Supporting Statement B for

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

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B. 1 Respondent Universe and Sampling Methods

Since no preliminary information is available on the characteristics of the study population that we are targeting for this study and because we will be exploring multiple characteristics potentially associated with the IDEAL status,a "traditional" sample size calculation was not conducted. We have already available data from 480 non-IDEAL participants 80 and older that had their follow-up visit after 2003 and therefore were assessed with the current protocol and have biological samples already available. However, of these 480 non-IDEAL visits, only 400 have complete data. Based on the current BLSA population, at least 100 individuals who are no longer IDEAL will become greater than 80 years old over the next 5 years. This was the rationale for selecting 500 ~~IDEAL~~ new IDEAL participants to be entered in the BLSA. We conducted a power calculation for allele frequency comparisons between genotypes assuming 500 "Elite Aging" individuals and 500 unrelated BLSA control participants. We calculated power across a range of detectable effect sizes using a strict significance threshold of $9.1x10^{-8,}$ corresponding to a conservative Bonferroni corrected genome-wide significance level of ~0.05 assuming 550,000 independent tests for the genes included in the Illumina chip. This sample size allows 80% power to detect relative risks between 1.5 and 2.0. when comparing allele frequencies between 500 cases and 500 controls. Power calculations assume a multiplicative model and a disease prevalence of 1%.

Likelihood of attrition whether because participants no longer choose to participate or because they "lose the ideal condition" after age 80, although impossible to estimate, is probably very high. We have therefore focused on addressing the main aims

of the study using data collected during the initial visit, and we should have enough "events" for analysis.

Probability sampling is not being used because there are an insufficient number of potentially eligible participants. In order~~ed~~ to achieve the desired sample size, all potentially eligible participants must be given an opportunity to participate in the screening process.

The rollout plan for recruitment is based on an analysis of the population density of residents 80 years and older found throughout the catchment area, coupled with geographic proximity to Baltimore. The catchment area consists of 150 miles around Baltimore. By identifying these target–rich segments of the geographic area available for recruitment, we plan to recruit in a manner that is both time-and resource efficient. We will begin outreach and marketing in the easily accessible cities/counties in the Baltimore area and reaching older adult residents primarily through their organizational affiliations (whether faith based, senior centers or senior residences). To further target our efforts appropriately, we will use census block density data to identify naturally occurring elder communities as well as neighborhoods with relatively high populations of older adults. As necessary, we will expand our efforts into areas with smaller populations of older adult residents.

We plan to launch the recruitment effort in waves as shown below:

- **Wave 1 (Recruitment commencement to 3 months)**
  Baltimore City
  Baltimore County
  Montgomery County, Maryland
  Arlington County, Virginia
  Fairfax County, Virginia
  Washington, D.C.

- **Wave 2 (3 months -6-months)**
  Prince George's County, Maryland
  Anne Arundel County, Maryland
  Philadelphia, Pennsylvania

- **Wave 3 (6 months -1 year)**
  New Castle, Delaware
  Counties in New Jersey: Camden Middlesex, Monmouth, Ocean, Burlington, Mercer
  Counties in Pennsylvania: Adams, Berks, Chester, Delaware, Lancaster, Lehigh, Luzerne, Montgomery, Northumberland, York

The first three months of recruitment focus on saturating and recruiting from the high density areas immediately around Baltimore, including Baltimore City, Baltimore County, Montgomery County, Maryland, Northern Virginia, and Washington, D.C. We will conduct thorough outreach in theses initial cities and counties of interest, broadening our recruitment area over time as we blanket a particular community with information and material regarding the study and recruitment. This timeline will be flexible, however, and should we have opportunities or identify a need earlier in the process to begin recruitment in other geographical areas we will do so.

We plan to expand to Philadelphia by month 6 of recruitment after focusing on Prince George's County and Anne Arundel County in Maryland. The first two waves of recruitment will be conducted in areas with a combined 80+ population of 203,097. We will also expand recruitment into outlying areas in the later part of the recruitment cycle, including more rural area and smaller towns, based on population density and other factors.

