Pre-proposal Conference

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THE NATIONAL CHILDREN'S STUDY

Outline of Presentation

- Background
- Specifics of study plan
  - Sampling
  - Overview of other aspects
- Other participating entities
  - Coordinating Center
  - Information Technology Development
- Specific questions

Guidelines

- Study of environmental influences on children's health and development.
- Longitudinal cohort study, beginning prior to birth continuing through age 21 years
- National in scope
- Sample size: approximately 100,000 live births
- Enrollment during or before pregnancy
- Environment is broadly defined (physical, chemical, biological, and psychosocial)

Challenges

- Collect multiple levels of data in a variety of settings
  - Environmental specimens in the home
  - Biologic samples at the time of delivery
  - Measures in the community
- Capture both intermittent and chronic exposures
- Capture exposures during critical periods of development

What is the Study Plan?

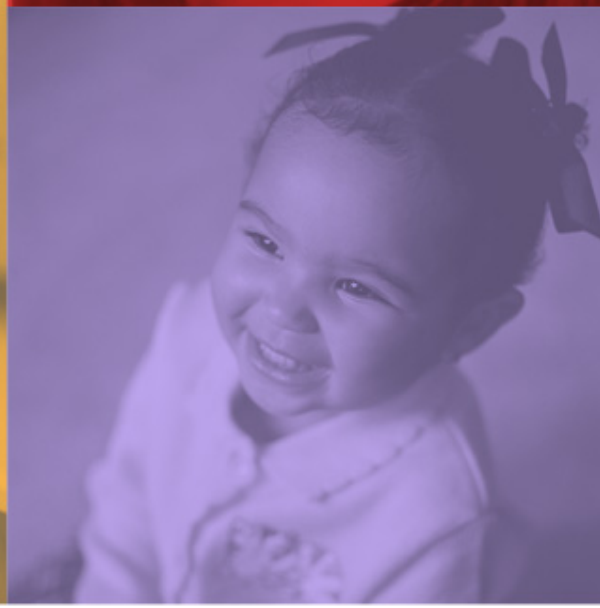
- The document that outlines the general study design of the NCS.
- Purpose is to guide offerors so that they are better able to develop their proposals
- Less detailed than a full study protocol or operational manual, yet more detail than many RFPs
- Study plan will evolve in greater detail with input from investigators from the Vanguard Centers and initial experience
- First public documentation of many aspects of the study, open for comment, revised version to be released in mid December

Other Study Documents

- Study Protocol: A document to be developed by the NCS Steering committee that specifies data collections for the NCS.
- Manual of Operating Procedures: A document prepared by the National Children's Study Coordinating Center, in collaboration with investigators from the Vanguard Centers and staff from the program office, that details all procedures to be used throughout the conduct of the Study.

Specific Aspects of the Study Plan

- Study Plan can be found on pages 43-75 of the RFP
- Specific topic for discussion
  - Section on sampling plan



