THE NATIONAL CHILDREN'S STUDY

HEALTH GROWTH ENVIRONMENT

Pre-Proposal Conference

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Goals of Presentation

- Review central components of the study design
- Purpose of the solicitation and mandatory requirements
- Answer general questions submitted in advance of the meeting
- Specific questions will be addressed in an amendment to the RFP

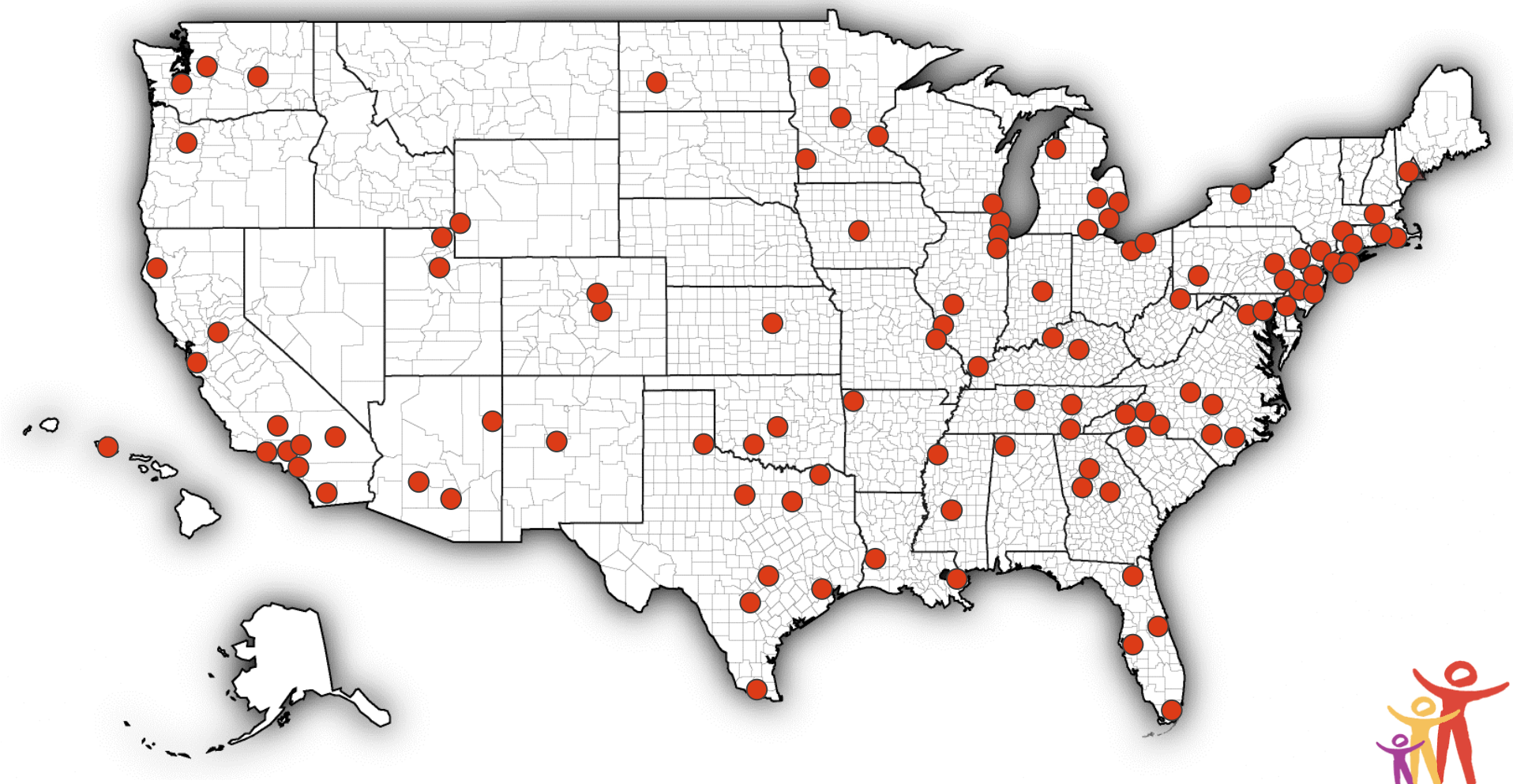
Study Design

- Enroll and follow ~100,000 children from before birth to 21 years of age
- Children will be enrolled primarily through enrollment of their mothers
- Mothers will be enrolled during or prior to pregnancy
  - Allows assessment of early in-utero exposures
- Children in the NCS will be representative of all U.S. children
  - Multi-stage, probability sampling approach

Study Design

- In the first stage of sampling 105 geographic areas were selected as the areas from which participants will be recruited
- These are referred to as the “Study Locations”
- Study Locations are single counties or in sparsely populated areas groups of adjacent counties

All Locations – Selected 2004



Study Design

- Primary method of recruitment is through household screening
- Data collections will follow a standard protocol and include:
  - Interviews, physical examinations, observational assessments, collection of environmental samples, and collection of biological specimens
  - Participants: mothers, fathers and children

Study Design

- Additional details about the study design
  - Attachment 4: Overview of Study Design and Methods
  - NCS Public Website
    - www.nationalchildrensstudy.gov
    - Research Plan

Question

- "How should we reconcile the RFP with the Research Plan document? The Research Plan contains data collection tasks and other activities that are not in the RFP…."
- Answer: Where there are inconsistencies the RFP takes precedence.

