National Heart, Lung, and Blood Institute

REQUEST FOR PROPOSAL NUMBER:

NHLBI-HC-06-01 Hispanic Community Health Study - Coordinating Center

Amendment No. 1

DATE OF ISSUANCE: October 14, 2005

The above numbered solicitation is amended as set forth below. **The hour and the date specified for receipt of Offers remains unchanged.** Offerors must acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by one of the following methods:

1. By acknowledging receipt of this amendment on each copy of the offer submitted. **Please note that this is the preferred method.**

2. By separate letter or telegram which includes a reference to the solicitation and amendment numbers.

3. By requesting a copy of the Standard Form 30 for this amendment and completing the information requested in items 8 and 15, and returning 1 copy of the amendment; (a hard copy of this amendment, including the Standard Form 30 may be requested from Kristiane E. Cooper, Contracting Officer, e-mail: cooperke@nhlbi.nih.gov).

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 letter or telegram, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

This amendment revises the RFP as stated below.

PART 1. The following questions and answers are provided for clarification and informational purposes based on inquiries from potential offerors. (Note that FC is a question pertaining to the Field Center – RFP No. NHLBI-HC-06-02, and CC is a question pertaining to the Coordinating Center – RFP No. N01-HC-06-01.)

1. (FC) QUESTION: The request for social security numbers may be problematic in that we have a significant … population in the … area who are undocumented. They may have social security numbers that are not their own. Is not having a valid social security number another exclusion? If so, this limits generalizability of the results. Also, methods to determine legal status or validity of documents are not well developed. Attempts to collect this information could also reduce response rates since many families are of mixed status.

   ANSWER: In Federal Studies, the actual provision of a SSN, though requested, is not required and statements are made that a study participant doesn't have to provide it and there will be no adverse consequences if they refuse. Regarding the validity of the number, we wouldn't really know if it is correct or not.

2. (FC) QUESTION: The timeline on page 12 does not match the timeline in the chart on page 11 (e.g, when IRB approval is to be obtained). Please clarify which timeline we should use.

   ANSWER: IRB approval is required to be completed prior to start of the actual study. Since the first year of the study is planning and preparation, the IRB approval was assumed to be completed at the end of that first year, but the primary issue is that it is needed prior to the start of the data collection process.

3. (FC) It is recommended that exams be conducted during evenings and weekends. Given the need for fasting for OGTT, does NHLBI have a recommendation as to how we can provide evening exam appointments?

   ANSWER: For those who are not able to participate in examinations during the week day, then morning weekend examinations should be scheduled. On rare occasions, a study participant may only be able to attend an afternoon or evening examination, and the study steering committee will need to decide whether an exception should be made to the fasting status.

4. (FC) QUESTION: Do all examinees need to receive OGTT, or just a sub-sample? Previous NHANES have found extremely low response rates for this component.

   ANSWER: All participants should be scheduled for the OGTT. While there are some refusals we have found that an encouraging and positive attitude by staff results in higher response rates to this portion of an examination.

5. (FC) How many exams are required or recommended? On page 3, it appears that there may be 2 rather than just the baseline exam.

   ANSWER: This RFP only requests one examination.

6. (FC) QUESTION: page 79, "Notes to Offerers...." specifies several examination components that should be included with separate budgets (eg, not part of the main budget). Please clarify whether the following components should be prepared as separate budgets:

   a. Data collection system (Note 9 is ambiguous)
   b. "Propose a cost-efficient direct assessment of overnight sleep disordered breathing..." (Attachment 3, p 7)
   c. "Measure activity levels using activity monitors worn by the participants" (Attachment 3, p 7)

   ANSWER: a) See revision to Note 9 under Part 4 of this amendment. It will be easier but not required to propose the budget separately. In response to questions b and c, a separate budget is not needed for these components.