Sample Design

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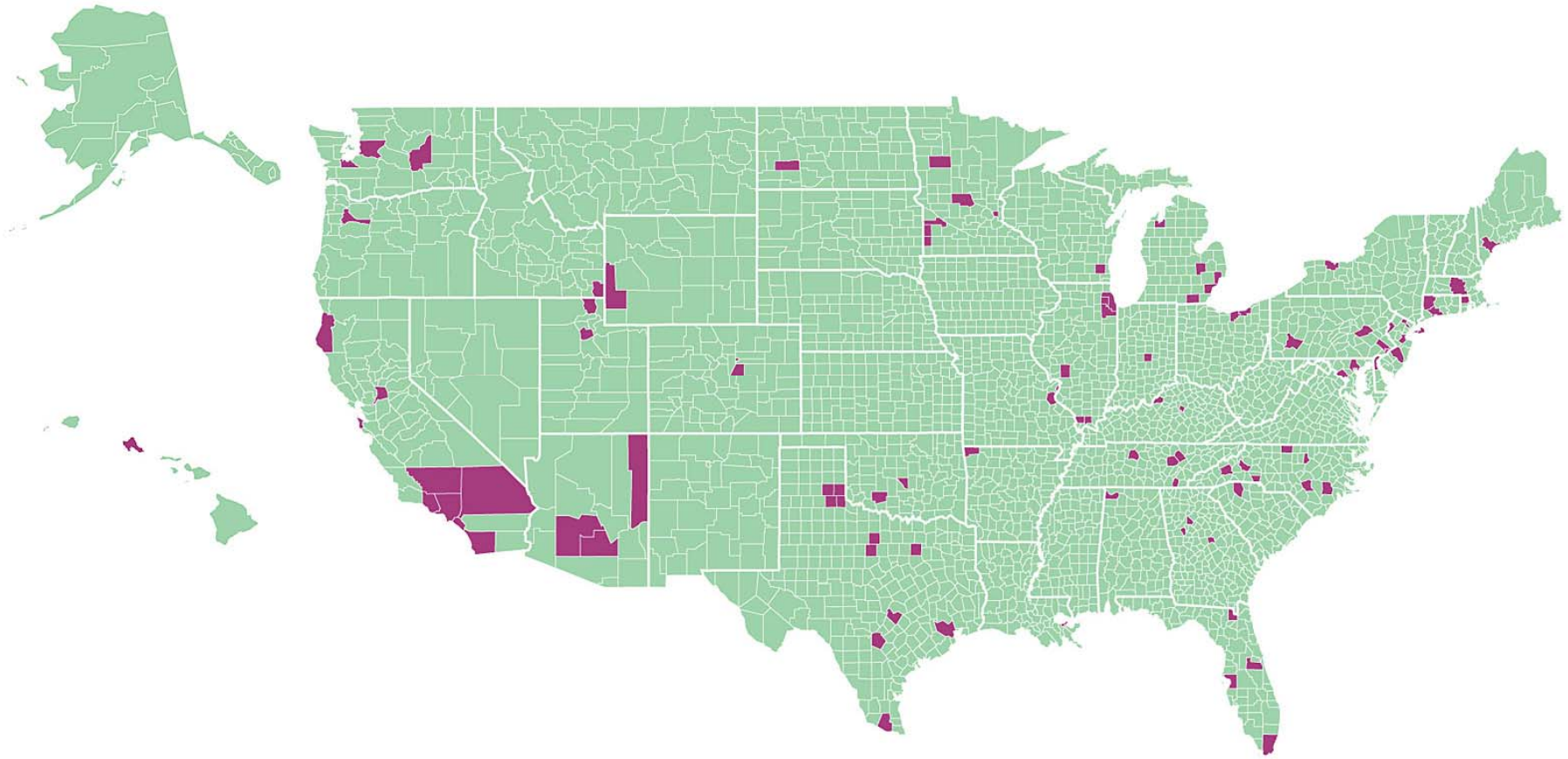
The Sample

- National probability sample
- 96 study locations were drawn from the full list of all counties in the United States
- 13 self representing counties
- Remaining counties were placed into strata based on:
  - Metropolitan status
  - Geography
  - Average number of births per year
  - Race, ethnicity, percent low birth weight

