



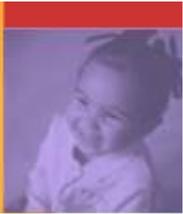
Pre-proposal Conference

**Ruth Brenner, MD, MPH,
Program Office, National Children's Study,
National Institute of Child Health and
Human Development**





Outline of Presentation

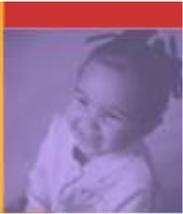


- Review of central components of the study design
- Purpose of the solicitation and mandatory requirements
- Answers to questions submitted in advance of the meeting





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
 - To allow assessments of early exposures, enrollment during early pregnancy or prior to pregnancy
- Children in the Study will be representative of all U.S. children
 - Multi-stage, probability sampling approach



Study Design

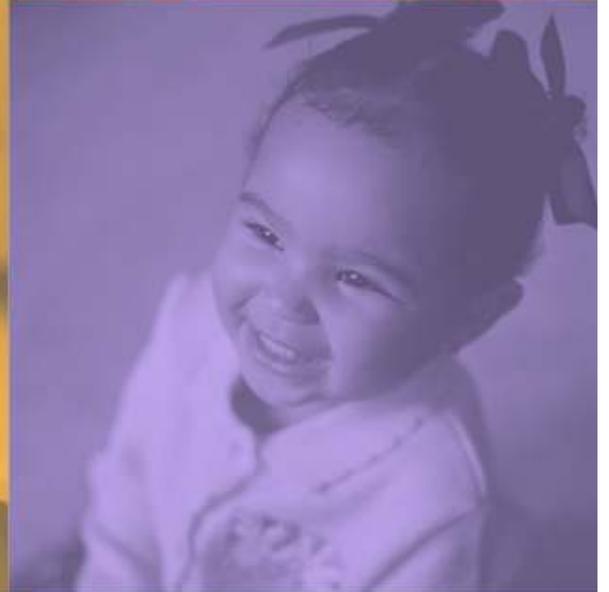
- In the first stage of sampling 105 Locations were selected as the geographic areas from which participants will be recruited
- Primary method of recruitment is through household screening
- Data collections will follow a standard protocol



Study Design

- Data collections include:
 - Interviews, physical examinations and observational assessments, collection of environmental samples and biological specimens
 - Participants: mothers, fathers and children
- See Attachment 4: Overview of Study Design and Methods
- **NOTE: Addendum 1 to the RFP: Table of Data Collections**





The Procurement





Purpose of the Procurement

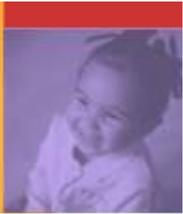


- Purpose: To award up to 20 new contracts to organizations that will be responsible for data collections in up to 30 Study Locations
 - It is anticipated that some organizations will oversee data collections in more than one Study Location
- No more than one Center will be awarded a contract for data collections in a given Location (i.e. no splitting of a Location between multiple contractors)
- It is anticipated that there will be subsequent phases of implementation such that data collections are ultimately occurring in all 105 Locations





Waves of Implementation



- Wave 1 – approximately 37 Locations (7 Vanguard + 30 with the current procurement)
- Wave 2 – approximately 35 additional Locations
- Wave 3 – approximately 35 additional Locations





Study Location

- What is a Study Location?

