THE NATIONAL CHILDREN'S STUDY (UPDATED BY NICHD/NIH, 4/13/2012)

- The National Children's Study (NCS) is a longitudinal birth cohort observational study whose overall goal is to improve the well-being of children and to identify the foundations of healthy adulthood by examining the effects of a broad range of environmental influences and biological factors on child health and human development.

- Originating legislation was the Children's Health Act of 2000, which includes:

  "(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and
  (2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.
  The study ... shall—
  (1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological, and psychosocial environmental influences on children's well-being;
  (2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures; and
  (3) consider health disparities among children, which may include the consideration of prenatal exposures."

- The NCS has two major phases: the Vanguard Study and the Main Study.

- The Vanguard Study, which started in the field early in 2009, has already accomplished one of its central goals – to test different recruitment strategies for effectiveness and cost. Of the several strategies tested, a provider-based approach proved most efficient and effective. However, it also showed that if - as had been planned earlier - the Main Study used the geographic areas needed to achieve what some epidemiologists term a "national probability sample," not even the provider-based approach would yield sufficient families within either a scientifically sound timeframe or a fiscally sound budget.

- Thus, the Main Study will use a provider-based participant selection and recruitment strategy that NIH and the Agency for Healthcare Research and Quality have both employed effectively in other studies. This approach uses HMOs and other health care provider networks as the primary source for recruitment. The NCS will gain additional participants through secondary sources (such as Title V clinics, Indian Health Service clinics, or contract research organizations) to assure inclusion of appropriate population groups, specifically those with health disparities. The use of these two coordinated selection and recruitment strategies will improve the quality of the Main Study beyond that of a conventional "convenience cohort" and allow analyses not feasible with either approach alone.

- The Main Study will no longer construct a "national probability sample" or be "generalizable" in the way some epidemiologists use those terms and will not be able to

calculate definitively the incidence of a specific disorder, for example. However, constructing a national probability sample was only one suggested means to accomplish NCS' intended purpose - and required scientific compromises and substantial extra costs. The provider-based recruitment model would have several advantages over the previous design in meeting NCS' intended purpose include characterizing enrollees more precisely, utilizing electronic health records, and building on previously collected data. Several alternative sampling strategies based on prenatal care providers are currently being evaluated. The NCS will also interface with other Federal, U.S-based, and international datasets to leverage the value of each. The NIH believes that the new study design meets the legislative mandate in a scientifically compelling and fiscally sound manner. (See table, page 3.)

- The Vanguard Study will continue in its current 40 locations, several years in advance of the Main Study, following the Vanguard Study children already recruited until they turn 21and piloting study methods. It will use a smaller number of contractors than in its earlier recruitment phase, thus realizing cost savings while improving scientific quality by achieving greater consistency in data and specimen collection among study sites.

- The 2013 President's Budget Request of $165M (a reduction of approximately 15% from FY12 appropriated level) for the NCS reflects these design changes. This budget level is appropriate in the eyes of NIH.

- The NCS is conducted through contracts, not grants. The Vanguard Study contracts expire over the next 17 months. None will be stopped early, and all new contracts will be openly competed, as will the Main Study contracts. According to Federal contracting rules, we may not divulge details to the public about the upcoming Vanguard Study and Main Study Requests for Proposals (RFP) in advance, in order not to give any potential contractor an advantage. Details will be publicly available as the RFPs are released later this year. Main Study contract funding opportunities will be announced in FY 2012 and are targeted to be awarded and begin activities in FY 2013, with recruitment to begin in FY 2014.

criteria? → informational briefing?

- The NCS will be an unparalleled, vast research resource containing diverse data, biological specimens, and environmental samples that scientists can use to answer fundamental questions about child health, growth, and development. It will enroll approximately 100,000 children in the Main Study and another 4,000 in the Vanguard Study. The NCS will produce an unprecedented amount of information about the effects of children's environments on their health. In addition, it will provide an historic and unique nationwide resource for scientists now and for years to come, allowing them to analyze the myriad factors that contribute to growth, development, health, and disease.

Comparison of national probability sample with new selection and recruitment strategy

Characteristic	National Probability Sample with NCS primary data collection	Convenience Sample of Prenatal Care Providers with NCS primary data collection augmented with provider health care records
Generalize biological associations	Yes	Yes, with limitations
Generalize psychosocial and behavioral associations	Yes in principle	Limited
Generalize economic associations	Yes in principle	Limited
Geographic dispersion	Yes	Yes
Detailed participant baseline description	Limited and resource intensive	Yes in principle
Operational Feasibility	Limited and resource intensive	Yes
Collect biospecimens	Yes	Yes
Collect environmental samples	Yes	Yes
Inclusion of women outside the health care system	Yes in principle if done by household address	No, but can be supplemented by additional targeted recruitment
Use of woman as sampling unit	Yes	Yes
Use of pregnancy as sampling unit	Yes	Yes
Separation of data collection from health care delivery activities	Yes	Partial, some overlap expected
Use of participant's home as a collection site	Yes	Yes
Allow replication of sampling frame for subsequent studies	Yes in principle	Limited
Linkage to Electronic Health Records	Limited and resource intensive	Yes in principle
Linkage to external databases to describe surrounding community	Yes in principle	Yes in principle
Ability to perform multiple analyses and case control studies	Yes in principle	Yes in principle
Archive data and specimens accessible to researchers	Yes	Yes