

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE E 1	OF PAGES 8
2. AMENDMENT/MODIFICATION NO. One (01)	3. EFFECTIVE DATE 07/09/03	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (if applicable)	
6. ISSUED BY CODE National Institutes of Health Division of Research Acquisition, OLAO/OA/OD 6100 Executive Boulevard, MSC 7540 Room 6E01 Bethesda, Maryland 20892-7540		7. ADMINISTERED BY (If other than Item 5) CODE SAME AS ITEM 6.		
8. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, State and ZIP Code) TO PROSPECTIVE OFFERORS "REPRESENTATIVE SAMPLING FOR THE HEALTHY AGING IN NEIGHBORHOODS OF DIVERSITY ACROSS THE LIFE SPAN (HANDLS) STUDY"		(√)	9A. AMENDMENT OF SOLICITATION NO. 260-03-15	
		x	9B. DATED (SEE ITEM 11) 06/11/03	
			10A. MODIFICATION OF CONTRACT/ORDER NO.	
CODE	FACILITY CODE		10B. DATED (SEE ITEM 13)	
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				

x The above numbered solicitation is amended as set forth in item 14. The hour and date specified for receipt of Offers is extended, x is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (if required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

(√)	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor _____ is not, _____ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

PURPOSE: To respond to offerors' questions.

The due date for submission of the proposal is unchanged (2:00 p.m. on August 11, 2003).

Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER Teresa A. Baughman Contracting Officer	
15B. CONTRACTOR/OFFEROR BY _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY _____ (Signature of Contracting Officer)	16C. DATE SIGNED

Question #1

The screening ratio will be driven by the proportion of the population that makes up the least frequent subgroup. In other words, if "high income African Americans males over 64" are the most infrequently occurring subgroup of all those required shown in Table 1, then the density of this subgroup in the population will determine how much screening has to be done overall, since all other cells in Table 1 will have been filled before that one is filled.

It would be very helpful to know the exact Census tracts that will be used in the study because that would allow us to make a reasonably accurate estimate of what screening ratio will be required.

If this is not possible, can NIA provide some estimate of the screening ratio to use for bidding purposes?

Response #1

The NIA is currently reviewing candidate census tracts. We estimate that the Contractor shall need to screen approximately 33,000 households overall. The tracts and the locations of the MRV have not yet been determined.

Question #2

Will the sample of African-Americans be limited to those born in the U.S or will it include persons born in Africa and the Caribbean?

Response #2

There are too few non-U.S.-born "African Americans" to specifically exclude them from sampling. Also, we will not exclude non-U.S.-born whites.

Question #3

Given gentrification trends, some neighborhoods may change radically over the course of the study. Are plans being made to follow the study population to other locations, or will those who have moved within Baltimore City be considered non-responders in future waves?

Response #3

The NIA plans on following participants wherever they go over the course of the HANDLS study. Over the twenty-year span of the study, the NIA will adjust the study locations to suit migration patterns inside (and perhaps outside) of Baltimore City.

Question #4

Asking questions about household income is very problematic in a short screening interview. Will it be necessary to do this or will the categorization of high and low income be based on something else, such as Census tract?

Response #4

As stated in the Statement of Work, Attachment 2 of the RFP, Section G.3., the Contractor shall use a short doorstep screening procedure to determine whether households are below 125% of the poverty index.

Question #5

It is typically very difficult to get examinees to come for the MRV exams on week days. What proportion of the MRV exam slots will be scheduled for evenings and weekends?

Response #5

It is anticipated that there will be MRV exams every other Saturday and at least two evenings per week. Evening sessions present a challenge because fasting blood samples are required. We may ask participants with evening appointments to donate a fasting sample in the morning (e.g., before leaving the neighborhood for work).

Question #6

In what type of location will the MRV be located (school yard, hospital parking lot, etc.)?

Response #6

Although the location of the MRVs have not yet been determined, the NIA is looking for places that are sufficiently public and easily accessible by anyone living in the census tract. The NIA is trying to avoid high traffic areas so we don't occupy scarce parking resources (e.g., some schools, major streets).

Question #7

Can you tell us anything about what is involved in the exam, for example, how much blood needs to be drawn? What other invasive or otherwise unpleasant techniques are involved?

Response #7

The exam shall include drawing approximately 50 ml of blood after an overnight fast.

***Alan - Don't we have a booklet that tells about what's required in the exam? If so, is it available electronically that I could pass on to the offerors?**

Question #8

If respondents report to the MRV who have not complied with the fasting requirements, will you examine them anyway or will they have to be rescheduled?