7. (FC) QUESTION: A laboratory panel is specified on Attachment 3, p 7. Are costs for the lab assays to be included in Field Center budgets, or will this cost be covered by the Core Laboratory or Coordinating Center budget?

   ANSWER: Sample acquisition and onsite processing costs will be incurred by the Field Center, but the actual costs for the laboratory assays will be borne by the Coordinating Center contract.

8. (FC) QUESTION: In addition to staff time to obtain diet assessments, there are also costs associated with tailoring nutrition data systems for use in the study. For example, computer programmer time may be needed to modify existing systems to accommodate Hispanic foods. Presumably, this would be organized by the Coordinator Center with the aim of making a system that would be used at each site. Are these costs to be included in FC budgets?

   ANSWER: Most of the costs to develop the nutrition instruments will be incurred by the Coordinating Center, but if a Field Center anticipates that they should contribute expertise for this process, they should so propose.

9. (FC) QUESTION: Please clarify the expectations regarding the use of mobile vans. Under the mobile van scenario, will the target number of subjects, pace of recruitment (eg, 6 ppts per day), and scope of the examination be the same as with the stationary clinic? Are these envisioned as 2 separate options, or will it be acceptable to use both stationary clinic and vans -- and if the combined option is acceptable, can there be a third proposed budget for such an approach (in addition to the van-only and clinic-only budgets)?

ANSWER: A Field Center will need space and facilities for handling all of the data and administrative responsibilities for the study, and will need space and facilities for the clinical examination. We are requesting that for the clinical examination, a Field Center prepare two proposals, one for a mobile van, and separately one for a fixed space. In either scenario the number of participants seen per day would be the same. While a Field Center could also propose both options to be done at the same time, on the surface it seems like the costs for both a van and an office space for the clinical exam would be higher than is needed.

10. (FC, CC) QUESTION: Is there an overall estimate of effort for the RFP besides that stated for the PI and Co-PI in Section L. Item 1.e?

ANSWER: Please see Part 3 below.

11. (CC) QUESTION: Are the separate Reading Center proposals to be part of the Coordinating Center budget summary?

ANSWER: Yes.

12. (CC) QUESTION: Are there page limits on the Reading Center proposals?
ANSWER: The technical plan for the reading centers should be included within the page limitation as specified in the RFP. Please note that we are deleting the requirement for a dental reading center.

13. (FC) QUESTION: Is there an assumed level of infrastructure at the Field Centers or is that the responsibility of the Coordinating Center (i.e., computers with internet connections)?

ANSWER: The Coordinating Center will be responsible for all of the computers and data processing infrastructure necessary for the data collection in the Field Centers.

14. (FC) QUESTION: How many hospitals/clinics are anticipated at each Field Center?

ANSWER: A Field Center will have one site at which the examination will take place. As noted in the Field Center RFP, we are requesting separate proposals for a mobile van as the clinic examination site, and a fixed clinic site. Hospitals will not be used other than as the source for hospitalized events. The number of hospitals within a Field Center will depend upon which Field Centers are selected.

15. (CC) QUESTION: Are the site visits to the Field Centers examining 100% of the study forms or just a random sample?

ANSWER: The site visits to the Field Centers would be examining procedures, processes and data collection and entry. The Coordinating Center should propose the optimal content of this site visit.

16. (CC) QUESTION: Is the Coordinating Center directly responsible for the sampling plans at the Field Centers or assisting with the Field Center sampling plans?

ANSWER: Each Field Center is responsible for proposing the sampling plan for their community, and the Coordinating Center will only assist later during the first year of the study to modify the plans if needed.

17. (CC) QUESTION: Are the Morbidity and Mortality Classification Committee (MMCC) costs to be paid by the Coordinating Center?

ANSWER: The costs for individual MMCC reviewers' effort and any travel to central training will be paid for by each Field Center. All other costs will be covered by the Coordinating Center.

18. (CC) QUESTION: Are the costs for Committee conference calls to be paid by the Coordinating Center?