National Children's Study Locations



Study Locations

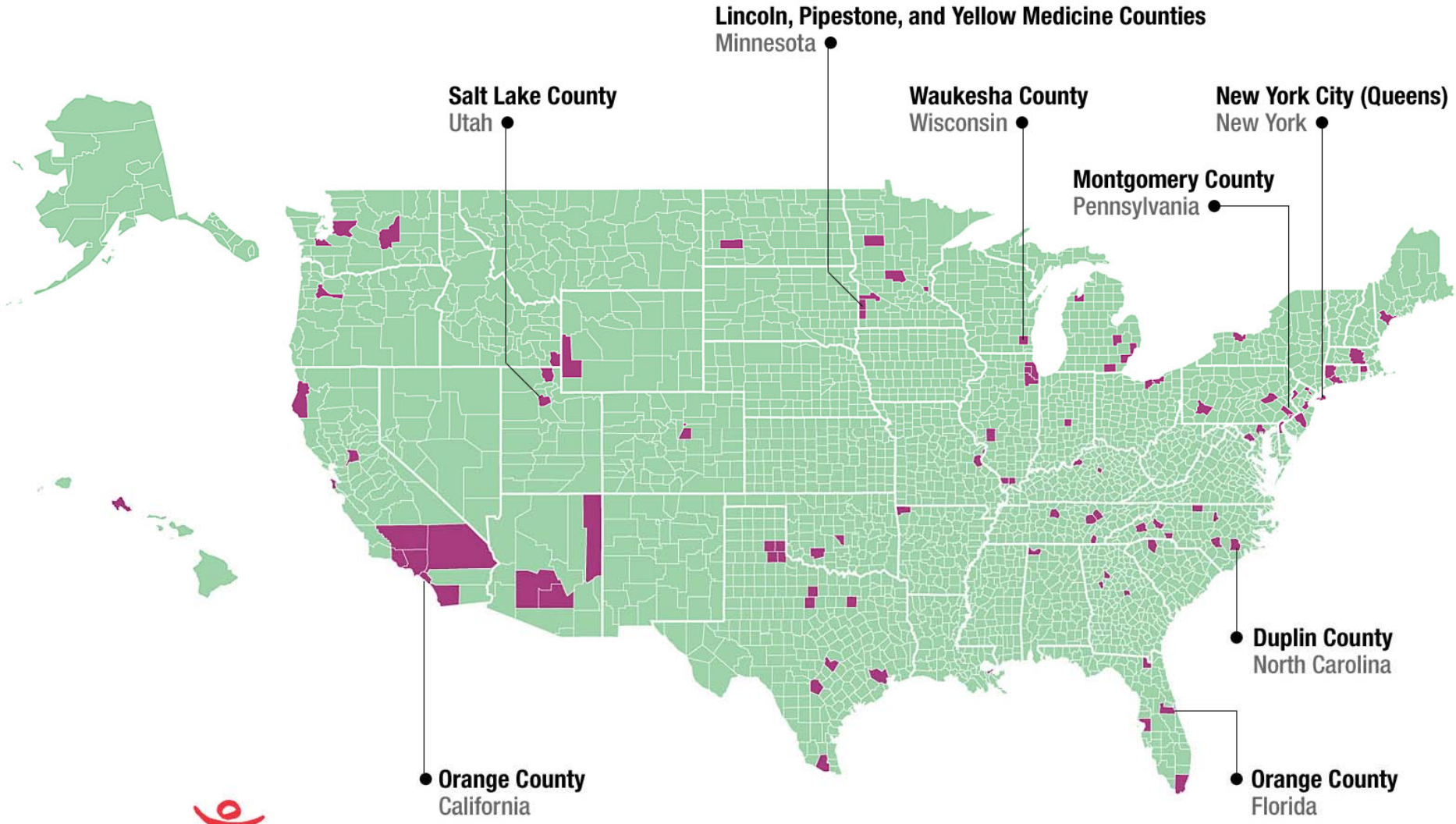
- Most study locations correspond to a single county
- Six of the ninety-six locations include more than one county due to the small number of anticipated births in these areas

Selection of Vanguard Locations

- From this list of 96 locations, eight locations were selected to potentially serve as the Vanguard Locations
- 96 locations were placed into strata
  - Geography
  - Metropolitan Status
  - Average number of births per year
    - 2 certainty, 4 metropolitan, non-certainty, 2 non-metropolitan
    - 2 Locations in each of the 4 U.S. Census Regions