Response #8

The examination will be performed and they will be asked to return the following morning after fasting. It is anticipated that a portion of the "inconvenience payment" shall be withheld until they return to donate a fasting blood sample.

Question #9

How long is the exam expected to take?

Response #9

The exam is expected to take approximately six (6) hours.

Question #10

What compensation will subjects receive for completing the interview and the exam?

Response #10

The NIA has not yet determined that, but will be based on NIH guidelines.

Question #11

Will participants receive any information or test results back from the exam?

Response #11

All participants will receive a report concerning their lab tests and other physical findings. The report will note lab tests that might indicate chronic or acute health problems and it will provide referral information when necessary.

Question #12

Is NIA planning to provide childcare for respondents who need it in order to participate in the exam? Is NIA planning to provide transportation for respondents who need it in order to get to the exam?

Response #12

The NIA is not planning on providing childcare. The NIA is planning on providing transportation.

Question #13

Scheduling. It is important that interviewers be able to schedule the exam appointment at the time they complete the household interview. Since most household interviewing will occur at night and on weekends, it is important that a central scheduling facility operate in the evenings and on weekends in order that the interviewer can immediately confirm the availability of the appointment time preferred by the subject. Will the Contractor be given the responsibility of coordinating this scheduling activity or will MRV staff handle this?

Response #13

As stated in the Statement of Work, Attachment 2 of the RFP, Section G.6., the Contractor shall perform the scheduling. To facilitate scheduling, the hours of operation of the MRV will be provided by NIA to the Contractor well in advance, and the Contractor shall provide NIA with an appointment file for each day's operation.

Question #14

The SOW lists expected response rates of 98% for the screening and 85% for the examination rate (those who have completed both 2- hour interview and exam). Is there an expected response rate for the household interview alone?

Response #14

The NIA has not derived an expected response rate for just the household interview.

Question #15

Would it be possible to see a draft of the household interview at this time?

Response #15

The draft of household interview has not yet been finalized and it has not yet been approved by our Institutional Review Board (IRB) or by the Office of Management and Budget (OMB). Therefore, the NIA cannot provide it at this time.

Question #16

Will NIA provide a programmed version of the household interview for the Contractor? If yes, in what language will it be in?

Response #16

Section G of the Statement of Work, Attachment 2 of the RFP, states that the Government will provide the questionnaire in the form of a web page. In addition, the Statement of Work, Section G.2. states that the 24-hour dietary recall is programmed in Blaise.

Question #17

If the programming has not yet been completed, is it NIA's intention that the Contractor conduct the pilot study using a hard-copy version of the household interview? (If it is the Contractor's responsibility to program the instrument, we do not think there will be time to program a 1 ½ hour interview in the 6 weeks start up time allotted.)

Response #17

The Statement of Work, Section G. states that the Government will provide the household interview in the form of a website. Also, refer to the NOTE, which states, "The Government will consider reasonable alternative methods for collecting the household interview if an Offeror proposes them."

Question #18

The SOW states: The government will supply the content of (the) household interview in the format of a web site that operates on a portable computer. This implies that interviewers will access a computer-assisted instrument via the Internet to conduct the household interview. Is that NIA's intent? If yes, this means that each sampled household will need an Internet connection. (In our view, wireless Internet connections are not technically feasible at this point.) Please clarify.

Response #18

See response to Question #17 above.

Question #19

Dietary recall. The RFP mentions that the dietary recall interview will be conducted using Blaise-based CAI. It is our experience that dietary recall interview data require an extensive amount of "back-end" coding and data preparation. Will that be the responsibility of the Contractor?

Response #19

The NIA will perform "back end" coding of the nutritional questionnaire in collaboration with a nutritional epidemiologist and the Department of Agriculture.

Question #20

The list of government-furnished items in Appendix 18 does not include the screening interview or the household interview. Is that an oversight?

Response #20

The Statement of Work, Section G.1. states that the NIA shall provide these items. It was inadvertently omitted from Attachment 18 of the RFP.

Question #21

We are very interested in learning more about the pilot project conducted by NIA IRP described in the statement of work in the RFP. For example, we were wondering who the principal investigator was on the study, if there was additional information about the methodology, and who conducted the pilot.

Response #21

The NIA IRP Intramural Investigators conducted the pilot project. The pilot was part of the acquisition planning process and therefore, no additional information is available.