ANSWER: Yes.

19. (CC) QUESTION: Are the costs for Committee meetings (room rental, AV, coffee breaks) to be paid by the Coordinating Center?

ANSWER: Yes.

20. (CC) QUESTION: Is a limited access data set required for each year's exam data or is it required only at the end of the study?

ANSWER: It is required in the time frame specified on the web site listed in the RFP.

21. (FC) QUESTION: Is there a limitation on the geographic 'catchment' area used to accrue the sample of 4,000? For example, …, we would want to sample from the greater metropolitan area and surrounding counties for good representation.

ANSWER: A Field Center will need to determine the area and sampling plan appropriate for their community. The plan will be assessed on how well it can accomplish the goals of the study, i.e. to obtain high recruitment rates, a representative sample of sufficient size and stability, and one in which the population can be successfully followed over time.

22. (FC) QUESTION: Any feedback we might receive about a priori preference for an established vs. growing Hispanic community would be appreciated.

ANSWER: The primary consideration is how well the selected population can achieve the goals of the study.

23. (FC) QUESTION: A related question is, is there a preference for sampling from a community in which Hispanics are a majority (a 'minority-majority' community) versus a community in which Hispanics are a minority?

ANSWER: If the goals of the study are achieved, then whether the community is majority or minority Hispanic is not a consideration. Cost considerations may play a role if it becomes much more expensive to recruit and maintain a cohort where Hispanics are a minority.

24. (FC) QUESTION: We note that the sample should be comprised of at least 51% of one of the 4 Hispanic origin groups, and that at least 20% should be from the other 3 groups. Is this interpretation correct? Our Hispanic community is mostly of Mexican origin, and some Latin/South American, so our sample would look more like 70-75% of Mexican origin, the balance (20-25%) of Latin/South American origin, and very small numbers of persons of Cuban and Puerto-Rican origin (1-5%).

    ANSWER: The distribution that you have described is consistent with the requirements in the statement of work.

25. (FC) QUESTION: We note on page 4 of Attachment 1 of the RFP that persons who "plan on moving away in the next 3 years" should be excluded. Our interpretation is that "moving away" means out of the area, not literally move from house to house, for example. Is this correct?

    ANSWER: "Moving away" means moving out of the area so that follow-up and future contact would become very difficult.

26. (FC) QUESTION: What limitations are there on scientists involved in a Field Center using/analyzing/publishing the data that's collected?

    ANSWER: Field Center investigators are expected to be collaborating researchers by authoring and co-authoring papers from the study. Analyses will be conducted both at the Coordinating Center and at the Field Centers under procedures and policies to be determined by the Steering Committee.

27. (FC) QUESTION: What limitations are there on collecting data in addition to that prescribed to occur in the assessments/evaluations?

    ANSWER: A Field Center could propose additional studies not specified in the statement of work, but these additional studies must be agreed to by the NHLBI prior to funding though the contract. Once the contract is established, collection of information other than that established by the contract will be governed by an ancillary study policy determined by the Steering Committee. These policies encourage ancillary studies funded under other mechanisms, but need to be approved by the Steering Committee, the NHLBI, and the Observational Studies Monitoring Board and must not interfere in a harmful way with the conduct of the primary study. Review of study abstract and manuscripts will also be conducted prior to submission under procedures and policies to be determined by the Steering Committee.

28. (FC) QUESTION: Given that this RFP is to identify and collect specific data on a sample and track the sample over time, to what extent will investigator's scientific track record of publications and previous research in relevant areas be a prominent criterion in the review?

ANSWER: The evaluation criteria (Field Center RFP, page 84, item c.2) describes the evaluation of the proposal in regards to the investigator's qualifications.

29. (FC) QUESTION: How are the Field Centers supposed to address the problem of finding a disease or condition during the screening exams? Is the patient just referred elsewhere? If not, who pays for the additional diagnostic tests and/or therapy?