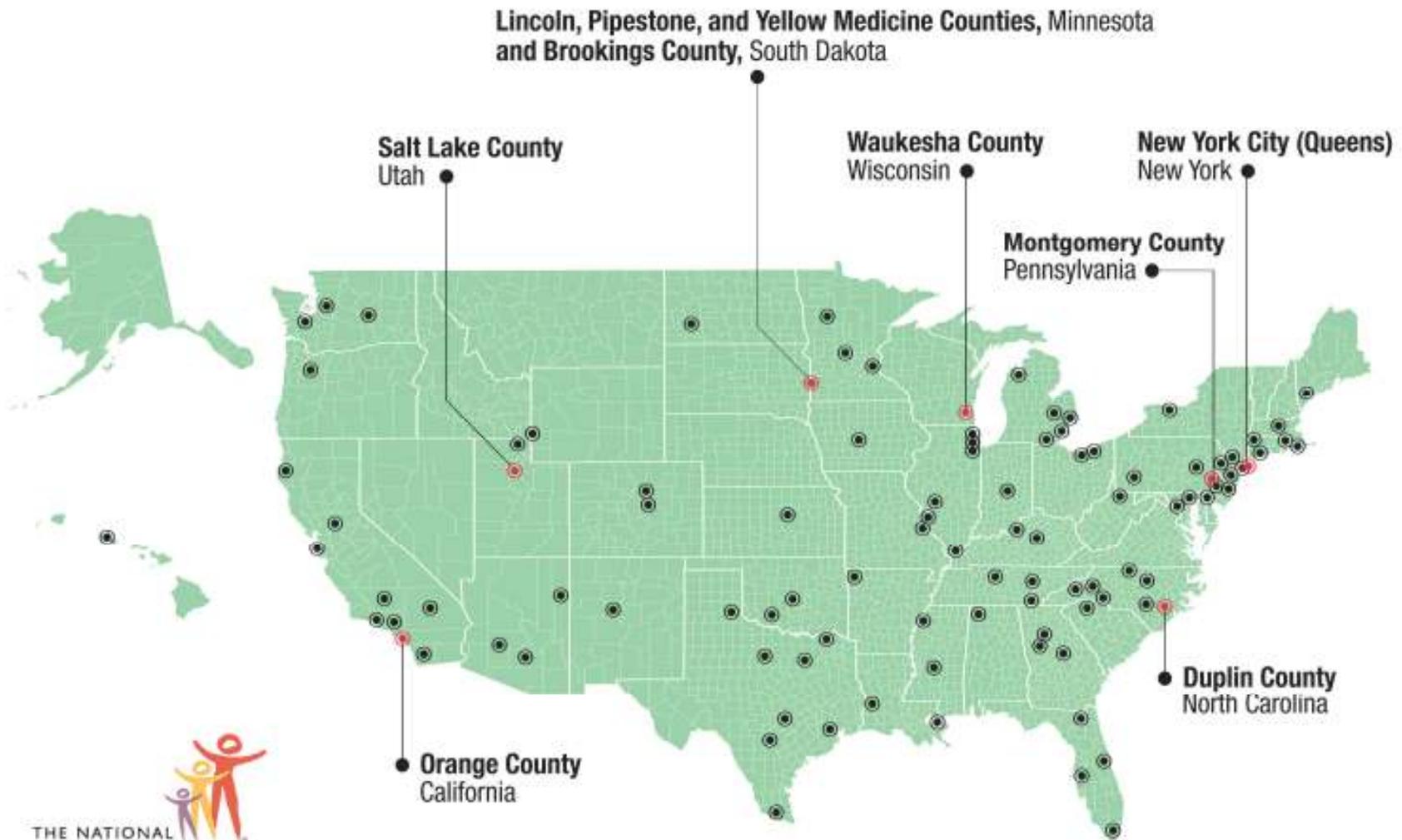
In the full NCS, the Study Locations are the 105 geographic areas (counties, or in sparsely populated areas, groups of contiguous counties) that were selected as a result of the first stage of sampling.

- See Attachment 9 of the RFP
 - Study Map and List of Locations



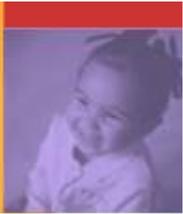
National Children's Study Locations

Vanguard locations labeled





Study Locations

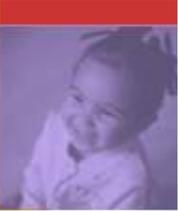


- These are the areas from which Study participants will be recruited.
- Contracts have already been awarded for data collections in 7 of these locations
- For this solicitation offerors must submit a proposal for data collections in one of the remaining 98 locations





Mandatory Criteria #1 (Section M)



Offerors shall prepare proposals to serve as a Center to conduct data collections at one or more than one of the remaining 98 pre-specified Study Locations

Most study locations correspond to a single county

Six of the ninety-eight locations include more than one county due to the small number of anticipated births in these areas