The plan is to conduct approximately one hundred recruitment presentations per year. The presentations will explain the purpose of the IDEAL Study, the eligibility criteria, and what is required of participants. Presentations will be made to audience of at least 20 potentially eligible seniors. The goal is that each presentation will generate 15 people who are either willing

to participate or who know someone who may qualify and is willing to participate in Stage One (telephone interview) of the screening process. The annual response rate is:

$$\frac{\text{The number of people who complete the interview (1,500)}}{\text{The number of people who receive the presentation (2, 000 +)}} = \text{approximately75\%}$$

The recruitment effort will also include newspaper, radio and television promotion, which will provide information about the IDEAL Study and a number for interested potential participants to call to participate in the telephone interview. While it is not possible to determine how many people will be exposed to the media campaign the hope is that it will allow us to make up the difference when the response rate from the presentations is less than desired.

As we identify "best sources" for recruitment and develop relationships with agencies and personnel, we will cycle back through recruitment locations in subsequent years. We may present the study again at the most fruitful locations, refresh materials and renew contacts as staff turnover occurs, orienting new staff to the study goals and criteria for inclusion. We will also remind contacts that over the life of the project, some potentially eligible individuals will "age into" the target population of interest and should be brought to our attention at that time. In other words, we will facilitate tracking of 78 and 79 year olds who will soon turn 80 and are healthy and interested in the study.

The recruitment waves are a framework for organizing, scheduling, and tracking our recruitment efforts according to general geographic areas (e.g., cities and counties). Although we are prioritizing according to 1) proximity to Harbor Hospital and 2) population density of persons 80 and older, beyond the first year or so, we do not expect to be exclusively in any one area or wave at a time, but rather to continue to be responding to and providing information for contacts in all the areas where we have established ties. For example, we may return annually to

certain areas and events in order to look for prospective participants who have aged into the IDEAL population since we last did recruitment. Only if we were to reach the overall recruitment ceiling, i.e., 500, would we end our recruitment efforts, but there are no interim caps or allotments set by wave.

~~Probability sampling is not being used because there are an insufficient number of potentially eligible participants. In ordered to achieve the desired sample size, all potentially eligible participants must be given an opportunity to participate in the screening process.~~

B. 2 Procedures for collection of information

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. 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 are working 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.

The plan is to do 100 presentations per year. We will identify the appropriate organizations in each of the recruitment areas. We have identified 50 organizations in the Baltimore City and County area. The Recruitment Coordinator will send a recruitment letter (Attachment1) to the appropriate person at each organization. The letter will be followed by a phone call to answer any questions, schedule an appointment for a presentation, or arrange to send print material for display. The presentation will be 15 minutes in length and have a standardized format and content. There will be a team of three to five presenters who will be given standardized training which will include the opportunity to practice the presentation and receive feedback from experience recruiters. To minimize travel costs the Recruitment Coordinator will make every effort to group the presentations to allow a single presenter to make multiple presentations on the same day.

During the presentation the audience will be given an 800 number for those who are interested to call to complete Stage One of the recruitment. The number will also be included in the study brochure and as a tear-away on the study poster. Stage One is a ten minute telephone interview that consists of questions concerning demographics, physical ability, health status, and medical conditions. Please see Attachment 4 for a copy of the telephone interview.

Those who are eligible after completing the telephone interview will be asked to complete the second stage of the screening process. The physical exam will be scheduled at the participant's convenience. The physical examination is a modified version of the full BLSA assessment protocol consisting of the following components:

- General appearance (alertness, awareness, posture an motor behavior, appearance, mood, apparent mental health and functional status)
- Vital signs (blood pressure)
- Heart and lung auscultation
- Sensory systems including

  Vision (Jaeger Eye Card)

  Hearing (Whisper voice test)

  Sensory proprioception (Test awareness of the body in space using the feet)

  Neuropathy (Monofilament)

  Neurological (The Romberg Test)
- Movement and strength of the upper and lower extremities.