ANSWER: The study would not be responsible for costs related to health problems found during the clinical examination. According to usual procedure, the study would inform the participant and his/her physician (if prior approval has been given by the participant to do so). If the study participant does not have a health care provider, the study usually provides a list of possible providers. If the participant has difficulty in paying for a provider, then the study should identify low cost or free community clinics.

30. (FC) QUESTION: The RFP states that "While the study may recruit more than 51% of a single origin, the study should have if possible, recruitment of at least 20% of one of the other specified Hispanic groups." The Hispanic population in … is almost exclusively from Mexico, with a few from Central America. It would not be possible to recruit Cubans or Puerto Ricans. Accordingly, if the 20% rule is firmly applied, it would seem that the acceptability of our proposal would depend on our unlikely ability to enroll at least 800 Hispanics of Central American origin. Does that exclude us from being competitive? Would we be less competitive if we enrolled Hispanics who were 100% from Mexico?

ANSWER: The request to include 20% of a Hispanic group other than the primary one is a suggestion only (thus the words "if possible"), and not mandatory. The proposal will be reviewed on the basis of how well it is capable of fulfilling the scientific objectives of the study in accord with the review criteria listed in the RFP.

31. (FC) QUESTION: Are you able to disclose the total budget (for direct costs) for the entire project and/or for the individual Field Centers?

ANSWER: No

32. (FC) QUESTION: Do the Field Centers need to budget for translation of survey instruments into Spanish? Or is that the responsibility of the Coordinating Center?

ANSWER: Translation is part of the Coordinating Center budget.

33. (FC) QUESTION: Do the Field Centers need to budget for equipment and blood tests?

ANSWER: The Field Centers should budget for venipuncture, blood processing and shipping.

34. (FC) QUESTION: Is it advisable that Field Centers include in its team expertise in each domain of the study (e.g., sleep, nutrition, dentistry, audiometry)?

ANSWER: Yes, as much as possible but at a low level. We realize that a center may not have full expertise in all aspects, but some are more crucial than others such as nutrition.

35. (FC) QUESTION: Do the Field Center proposals need to include sources of instruments we would consider or do we need to develop a draft instrument?

ANSWER: A Field Center should propose an instrument that they would recommend that the study use. They may be existing instruments, or may be developed by the investigators. The actual instrument proposed needs to be included in the response. The final protocol including instruments to be used will be decided upon by the Steering Committee during the first year of the study.

36. (FC) QUESTION: We see that the baseline interview should be about 2 hours long. Does the 2 hour estimate include the consent process and pre and post test counseling?

ANSWER: The 4 hours specified in the RFP is for the period of time when the participant enters the clinic to when they leave. As a guide, we are suggesting that 2 hours of this time be used for interviews, and the other 2 hours for the procedures. The time for consent and counseling needs to be included within these time periods.

37. (FC) QUESTION: Is it expected that we should propose measures additional to the ones that are listed in the instructions for the application? Can we propose to do qualitative work to guide the design of the study?

ANSWER: It is not expected that additional measures would be proposed. However, if the investigators have a compelling idea which they feel should be addressed, and it is not in the RFP, then they should propose it, with separate budget clearly delineated. By qualitative work, it is assumed that you mean developmental work regarding design and implementation of the design. In the first year of the study this type of work will be done and the investigators should propose what is necessary.

38. (FC) QUESTION: How long do you expect the yearly follow up interviews to be?

ANSWER: They need to be done in a reasonably short time frame so as not to overly burden the participants. The investigators can propose a content that they feel meets the need to obtain data but also to balance this burden.

39. (FC) QUESTION: Do the Field Centers have to collect data on each component of the objective measures and blood tests? Does each Center have to conduct the sleep study?