National Children's Study Locations

Vanguard locations identified by name



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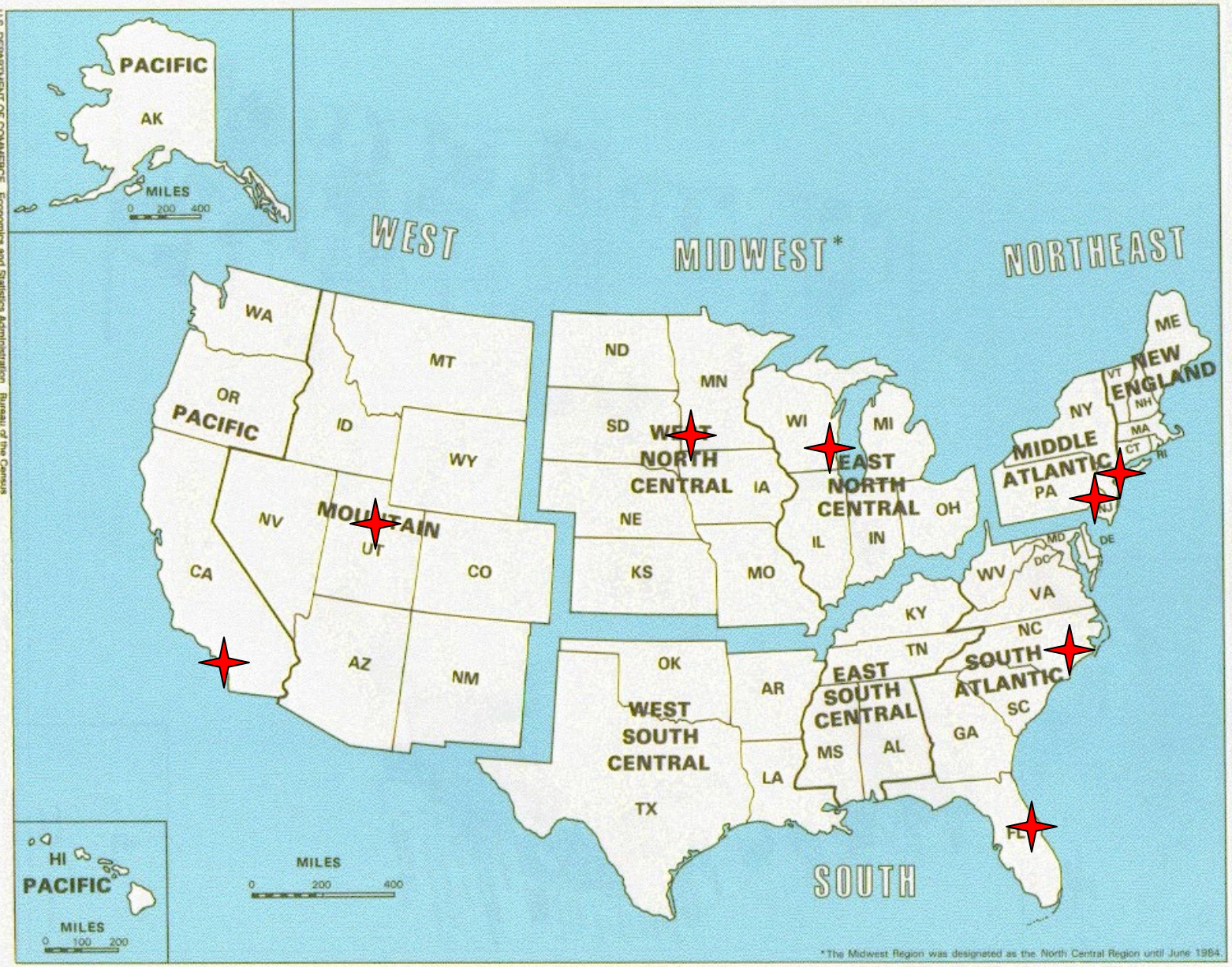
HEALTH GROWTH ENVIRONMENT

Anticipated Awards

- The number of awards that are made is dependent on availability of funds and the quality of proposals received
- Anticipate a total of 3-8 awards
- There will be no more than 1 award for collection of data in a single location
- If there are three awards, our goal is to make one award in each of the three categories of certainty, non-certainty, and non-metropolitan
- If there are 4 awards, our goal is to have one Vanguard Location in each of the four census regions

Mandatory Evaluation Criteria

- Offerors must be located in the same Census Region as the Vanguard Location. Thus, an offeror's organization must be physically located within the same Census Region as the Vanguard Location for which they propose to serve as a Vanguard Center.