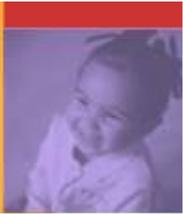
Questions

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





Mandatory Qualification Criteria

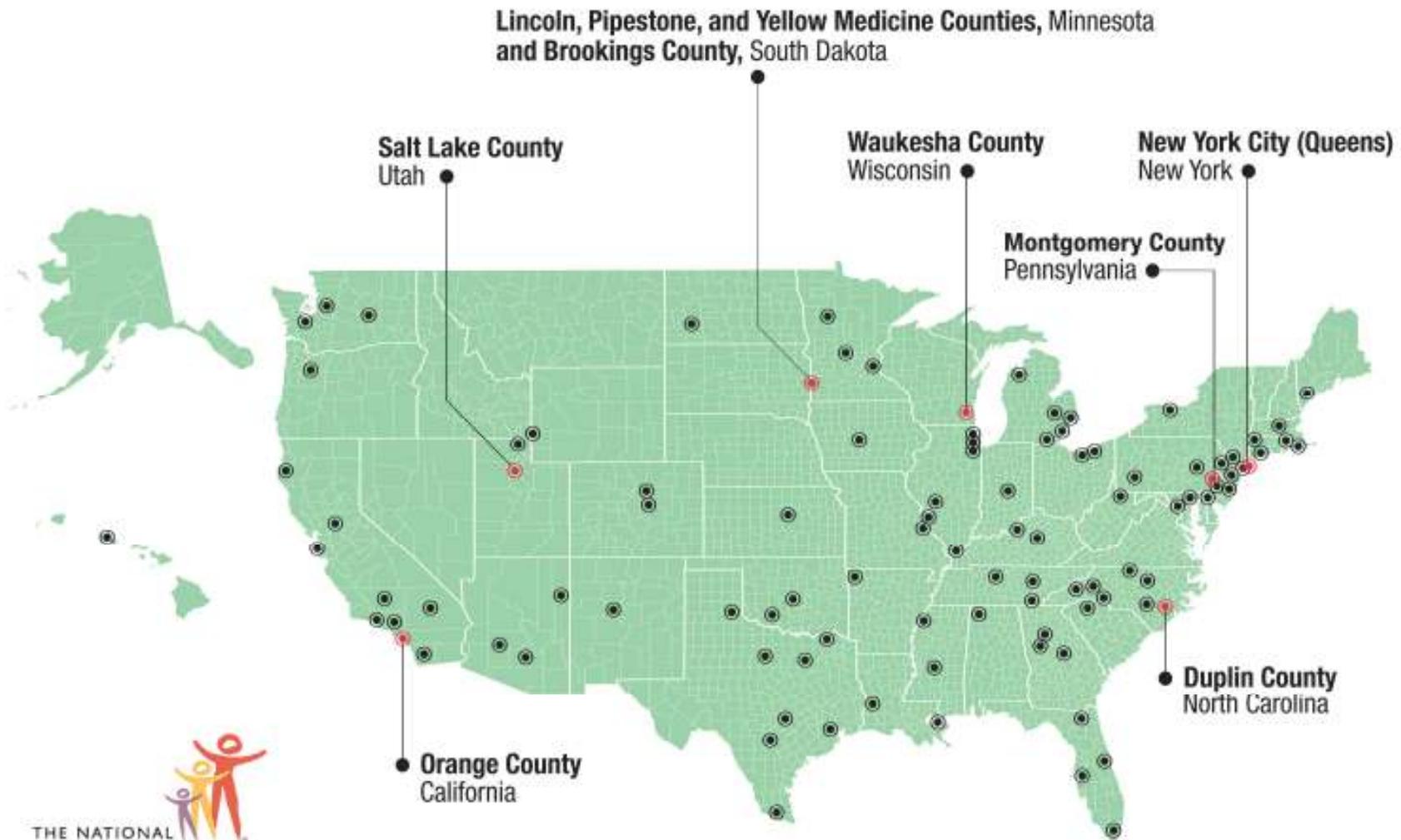


- Criterion #1: Offeror must propose to conduct data collections in one or more of the 98 pre-specified Study Locations AND the Study Location must be
 - In the same state as the Study Center
 - In a state that is contiguous with the state of the proposing Center
 - In a state that is not contiguous but separated from the border of the state of the proposing Study Center by no more than 100 miles