ANSWER: We expect each Field Center to respond to all aspects of the proposal. The blood tests will be conducted by under the Coordinating Center contract. Yes, each Field Center is required to conduct a sleep study. We suggest that offerors who wish to submit proposals under the Field Center RFP, read the Coordinating Center RFP carefully to be able to separate Field Center from Coordinating Center functions.

40. (FC) QUESTION: Do we need to collect the objective “clinical” measures and blood tests on each participant or is it advisable to propose to do them on a sub-sample? If a sub-sample, what fraction do you suggest?

ANSWER: The requirements stated in the RFP should be proposed for all participants.

41. (FC) QUESTION: How often do you estimate we will need to do the clinical appraisals?

ANSWER: The RFP calls for one direct examination/interview of the participant, annual telephone (or home) follow-ups, and assessment of hospital records for the specified events.

42. (FC) QUESTION: Are the medical chart reviews only limited to incidence cases of cardiovascular and lung events?

ANSWER: They are limited to cases of cardiovascular and lung events. Whether or not they are new (incident) cases will depend on the information gained from the review.

43. (FC) QUESTION: Will the Field Centers be able to own/have a copy of all the data that comes from their Center or will the Coordinating Center have control over the data?

ANSWER: The Coordinating Center will receive and maintain control of the data for analysis purposes. The Field Centers will receive copies of all centers' data from the Coordinating Center and are expected to participate in analysis. The Steering Committee will decide the policies for distribution and analysis of these distributed data sets.

44. (FC, CC) QUESTION: Will most of the publications be expected to come from the Coordinating Center or the Field Centers or both?

ANSWER: Both.

45. (FC, CC) QUESTION: We have an investigator who wants to work with us but is being included in the team of a potential Coordinating Center as well. Is it appropriate and allowable to have him be part of our application as a Field Center as well as the other, separate Coordinating Center application?

ANSWER: Yes, a person could be on both a Field Center proposal and a Coordinating Center proposal.

46: (FC) QUESTION: Dominicans are currently the fourth largest group of Hispanics living in the US. However, the 2000 Census only had Mexican, PR and Cuban as the three ethnic categories Latinos could self identify. (all other groups had to electively write in their sub group membership). For this reason, in most tabulations of Latinos, Dominicans are still included in the category of "Other South/Central American". Thus I wanted to make sure that indeed, for the purposes of the RFP, customary conventions are being followed in which Dominicans would be considered under the category of "South/Central Americans".

ANSWER: The study has been designed to emphasize the four Hispanic/Latino groups in the United States with the largest population size. Each center must have at least 51% or more of one of the 4 designated groups. However, since we do not wish to exclude any Hispanic/Latino group, the remainder can be of any of the other remaining Hispanic groups, including Dominicans.

47. (FC) QUESTION: Do all of the baseline assessments for the participants have to happen within one 4-hour period? Or can the assessments be split up? For example, can questionnaires be conducted on Day 1, health exams be conducted on Day 2? All of the assessments combined would total 4 hours.

ANSWER: All of the baseline assessments will need to be completed within a 4 hour consecutive period.

48. (FC) QUESTION: Are there residency criteria for study participation? If not, will you be collecting residency status of these participants? If so, what guarantees can we provide that the patient information will be kept confidential and used for study purposes?

ANSWER: There are no residency requirements. Note, though, that the RFP requests that the study population have sufficient stability such that future contacts would yield a high response. While data for analytical purposes will be shared with other researchers, data will not be shared with other government agencies such as the INS, or IRS. The Coordinating Center will apply for a Certificate of Confidentiality on behalf of the study, which protects the investigators from being compelled to disclose identifying information.

49. (FC) QUESTION: Can people who came to the United States directly from Spain qualify as one of the other "specified Hispanic groups?

ANSWER: The requirement is for more than 50% of the recruited population to be of the origin described in the RFP. However the remainder of the recruited population can follow the definition of Hispanic as described in the opening paragraph in the statement of work, i.e. could include those whose origin is self-designated as Spain or Portugal.