Census Regions and Divisions of the United States
MAPS
U.S. DEPARTMENT OF COMMERCE Economics and Statistics Administration Bureau of the Census
UNITED STATES IV-3
PACIFIC
AK
MILES
0 200 400
WEST
MIDWEST*
NORTHEAST
SOUTH
WA
OR
CA
ID
NV
MT
WY
UT
AZ
CO
NM
ND
SD
NE
KS
MN
IA
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IL
MI
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OH
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PA
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VT
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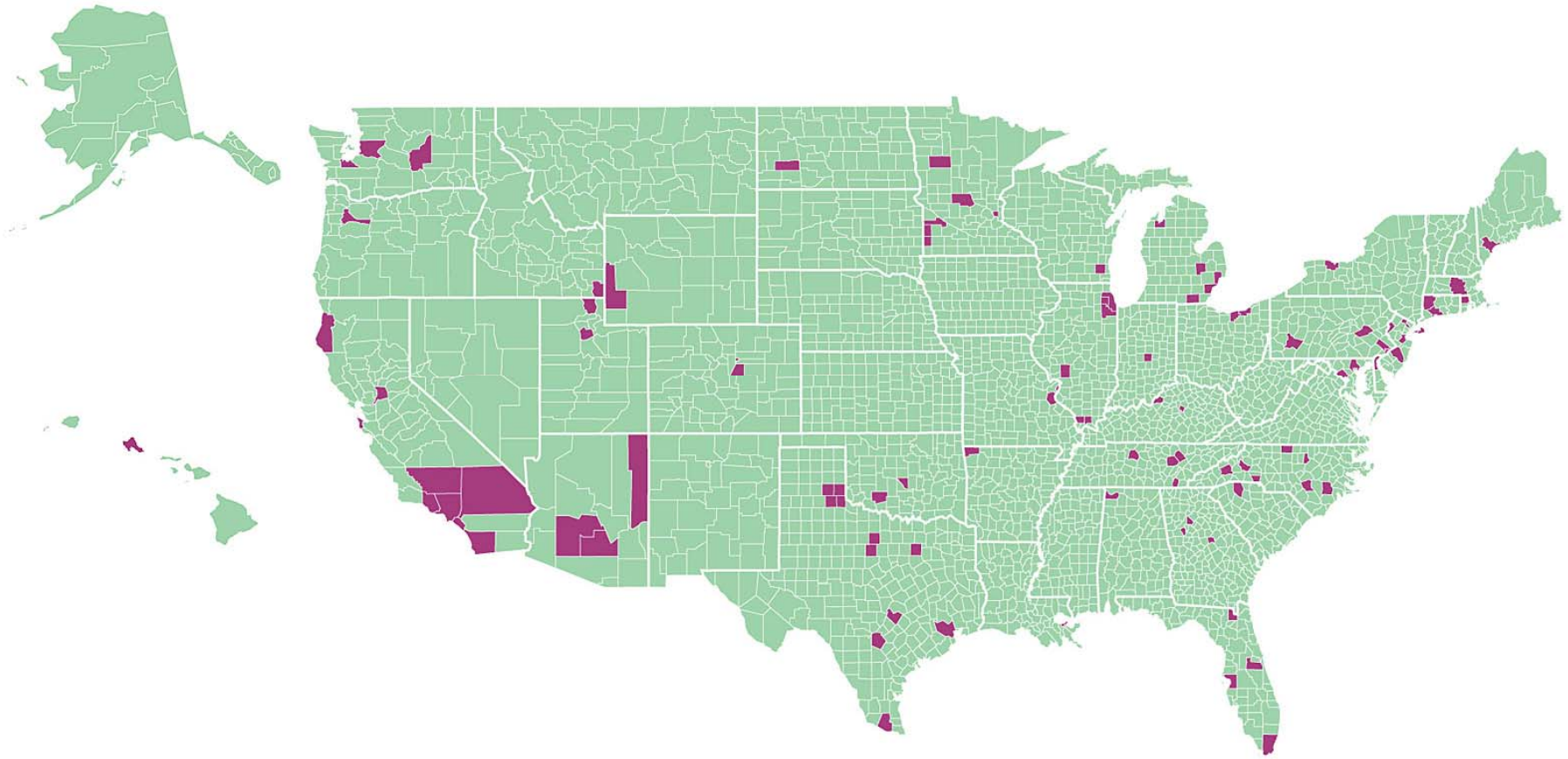
MA
CT
RI
NJ
MD
DE
DC
WV
VA
KY
TN
NC
SC
GA
FL
MS
AL
LA
AR
OK
TX
WEST NORTH CENTRAL
EAST NORTH CENTRAL
MIDDLE ATLANTIC
NEW ENGLAND
EAST SOUTH CENTRAL
SOUTH ATLANTIC
WEST SOUTH CENTRAL
HI
PACIFIC
MILES
0 100 200
MILES
0 200 400
*The Midwest Region was designated as the North Central Region until June 1984.