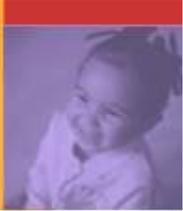
National Children's Study Locations

Vanguard locations labeled





Enrollment of Participants

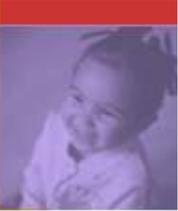


- Participants will be identified through screening of households in selected neighborhoods (See Attachment 4)
- In general, the goal is to enroll a sufficient number of women such that 1000 live births are enrolled over a four year period in each Study Location
- Exceptions: Cook County, IL; Harris County, TX; Los Angeles County, CA





Mandatory Evaluation Criteria #2



- Offerors submitting a **BASE** proposal for data collection in Cook, Harris, or Los Angeles County must also submit an **OPTION** proposal (or proposals) that describes the Center's capacity and plan for enrollment of additional births in subsequent waves





Base Requirement

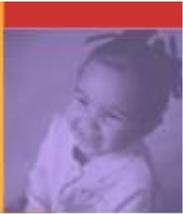


- See Attachment 6 – Additional Technical Proposal Instructions
- Technical proposal must address the base requirement
- Offeror will describe how they will conduct tasks in the Statement of Work in **one** of the 98 Locations
 - Offeror may choose any Location for which they are eligible
 - Same requirement applies to current Vanguard Centers





OPTION REQUIREMENT



- Offerors **may** submit proposals to perform the OPTION requirement in one or more Secondary Locations (in addition to the Location included in the Base proposal)
- Offerors are encouraged to submit OPTION proposals
- There is no limit to the number of option proposals that may be submitted, as long as the mandatory criteria are met



Evaluation and Award of Contracts

- Only those offerors selected for award of a contract based on the Base Proposal (i.e. NCS Study Center and the primary location) will be eligible for award of one or more OPTIONS
- Evaluation of Option Proposals is independent of evaluation of Base Proposal
 - Specifically, if a Center scores low on an option proposal that will not effect the score on the Base Proposal



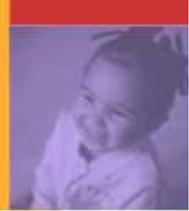
Evaluation and Award of Contracts

- If a Center is awarded the Base Proposal and Options, the order and timing of implementation of data collection in the multiple Locations will be discussed as part of the negotiations, with the expectation that at least one Location would be implemented in Wave 1
 - Maintains flexibility in achieving representative sample with each wave of implementation





Mandatory Evaluation Criteria #2

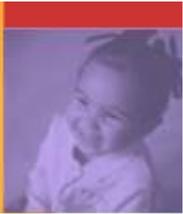


- Offerors submitting a **BASE** proposal for data collection in Cook, Harris, or Los Angeles County must also submit an **OPTION** proposal (or proposals) that describes the Centers capacity and plan for enrollment of additional births in subsequent waves





Cook, Harris and Los Angeles



- To maintain the representative, self weighting nature of the sample, areas with large number of births need to enroll a greater number of children in the Study
- For LA the number is 4000, for Cook and Harris the number is 2000
- The method for doing this is to add additional neighborhoods within the counties in subsequent waves of implementation
- Because there will be no more than one contractor conducting data collections in the same Location, offerors must demonstrate their ability to expand



Example

2009 2010 2011 2012 2013 2014

WAVE 1

Enroll 250 births/year from neighborhoods 1-10

WAVE 2

Enroll 250 births/year from neighborhoods 11-20



Summary

Cook, Harris, and Los Angeles

- First Wave of Implementation:
Enrollment goals are the same as for other Study Locations
Therefore Base Requirement is the same
- In subsequent waves additional “segments” neighborhoods will be added
- Because there will be no more than one contractor conducting data collections in the same Location, offerors must demonstrate their ability to expand