50. (FC, CC) QUESTION: What is the total budget allocated for this RFP? Please advise about the budget limitation in terms of total direct cost per year and for the entire project.

ANSWER: As standard policy we do not provide budget information in our Requests for Proposals (RFPs). We rely on potential offerors to use their expertise to determine a reasonable cost for the work included in the statement of work. However, additional guidance related to the level of effort is being provided as part of this amendment.

51. (FC, CC) QUESTION: The Field Center RFP defines Hispanic as including Portuguese-speaking individuals. Do the questionnaires need to be translated into Portuguese as well as Spanish?

ANSWERS: Questionnaires would need to be translated into Portuguese if needed. There may or may not be Portuguese only speakers in the study.

52. (FC, CC) QUESTION: Can we assume that identical measures will be taken at all four Field Centers? (The Field Center RFP implies that the individual centers can propose questionnaires other than those included in the RFP.)

ANSWER: Yes, assume that identical measures will be taken in all Field Centers. If a new component is proposed by a Field Center, it would be included in all Field Centers if it is of value, is agreed upon by the Steering Committee and NHLBI, and if there are funds.

53. (CC, FC) QUESTION: The RFP indicates that the Coordinating Center will provide methodological assistance and guidance to the sampling plans developed by the Field Centers. Does NHLBI intend that a strict probability sampling design will be used by the Field Centers to develop the sample?

ANSWER: It is unclear what the sampling design will be until after the Field Centers have responded. There may be a variety of designs.

54. (CC, FC) QUESTION: Can we assume that all interview and examination data will be collected using CASI and that the Coordinating Center will be responsible for programming the instruments? Will the Coordinating Center be responsible for providing computers to the Field Center?

ANSWER: The Coordinating Center is responsible for providing computers to the Field Centers for the data acquisition process. There is no prior assumption on the method of data acquisition and the Coordinating Center should propose the method that it deems as optimal for this study. The Coordinating Center will be responsible for all programming regarding data entry, quality control, data management, and data delivery to the Coordinating Center.

55. (CC, FC) QUESTION: Who is responsible for the final questionnaire design? What is the role of the Coordinating Center in pretesting?

ANSWER: The content of questionnaires is determined by the Steering Committee and NHLBI. The design of the questionnaire regarding layout, format and data entry is the responsibility of the Coordinating Center with final approval by the Steering Committee. The forms design will need to be established in the context of the methods for data entry. The Coordinating Center will assist in designing the pretest, collating pretesting responses and determining if changes are needed.

56. (FC) QUESTION: Could the sleep study take place at community location, such as, on a mobile van, a community office building or at the participant's home? Or, instead, must the sleep study be conducted at a hospital-based sleep center? Our sleep study team has experience doing all four scenarios, and we are leaning toward a sleep study that would be conducted at the participants' homes.

ANSWER: The sleep study needs to be a "cost efficient" sleep study as specified in the RFP. Each offeror needs to provide their proposal for this study realizing that cost will be an issue. The study which will be used will be determined based on cost and on the informational value of the data.

57. (FC) QUESTION: The RFP mentions studying "environmental context" as a potential predictive factor. Are you able to provide any insight on what is meant by "environmental context?" Our multi-disciplinary team has come up with both questions that would be targeted toward the participants as well as community-level variables, but there is some vagueness about what is meant by environmental context.

ANSWER: The environmental context refers to the community environment in which the participant lives. This can include the "built environment", the economic environment, the opportunities for exercise, recreation, adequate purchase of healthy foods, community based opportunities, community stress and crime, etc. The list could be very extensive and the offeror needs to provide their best proposal in this regard.

58. (FC) QUESTION: When using a community facility for the place of data collection, must we use the facility's staff and equipment or would it be allowable for us to supply our own staff and equipment?

