

Questions and Clarifications





Materials Provided

Evaluation Criteria – Section M

Statement of Work – Attachment 3

Overview of Study Design and Methods –
Attachment 4

Reporting Requirements and
Deliverables – Attachment 5

**Additional Technical Proposal
Instructions – Attachment 6**



Materials Provided

- Additional Business Proposal Instructions- Attachment 7
- Estimate of Effort by Annual Contract Year- Attachment 8
- Study Map and list of Locations –Attachment 9
- Timeline of Activities – Attachment 10
- Pre-proposal Conference Information- Attachment 11
- Table of Study visits/year – Attachment 12
- Definitions – Attachment 13



Additional Technical Proposal Instructions

- Description of Base and Option Requirements
- “Proposals for the OPTION shall be submitted with the BASE proposal”
 - These can be submitted in a single volume as long as the options are clearly delineated in separate sections
 - In Option proposals, the offeror can refer to information in the Base proposal (i.e. there is no need to repeat or attach the same information in the Option if already covered in the Base Proposal)



Additional Technical Proposal Instructions

- Page limits:
 - Base Requirement – 25 pages technical proposal; attachments -75 pages
 - Options – 15 pages technical proposal; attachments 35 pages
 - No Change; however, for Key Personnel a modified resume is acceptable (educational background, recent experience, listing of relevant publications); Biosketch is acceptable for other investigators



Estimate of Annual Effort by Contract Year

- These estimates are provided as guidance
- Offerors can (and are encouraged to) calculate their own staffing needs based on the requirements
- Offerors are also encouraged to explain the assumptions underlying their estimated staffing needs



Specific Questions

- Structure of estimates
 - Study Center Infrastructure estimates
 - Per Location staffing estimates
 - Staffing for data collections
- Role of multiple PI's
 - There is a need for scientific oversight at the Study Center and at each Study Location (Center PI versus the Location PI)
 - This could be the same person or two different people providing this oversight
 - From a contracting standpoint, there is only one Principal Investigator for the Proposal

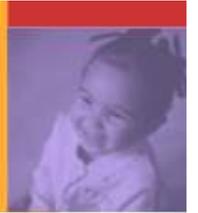


Assumptions for Staffing Estimates

- The level of effort estimates assumed multiple staff members doing the household listing and screening, working independently rather than as teams (may propose otherwise)
- Staffing time for phone calls (e.g. scheduling of visits, reminder calls, etc) to be placed by local centers were included in staff estimates
- Level of training for data collectors
 - Up to the offerors to propose staffing needs
 - Ultrasounds must be performed by an American College of Radiology Certified Ultrasound Technician
 - Staffing estimates did not assume the need for an industrial hygienist



Timeline of Activities – Attachment 10



- **Correction:**
 - The time period for “Listing, HH Enumeration” should have a start date of 7/1/09 and an end date of **12/31/09**
 - This is consistent with the 6 month period allotted for this activity in The Overview of Study Design and Methods.



Estimated Number of Study Visits per Year -Attachment 12- Table

- Footnote was truncated
- New Table will be posted in an amendment to the RFP
- The new footnote will include a description of the abbreviations used in the headings of the second table



Attachment 12 - Table

Attachment 12 - ESTIMATED NUMBER OF STUDY VISITS PER YEAR

PARTICIPANT VISITS PER PSU

PARTICIPANT VISITS PER PSU	Screeners¹	Preconception	T1²	T2³	T3⁴	Birth	6 month	12 month	TOTAL
Total Visits	12159	263	863	670	670	571	474	367	16037
Year 1	0	0	0	0	0	0	0	0	0
Year 2	2786	29	68	0	0	0	0	0	2883
Year 3	5573	84	313	240	240	149	15	0	6614
Year 4	3800	78	253	231	231	225	251	146	5215
Year 5	0	72	229	199	199	197	208	221	1325

(1) Number of screeners in Year 2 and Year 3 are initial screeners--a total of 8,359. Number of screeners conducted in Year 4 (3,800) are in-person re-screenings.

(2) T1 = First Trimester Visit

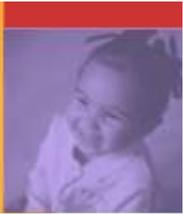
(3) T2 = Second Trimester Visit

(4) T3 = Third Trimester Visit





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