National Children's Study Locations



Primary Sampling Units

- 101 Primary Sampling Units in our 96 Study Locations
- Targeted enrollment per Primary Sampling Unit is 250 live births per year
- For the Vanguard Locations, each location is one Primary Sampling Unit

National Probability Sample

- Three stages of sample selection
  - Selection of primary sampling units
  - Selection of segments within counties
  - Selection of households/individuals

Selection of Segments

- Several options for defining boundaries of segments
  - Census boundaries
  - Neighborhood boundaries
  - School catchment areas
- Solicit input from the successful offerors to help define the segments
- To maintain the integrity of the sample, offerors will not be involved in the actual selection of segments

Recruitment of Study Participants

- Household Recruitment Approach
- Supplemented with recruitment through other mechanisms such as prenatal care providers
  - Anticipate that some groups of women (e.g. women not planning pregnancy) might be under-represented in the household screening approach
- Offerors can suggest alternative approaches that would meet the goals of The Study

Recruitment of Study Participants

- Participants be included in the Study as early in pregnancy as possible
- Enrollment of a sufficiently large population of women such that 250 live births are enrolled in each of the enrollment years
- Live births are statistically representative of all live births in the targeted Vanguard Sites

Proposed Schedule of Visits

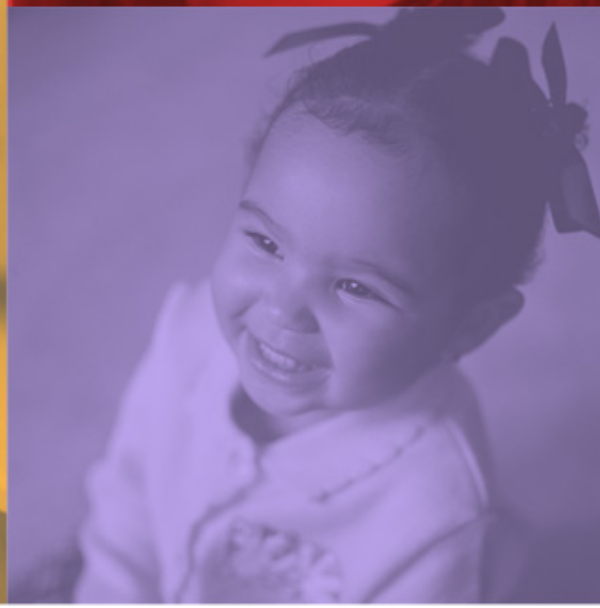
Screening	18 months (Home)
Preconception	3 years (Clinic)
1st Trimester (home)	5 years (Clinic)
2nd Trimester (clinic)	7 years (Home)
3rd Trimester (clinic)	9 years (Clinic)
Delivery	12 years (Clinic)
1 month (Home)	16 years (Home)
6 months (Home)	20 years (Clinic)
12 months (Home)	

Proposals

- Proposals should focus on the 5-year contract period (15 months start-up, preconception and pregnancy, follow up through 3 years of age)

Types of data collections

- Questionnaires and Interviews
  - Face to face
  - Remote (computer, telephone, mail)
  - Diaries
- Environmental samples and observations
  - Air, dust, soil, water, home observations
- Examinations
  - Clinical and behavioral assessments
- Biologic samples
  - Blood, Urine, Cord Blood,Placenta, Breast milk



Participating Entities

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Participating entities

- In place
  - Scientific support
  - **Information technology development**
- Over next year
  - **Clinical / data coordinating center**
  - Initial study centers
- Following
  - Sample Repository
  - Laboratory services