ANSWER: If you are referring to the baseline examination, the staff will be paid for by the contract. If you are anticipating use of other facilities as part of the examination they could be staff of that facility but paid for by the contract. A key condition, however, for all staff is that they are all trained in a common protocol. Regarding abstraction of hospital records in the follow-up period, abstractors are most likely to be staff in the study itself, again requiring standard training and certification.

59. (FC, CC) QUESTION: To what extent will investigators at Field Center sites have early or ready access to the data being collected (before its public release)? Will there be an enhanced ability to apply for ancillary studies on Hispanic health issues if one is a participating site?

ANSWER: We anticipate the Field Centers, in conjunction with the Coordinating Center, will indeed be conducting research as the data are not only to be collected but also analyzed and findings published, as outlined in the general and detailed descriptions of the technical requirements. Per the NHLBI limited access data policy referenced in the RFP, there is a two year period of time, starting when the data set is available for within-study analysis, before it is released to requestors. Ancillary studies will also be possible, under guidelines to be established by the Steering Committee. These would likely benefit from collaboration with main study investigators.

60. (CC) QUESTION: Is the CC technical proposal expected to include a proposal for each of the five reading centers named in the RFP?

ANSWER: Yes

61. (CC) QUESTION: Is the CC budget expected to include the cost of the five reading centers? How should each reading center budget be included in the CC budget?

ANSWER: Yes. As separate worksheets in your cost excel spreadsheet or otherwise as clearly separate modules.

62. (CC) QUESTION: For budgeting purposes, what assumptions should we make about who in the study will require a test to be read by a reading center? For example, will all 16,000 subjects get a sleep study, will all 16,000 get spirometry, will all 16,000 get an EKG, will all 16,000 get a nutritional intake assessment, and will all 16,000 get audiometry?

ANSWER: Yes, your budget should reflect costs for all 16,000 patients.

63. (CC) QUESTION: Is the CC technical proposal expected to include a proposal for central laboratory services (or is this something that the field centers will each do and the CC only receives and manages the central laboratory results?)

ANSWER: Yes, the Coordinating Center should include the central lab services. Obtaining the specimen, any processing and shipping is the responsibility of the Field Center.

64. (CC) QUESTION: Is the CC budget expected to include the costs of running blood tests and storage of blood products for future testing? Do we assume that all tests will be run on all 16,000 subjects?

ANSWER: Yes.

65. (FC) The RFP states "primary sampling unit will be the household." Does this mean that each household must be visited & enumerated prior to booking subjects for interviews/exams?

ANSWER: The offeror will need to determine the optimal method to identify and recruit the participants. The household will be the primary sampling unit, and persons in that household between 18 and 74 will need to be sampled to obtain 2500 persons age 45-74 and 1500 persons age 18-44.

PART 2. Changes to Technical Requirements

1. In the Coordinating Center RFP (RFP No. NHLBI-HC-06-01) Statement of Work under Paragraph C. Detailed Description of the Technical Requirements, item 11.d. Dental Examination Reading Center is deleted as a requirement from the RFP.

PART 3. Estimate of Effort

In Section L – Instructions, Conditions and Notices to offerors, Part 1. General Information, paragraph e. Estimate of Effort, is deleted in its entirety and replaced with the following:

It is expected that a completion type contract will be awarded as a result of this RFP. The level of effort devoted to this project must be compatible with the scientific and technical approach proposed to cover the activities in the Statement of Work. Professional, technical, and support staff should have experience pertinent to that required for the Coordinating Center (if submitting a proposal for the Coordinating Center) and Field Center (if submitting a proposal for the Field Center) Statements of Work. The following staffing patterns are to be considered broad guidelines. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

Coordinating Center – RFP No. NHLBI-HC-06-01; Level of Effort (full-time equivalents) *****

