



Briefing for Pre-proposal Conference
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Rationale for the National Children's Study

From The President's Task Force on Environmental Health and Safety Risks to Children, 2000*

- Compared to adults, children are especially vulnerable to environmental exposures – metabolism, behavior
- Exposures to some agents demonstrate potential for serious developmental effects – lead, prenatal alcohol
- Current known exposures of high frequency – pesticides, violence, media
- Numerous high burden conditions with suspected environmental contribution – learning disabilities, autism, diabetes, asthma, birth defects, premature birth
- Existing research too limited in size and scope to answer the questions
- Life-course (longitudinal) design needed to correctly link with multiple exposures and multiple outcomes

* Reappointed 2001 and 2003



Children's Health Act of 2000

- (a) Authorize NICHD to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.
- (b) Established a consortium of representatives from appropriate Federal agencies (including the CDC and EPA) to--
 - (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.
- (c) There are authorized to be appropriated to carry out this section \$18,000,000 for fiscal year 2001, and such sums as may be necessary for each the fiscal years 2002 through 2005.



Study Concepts

- Longitudinal study of children, their families and their environment
- National in scope
- Hypothesis driven
- Environment defined broadly (chemical, physical, biological, psychosocial, cultural)
- Study common range of “environmental” exposures and less common outcomes (n ~ 100,000)



Study Concepts (con't)

- Exposure period begins in pregnancy
- Environment & genetic expression
- State-of-the-art technology – tracking, measurement, data management
- Consortium of multiple agencies
- Extensive public-private partnerships
- National resource for future studies



Organization and Process for Scientific Development

- Interagency Coordinating Committee – appointed program staff of lead agencies – HHS/NICHD, NIEHS, CDC & EPA – **Operational Decisions**
- Chartered Federal Advisory Committee – **Advice, manage working groups**
- Working Groups (22) – non-Federal and Federal scientist & investigators (approx. 250) – hypotheses, design, measures – **Consultation and findings**
- Program Office at NICHD – Federal Staff – **Operations**
 - **Epidemiology – pediatric, environmental**
 - **Behavioral Science**
 - **Developmental toxicology**
 - **Environmental exposure assessment**
 - **Sampling statistics**
 - **Genetics**
 - **Information technology**



Organization and Process for Scientific Development (cont.)

- Workshops - 27
- Pilot Studies - 12
- Scientific Reviews - 9
- A total of 2,425 individuals contributed to the scientific development



Major steps and decisions

- Advisory Committee and Working Groups
- Hypothesis guided
- Contract mechanism
- Sampling strategy
- Center based structure



Advisory Committee and working groups

- Participate in scientific development to provide broad and detailed scientific input and consultation
- To gain awareness and support for the study among scientific community and other stakeholders
- Advisory Committee and Working Group members = 478
- Advisory Committee and Working Groups cannot participate in Scope of Work development
- Advisory Committee is being revitalized: Ethics, scientific considerations, community engagement, other



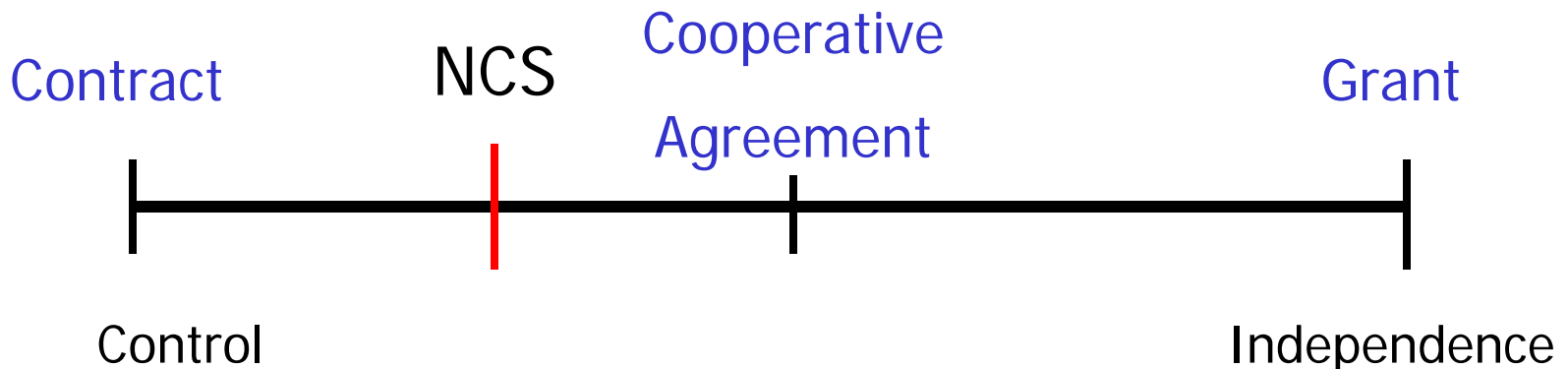
Hypotheses are important

- To provide boundaries and framework
- Assure answers to “big issue” questions
- Hypothesis required for costly elements but not for every possible question
- Important for child health & development (prevalence, severity, morbidity, mortality, disability, cost, public health significance)
- Require the large sample size (~100,000)
- Measurable with study of this size
- Requires longitudinal follow-up
- Will evolve as science and study evolves



Why a contract mechanism?

- To assure a consistent rigorous core protocol carried out at all sites
- To assure NCS addresses goals of funding agencies





Sampling and (not versus) Center strategies

- National probability sample important
 - Exposure-outcome relationship representative of the U.S. population
 - Important exposures with varied and unknown distributions are not missed
- Centers of excellence important
 - Broad scientific input
 - Measures require center based expertise and facilities
- Probability sample by Centers
 - Unique & challenging combination
 - Requires flexibility and adaptation of centers to the scientific design
 - Requires support, back-up and guidance by coordinating center



Process for scientific input

- Federal Advisory Committee
 - Short pause during RFP's
 - New chair and executive secretary
 - Some new members
 - Working groups as needed
- Workshops
- RFP's - comments and reviews
- Investigators at CC and Study centers
- National and regional meetings
- Assembly list serve



Participating entities

- In place
 - Scientific support reviews, analyses, surveys
 - Information technology development
The prime IT contractor has excluded self from CC
- Over next year
 - Clinical/data coordinating center
 - Initial study centers
- Following
 - Sample Repository
 - Laboratory services



Projected Time Line

- | | |
|----------------------|---|
| 2000-2005 | Pilot study/methods development work |
| <i>Periodically:</i> | Meetings, peer reviews, consultations |
| Mid 2004 | Finalize specific hypotheses, develop study design |
| Late 2005 | Select initial centers |
| 2006 | Complete and pilot full protocol |
| Early 2007 | Enroll first participants with initial centers |
| 2006-2007 | Select additional centers |
| 2009-2010 | First preliminary results available from pregnancy |
| 2007-2030 | Analyze data as collection continues, publish results throughout: hypothesis specific, public use datasets, RFA's |



Status of funding

- Total projected cost of study is \$2.7 B based on pre RFP assumptions.
- Anticipated FY '05 funds in the president's budget allow us to initiate the announced procurements.
- Professional judgment estimate for the '05 budget was approximately double the anticipated funds allocated.
- Contract guidelines do not permit announcing the amount of funds budgeted for contract procurements.



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Contact Information

Check the Web site:

<http://NationalChildrensStudy.gov>

- Join the listserv for news and communication at <http://NationalChildrensStudy.gov>
- Contact us at ncs@mail.nih.gov