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The Procurement

Goal of the Procurement

- To award contracts to organizations that will be responsible for data collections in specified Study Locations
- These specified locations include 58 of the 105 Study Locations (contracts have already been awarded for data collections for the other 47 Locations)
- See attachment 11

Questions

- Study Location versus a Study Center
  - Study Locations: the 105 geographic areas (counties, groups of contiguous counties) that were selected in the first stage of sampling
  - Study Centers: The organizations or entities responsible for carrying out the data collections

Waves of Implementation

- NCS is being implemented in three waves
- Anticipated dates for initiation of household screening
  - Wave 1 –January 2010
  - Wave 2– January 2011
  - Wave 3 –January 2012
- Goal is to achieve a sample that is reflective of all births in the United States with each wave of implementation

Clarification to the RFP

- Statement of Work (Last paragraph, 1st page)
  - It is stated that field work for Wave 1 will begin in 2009
- Enumeration and screening of households for Wave 1 Locations is scheduled to begin January, 2010 as described in the Overview of Study Design and Methods and shown in the Study Timeline: Attachment 10

Waves of Implementation

- Wave 1: Contracts have already been awarded for 34 of the 37 Study Locations
  - 7 Vanguard Locations
  - 27 Wave 1 Locations – awarded in 2007
  - The current procurement includes the remaining 3 Locations to be implemented with Wave 1
- Contracts have also been awarded for 13 Wave2/Wave3 Locations
  - Remaining 55 Locations are included in the current procurement

Correction to RFP

- 55 Locations have been grouped into strata
- Section M of the RFP lists the strata
  - RFP Amendment: Stratum Four in the East incorrectly listed Warren, NY. Corrected to Warren, NJ
- Attachment 11 shows the Study Map and List of Locations

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Specifics of the Current RFP

Mandatory Criteria

- Offerors shall prepare proposals to serve as a Center to conduct data collections at one or more than one of the 58 specified Study Locations (Mandatory Criteria 1)
  - ATTACHMENT 11- List of Study Centers
- A separate proposal must be submitted for each Location in which the offeror is proposing to collect data
- NOTE: This is different from the RFP released last year

Evaluation con't

- No more than one Center will be awarded a contract for data collections in a given Location (i.e. no splitting of a Location between multiple contractors)
- A single offeror can submit proposals for multiple locations
- Each proposal will be evaluated independently, thus the information about the Center should be included in each proposal
  - Exception: Harris county

Mandatory Qualification Criterion #1

The Study Location must be:

- In the same state as the Study Center
- In a state that is contiguous with the state of the proposing Center
- In a state that is not contiguous but separated from the border of the state of the proposing Study Center by no more than 100 miles
- Location of the Study Center is considered to be that of the location of the primary institution in the proposal

Questions

- Will proposals for collection of data in a county that is not included in the list of 58 Study Locations be considered?
  - NO
- Can existing Vanguard and Study Centers submit proposals?
  - YES

Enrollment Goals

- Participants identified through screening of households in selected neighborhoods
- Goal is to enroll a sufficient number of women such that 1000 live births are enrolled over the 4 year enrollment period in each Primary Sampling Unit
- Note that for both Wave 1 and Wave 2 Locations, the enrollment period extends beyond the 5 year contract period

Exceptions to Enrollment Goals

- Six Exceptions – 600 births over 4 year enrollment period
  - Stark, ND
  - Baker, FL
  - Childress, Collingsworth, Donley, and Hall, TX
  - Stephens and Young TX
  - Lincoln, Uinta, WY and Bear Lake, ID;
  - Becker, Clearwater, Mahnomen, MN

Question

- Will enrollment targets be adjusted for other Study Locations with relatively low numbers of births per year?
  - Not at this time.
  - As part of their technical approach, offerors can describe challenges to achieving an enrolled sample of 250 per year for their specific county and suggest alternate approaches that the review panel can evaluate

Mandatory Criteria #2
Harris County, TX

- Harris County, Texas contains two PSUs
- Data collection in one of the PSUs will be implemented with Wave 2, data collections in the second PSU will be implemented with Wave 3
  - The method for doing this is to add additional neighborhoods (segments) within the county with wave 3
- Because there will be no more than one contractor conducting data collections in a single Location, offerors submitting a proposal for Harris County must demonstrate their ability to expand
- The wave 3 PSU must be submitted as an option proposal

Materials Provided

- Evaluation Criteria – Section M
- Attachments
  1. Packaging and delivery
  2. Intent response sheet
  3. Statement of Work
  4. Overview of Study Design and Methods
  5. Reporting Requirements and Deliverables
  6. Delivery Schedule
  7. Additional technical proposal instructions

Attachments Continued

8. Additional business proposal instructions
9. Estimates of effort by annual contract year*
10. Timeline of operational activities*
11. Map and list of Locations
12. Estimated number of visits and calls*
13. Incentive plan
14. Definitions

*Separate estimates provided for wave 1 and wave 2

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Specific Clarifications

Questions and Clarifications

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

Collection of Data from Medical Records

- Current plan includes abstraction of maternal and newborn records following delivery
- Technical and business proposals should not include work and costs associated with other medical record abstractions

Biosketch versus Abbreviated Curriculum Vitae

- Additional Technical Proposal Instructions
  - Abbreviated Curriculum Vitae for Key personnel (Principal Investigator and the Study Coordinator/Operational Manager)
  - Biographical Sketch other named study staff
- Biographical Sketch should follow the NIH format
- Abbreviated Curriculum Vitae – suggest no more than 6 pages
- Both the Biosketch and the abbreviated Curriculum Vitae count toward the 100 page limit for the technical proposal

Other Questions

- Received a number of specific questions about local processing of biospecimens
- Estimates of visits shown in attachment 12
- Other topics
- We will evaluate and provide responses to questions as a posting to fedbizopps
- We will continue to receive questions until April 11th.

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