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8
PI	30%	30%	30%	30%	30%	30%	30%	30%
Co-PI (Statistical)	20%	20%	20%	20%	20%	20%	20%	20%
Co-PI (medical)	20%	20%	20%	20%	20%	20%	20%	20%
Other Investigators	40%	70%	70%	220%	220%	220%	220%	220%
Project/Operations Directors	150%	150%	150%	150%	150%	150%	150%	150%
Other	400%	555%	655%	655%	655%	655%	655%	655%

*** The level of effort guidance provided for the coordinating center above does not reflect effort for the central laboratory and reading centers.**

Field Center -RFP No. NHLBI-HC-06-02; Level of Effort (full-time equivalents) *****

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8
PI	25%	25%	25%	25%	25%	20%	20%	20%
Co-PI	10%	10%	10%	10%	10%	10%	10%	10%
Other Investigators	40%	40%	40%	40%	25%	25%	25%	25%
Other	515%	1,380%	1,380%	1,380%	630%	630%	630%	630%

*** The level of effort guidance provided for the field center above does not reflect effort for the dental and hearing examinations.**

All staffing levels proposed should be accompanied by specific justifications as to the type and hours of work expected to be performed by all personnel. Offerors will be required to propose levels of commitment whether compensated or donated effort, necessary to complete the work described in their proposals. It is expected that realistic levels of effort will be proposed such that an offeror's understanding of the work will be apparent.

PART 4. Other administrative changes and corrections. These apply to RFP No. NHLBI-06-01 and RFP No. NHLBI-06-02 unless otherwise indicated below.

1. In the RFP, Article H.11. Publication and Publicity, the following statement: "This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No."

   is changed to the following:

   "This project has been funded in whole or in part with Federal funds from the National Heart, Lung, and Blood Institute, National Institutes of Health, Department of Health and Human Services, under Contract No."

2. The "Technical Proposal Cost Summary" included in the Attachments under Section J is modified to reflect an 8 year period of performance instead of 7 years. Please adjust the format to include 8 years in your proposal.

3. The "Breakdown of Proposed and Estimated Costs" included in the Attachments under Section J is modified to reflect an 8 years period of performance instead of 7 years. Please adjust the format to include 8 years in your proposal.

4. Under Section J. Attachment 27, Disclosure of Lobbying Activities, OMB Form SF-LLL is deleted from both RFPs as Informational Attachments.

5. In the Coordinating Center RFP No. NHLBI-HC-06-01, the "Roster of Employees Requiring Suitability Investigations" included as Attachment 29, is revised to reflect "to be filled out by the NHLBI Project Officer..."

6. Section L, Item13, Small Business Subcontracting Plan, the last paragraph that refers to establishing minimum subcontracting goals is hereby deleted from the RFP.

7. Under Section M, Evaluation Factors for Award, Part C., Technical Evaluation Criteria, the sentence included in the first paragraph "The criteria listed below are listed in order of their relative importance with weights assigned for evaluation purposes." is revised as follows: "The criteria listed below include weights assigned for evaluation purposes."

8. In Attachment 1 of RFP Nos. NHLBI-HC-06-01 and NHLBI-HC-06-02, Packaging and Delivery of the Proposal, the address to be used if using U.S. Postal Service is revised to reflect "Review Branch, Division of Extramural Activities" instead of Research Branch, Division of Extramural Activities."

9. In Attachment 3 of the RFP, Statement of Work, the acronym CHD stands for Coronary Heart Disease and the acronym SES stands for Social Economic Status.

10. For clarification purposes, all references to the words supplemental materials included throughout the RFPs are renamed as appendix and appendix materials.

11. In the Field Center RFP (RFP No. NHLBI-HC-06-02), on page 80, under Section L. – Instructions, Conditions and Notices to Offerors, 2. Instructions to Offerors, c. Business Proposal Instructions, Note No. 9 is revised as follows:

[Note 9 to Offerors: Though the data system will be determined later, for budget purposes, the Field Center should assume a data collection system which it would prefer, and justify and explain associated costs in the proposal.]