondents. Additionally, the exam will include 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 will conclude the visit at the end of the physical exam and will not conduct the EKG or blood draw.

This study is covered under the Privacy Impact Assessment for BLSA that was approved in 2003 and is annually reviewed and updated by NIA. An assessment of the IDEAL study was done by the NIA Information Systems Security Office to determine whether the BLSA PIA required modifications. It was determined that no modification were necessary. A Privacy Impact Assessment (PIA) is currently being conducted for this study.

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 information collection must be undertaken to identify participants who are currently eligible 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 one telephone interview and, if eligible, one physical exam, during the screening process. The interviewer may find it necessary to contact the participant a second time to clarify a response given during the 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, the second contact will be made 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 September 17, 2010 in Vol. 75, page 57038. The purpose of the publication was to provide an opportunity for public comment regarding this information collection. No public comments 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) and NIH-AARP Cohort Study (National Cancer Institute). Westat will subcontract media strategies and buying services to Boscobel Marketing Communications Inc. The information collection protocol was developed by the investigators based on their 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 is being reviewed by the Westat IRB. Westat will be responsible for obtaining informed consent from all individuals who participate in the screening. Verbal consent will be obtained prior to administering the telephone interview. For a copy of the script used to obtain verbal consent for the telephone interview see Attachment 9. For Stage Two screening, written informed consent will be obtained at the time of the visit and before any component of the exam or blood collection is done. The consent will include 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 used during the physical exam see Attachment 10. We are applying for a Certificate of Confidentiality for this project.

Westat will train the data collection staff in the informed consent process. They will be 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 will be 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) will be 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.

Westat recognizes the importance of maintaining the confidentiality of the PII. The PII will be stored in separate, encrypted tables with password protection access limited to authorized personnel. We will also comply with the Federal Information Processing Standards (FIPS PUB 41) and Computer Security Guidelines for Implementation of the Privacy Act of 1974. Westat has well established procedures to protect the confidentiality of identifying information both for hardcopy forms and electronic data files. All Westat staff 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. Upon completing testing of study samples, Quest Diagnostics will post their laboratory test results reports to a secure web site where only registered members of the project staff from Westat and the NIA can access and download them. Participant samples sent to Quest Diagnostics will carry the participant's unique study identification number only; thus no personal identifiers will be associated with the samples or tests results hosted on the secure website.

During the recruitment process, Westat 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.

A.12 Estimate of Hour Burden Including Annualized Hourly Costs

The recruitment goal is to enroll a total of 500 participants over a five year period or 100 participants per year. The estimated annual hour burden required for potential participants to complete the two stage screening process is based on projections that 1,500 individuals will complete the first stage consisting of the telephone interview which requires 10 minutes. Of the 1,500 Stage One participants, only 300 are expected to complete Stage Two of the screening process, the physical exam, which requires 90 minutes to complete. Of the 300 people who participate in Stage Two of the screening

process only 100 are expected to qualify to participate in the study. The annual hour burden is shown in the table below.

Type of Respondent	Number of Respondents	Frequency of Response	Average Time per Response	Annual Hour Burden
Individuals who complete the phone interview	1,500	1	0.167	251
Individuals who complete the physical exam	300*	1	1.5	450
Totals	1,500			701

*These 300 individuals are included in the 1,500.

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.

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 \$46,173. This includes the cost of forms development

and printing, computer services for collecting and storing the data, telephone charges for interviews, equipment used to conduct the physical exam, and lab analysis of the blood specimens. This project is monitored by the agency as part of the BLSA therefore there are no additional costs. The annual cost to the Federal government is \$15,391.

A.15 Explanation for Program Changes or Adjustments

This is a new project.

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.

Project Activity	Time schedule
Beginning of Recruitment Wave 1	1 week after approval
Beginning of Recruitment Wave 2	3-6 months after approval
Beginning of Recruitment Wave 3	6-12 months after approval
Recruitment continues	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.