  Extremities inspection

  Pronator Drift

  Leg Strength

In addition the potential participant will also be asked to complete physical performance tests consisting of tests of standing balance; a measured walk and chair stand; cognitive exams including the Blessed-Information –Memory- Concentration Test (BIMC) and Mini Mental State Exam (MMSE); 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 5), a consent form, and a list of pre-visit instructions(see

Attachment 6). 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 7 for a copy of the Physical Exam Form.

Westat will be using an electronic questionnaire and web capture system for collecting the telephone interview data. The interview will be completed by Westat's telephone interviewers via a secure web service. For the physical exam and medical history forms, Westat will use hardcopy Teleforms. For these forms, Teleform creates an image of the scanned form and extracts data according to rules defined for the form. Form templates are defined to identify skip patterns and valid response options. Subsequent data verification is done in a paperless environment using the scanned images of the forms, and hard copy forms are available in the library for reference to address scanning problems that may have resulted from handwriting that is difficult to read or forms that have been damaged before scanning. For the web capture interview, Teleform executes rules during data collection (including skip patterns and valid response options) and form images are available, as with scanned forms, for further review. Quality control steps are embedded throughout the Teleform processing cycle for both web capture and hardcopy scanning and data capture. For hardcopy scanning these include setting appropriate sensitivity levels for verifier review and procedures for handling blank fields. A data decision log is maintained where decisions affecting all forms and decisions affecting individual forms are documented.

As data from individual data collection forms are captured and reviewed for quality, data are exported to a SQL database. These are further reviewed and edited in accordance with study decisions. This includes generation and review of frequencies and cross tabulations as well as

comparison of IDs between the scanned data and the participant tracking data. Hand offs and deliveries of data are accompanied by appropriate documentation including logs of form verification and data decisions as well as data and file descriptions.

Lab test results will be accessed from the laboratory's secure website and imported into the database. The data will be checked to ensure that results are received for each sample submitted and that values are complete and within lab-provided ranges.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse.

As explained in Section B1, the goal is an annual response rate from the presentation of 75% based on the following equation:

$$\frac{\text{The number of people who complete the interview (1,500)}}{\text{The number of people who receive the presentation (2, 000+)}} = \text{approximately75\%}$$

We plan to maximize the number of respondent from each presentation using various methods. A system will be created to track the number of people who attend each presentation and the number who choose to participate in Stage One of the screening process. Each presenter will carry blank cards and a suggestion box. The audience will be invited to provide suggestion regarding ways to improve the presentation. The presenters will also conduct informal conversations with the organization staff who witness the presentation regarding ways to improve the presentation. The recruitment coordinator will be responsible for contacting all locations where posters and brochures have been placed to make sure that they have an adequate supply. The presentations will be augmented by local print, radio, and television advertisement that will provide

information concerning the study and the 800 number to call in and complete Stage One of the recruitment process.

We will be monitoring our recruitment activities closely, including by requesting detailed referral information during the telephone screener, in order to determine which activities and events stimulate the most calls. Therefore, the per-presentation response rate will be one of various gauges for evaluating the effectiveness of our recruitment efforts. Additionally, we will, by necessity, be adjusting our approach in different areas according to differences in availability and coverage provided by different outlets and presentation settings (e.g., local newspapers, community newsletters, senior centers, church groups, etc.). In some areas, in-person presentations may be of greater impact, whereas in others, communication through other media may factor more significantly. Regardless, if some approaches and some geographic areas are not yielding sufficient response to meet our needs we will reduce our efforts in these areas in favor of the ones that do provide better a response, and our tracking and self-assessment efforts will support this process.

If despite our best efforts we are unable to enroll at least 450 IDEAL participants, it may be possible to prolong the enrollment time by at least 1 year.

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B. 4 Test Procedures for Methods to be Undertaken

Although the presentations and print media have not been tested using a focus group. They have been designed by experienced recruiters and those who are familiar with the target audience.

B.5 Individual Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The purpose of this project is to recruit participants for the IDEAL Study, as such, there are no statistical analyses. The sampling plan was developed by Westat and Dr. Ferrucci at the National Institute of Aging (NIA).

The data will be collected by personnel hired and trained by Westat. The physical exam will be conducted by nurses with current licensures in the state of Maryland.

The data will also be analyzed by Westat.