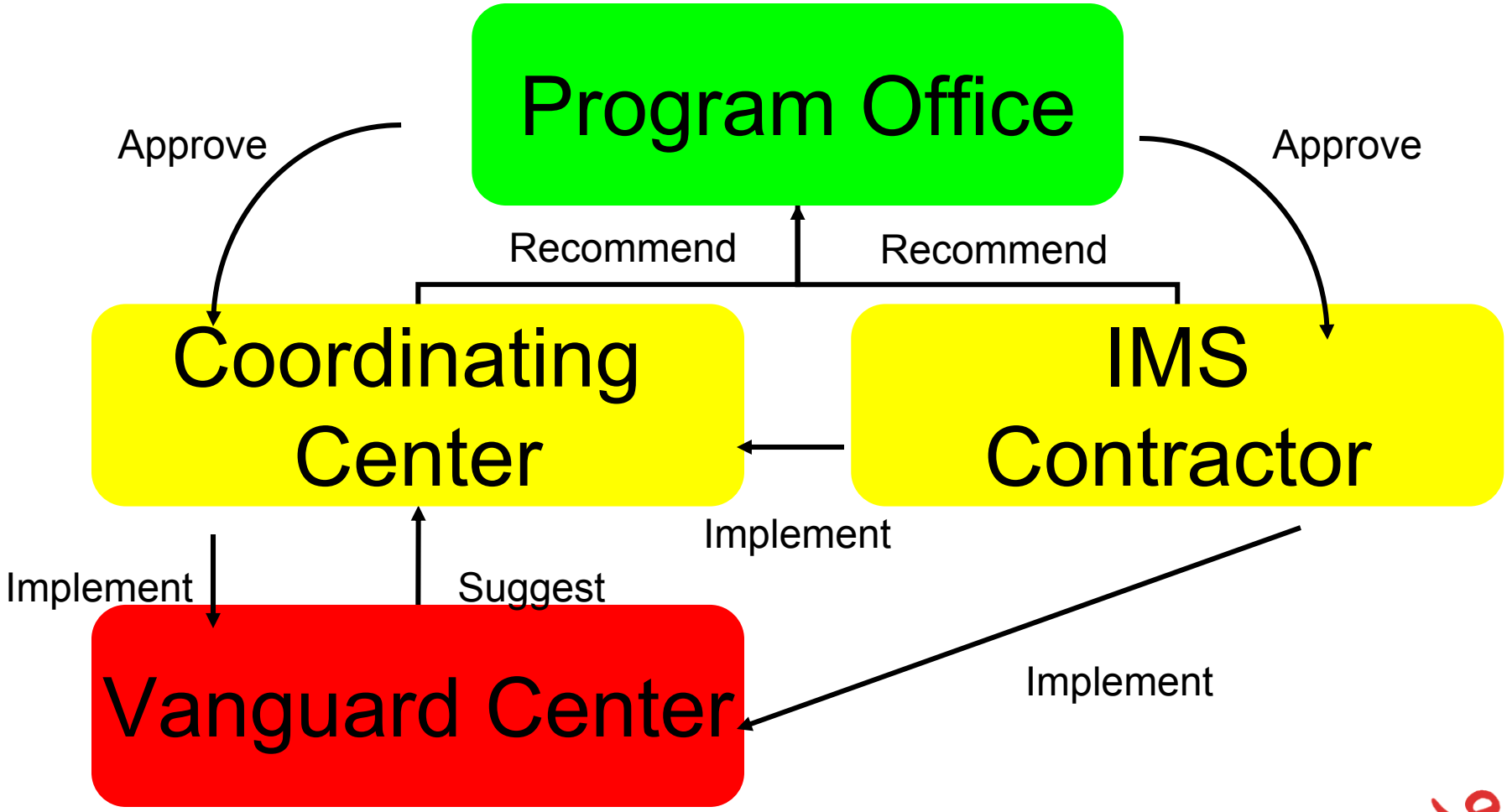
Key Roles for Coordinating Center

- Provide Scientific Support to NCS Program Office
- Implement and support IMS
- Develop Detailed Study Documents in conjunction with NCS Program Office, Vanguard Centers
- Develop and implement QA/QC Program

