



# Draft Concept of National Children's Study Main Study

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# Outline



- Study Concepts
- Main Study
  - Study sample
  - Study eligibility
  - Data collection schedule and content
- Areas for Consideration by the Committee
  - Preconception visit
  - Study sample
  - Recruitment
  - Study visits



# Main Study Concepts



- Assessments from before birth through 21 years of age
- Concentration of visits during prenatal period and infancy, periods of rapid development and vulnerability and with potentially important knowledge gaps
- Examine determinants and impact of health disparities
- Repositories of data and samples to serve as a resource for future studies



# The Main Study Sample



- Sampling Retreat May 27<sup>th</sup>
- Weekly sampling conversations from June 3<sup>rd</sup> through July 1<sup>st</sup>
- Topics
  - Physician based sampling
  - Main study sample
    - Realistic expectations of recruitment rates
    - Attrition
  - Additional primary sampling units
  - Alternative secondary sampling units
  - Recruitment period



# Sample Size



- General Goal: Enroll and retain a sufficient number of women such that there are 100,000 children enrolled in the study after 21 years
- Departure from previous stated goal of 100,000 children initially enrolled in study
- Justification is that for relatively rare outcomes, a larger sample size is needed to detect modest effect sizes, particularly for infrequent exposures



# Recruitment and Retention



- Assume an optimistic 2-3% yearly attrition rate
  - About 150,000-200,000 infants would need to be enrolled to have a sample of 100,000 at 21 years
- Vanguard experience showed that 80% of women enrolled during pregnancy were retained through birth of the child
  - Up to 250,000 pregnant women need to be enrolled
- Multiple ways to increase sample size
  - Improve recruitment rates
  - Increase the number of primary sampling units (PSUs)
  - Increase the number or size of secondary sampling units (SSUs)



# Eligibility – Exclusion Criteria



- Reside in study segment (geographic approach)
  - Pregnant adult women
  - Pregnant emancipated minors and minors
    - Emancipated minors per laws of jurisdiction
    - 14 years or older, not emancipated, with permission for enrollment from legally authorized representative
  - Non pregnant adult women
    - 49 years or younger
    - High probability of pregnancy
- > For discussion today



## Study Eligibility (Inclusion Criteria Continued)



- Children born to enrolled women
- Fathers of enrolled children as identified by enrolled women
- New adult caregivers or adult guardians of enrolled children



# Eligibility – Exclusion Criteria



- Women: Surgically, medically or genetically infertile and not responsive to interventions
- Unable to understand NCS participation and grant informed consent



# Data Collection Schedule



Pregnancy: 3 in person data collections

Birth: 1-2 data collections at place of delivery

2 months, 4 months: remote contact (e.g. phone)

6 month: in person visit

9 month: remote contact

12 months: in person

Data collection every 6 months through age 5 years

In person visit on the year, remote contact on the half year



# Types of Data Collection



- Questionnaires and diaries
- Select medical record abstractions
- Observations
- Physical measures
- Photographs and videos
- Biologic specimens
- Environmental samples
- Revisiting a matrix sampling approach



# Discussion Topics



- Target enrollment up to 250,000
- Increasing sample through increase in number of PSUs, increasing size of PSUs or increasing size or number of SSUs
- Adaptive approach to monitor and adjust recruitment
- Flexible approach to recruitment
- Timing of visits during pregnancy
- Approach to preconception enrollment



## Discussion Topics (continued)



- Proposed visit schedule
- Balance between face to face and remote visits
- Flexible visit schedule (not as tightly linked to age)