Key Roles for Coordinating Center

- Develop and implement study coordination procedures
- Perform data management, processing, and analysis
- Support Vanguard Center's implementation of multi-stage probability sampling approach
- Serve as a Study Center for persons no longer living in places conveniently served by existing Vanguard or Study Centers

Change Management for IMS

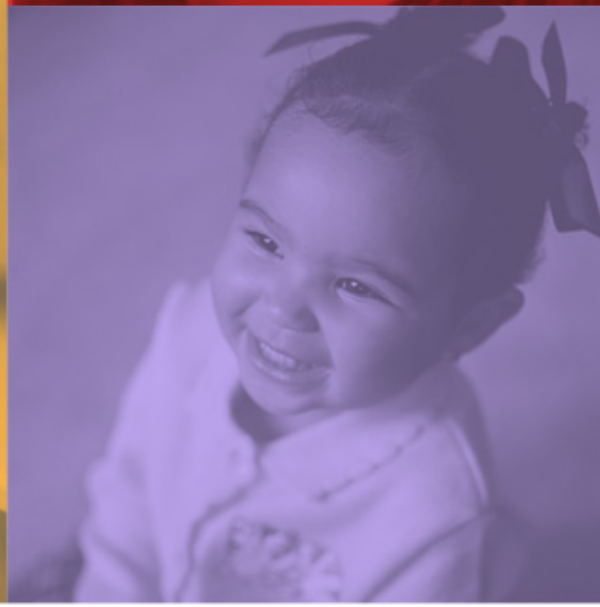


Coordinating Center Serving as Study Center

- The Coordinating Center will serve as a study center under two scenarios:
  - An enrolled child moves away from the study center which enrolled him/her and is now not living near an existing Study Center
  - One of the Study Centers fail and therefore there is a need to cover the catchment area represented by that Study Center

Call Center

- The Coordinating Center will operate a 24 X 7 Call center to serve multiple needs:
  - As a communications link among the various participating study entities
  - As a communications link between Study participants and the Study
  - As a mechanism to remotely collect study data



Specific Questions

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Questions

- **Will additional Study Locations be added?**
  - There is no plan to add additional locations beyond the published list of 96 locations
  - Within the already specified 96 locations, there is a possibility that additional adjoining counties may be added.
    - Non-metropolitan Locations
    - May effect the Vanguard Location in Minnesota
    - Unlikely to effect the Vanguard Location in North Carolina

Questions

- **Who can submit a proposal to serve as a Vanguard Center?**
  - Any organization in the same Census Region as the Vanguard Location.
- **Does the Vanguard Center have to collect data in the Vanguard Location?**
  - Study participants must reside in the Vanguard location as outlined in the Study Plan.

Questions

- **Are the Vanguard Centers part of the larger NCS?**
  - Yes. Data collected during the overlapping period of enrollment will be combined with data collected at the additional Study Locations. Together these are the data that will be used to make inferences to the nation.

Questions

- Will participants who reside in a Vanguard Location but give birth outside of the Vanguard Location be included in the pool of participants to be enrolled?
  - Yes.

Questions – Adjunct Studies

- Adjunct Studies are described in multiple places in the RFP
  - Statement of Work (pages 9 and 10); Study Plan (pages 52 and 68); notes to offerors (page 135); evaluation criteria (page 140).
- Studies that build on the core protocol that can be performed on all or a portion of the cohort
  - Community focused
  - Center focused

Adjunct Studies

- Looking for adjunct studies that effectively utilize and add to the core sample measurements
- Could be funded through the NCS or through other mechanisms
- Following establishment of the Steering Committee, a process for evaluating and approving adjunct study proposals will be developed

Adjunct Studies

- **How much detail should be included in the proposals for adjunct studies?**
  - Some information on page 135 (notes to offeror)
  - More detailed guidelines on this topic as a modification to the RFP
- **What access does a Center have to data from the adjunct study?**
  - Center conducting that study would have access to the data; however, details vary with the specific design of the particular adjunct study

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