



The National Children's Study

Protocol Development

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Overview

- Role of Program Office
- Definition of “The Protocol”
- Process
- Issues and challenges
- Timeline



Role of Program Office

- Draft the text of the study protocol
- Oversee and coordinate development of operational manuals
- Work with the contracting office to develop relevant procurement documents



Study Protocol

- Background, Goals, and Objectives
 - Outline the science in a precise fashion
- Study Design and Methods:
 - Who we will be enrolling (sampling)
 - When and where contacts will occur
 - What will occur when contacted
 - Limited information on how data will be collected (details in the operational manuals)



Study Protocol (continued)

- Human Subjects
 - Benefits and risks
 - Confidentiality
 - Consent and assent
- Data
 - Analyses
 - Data sharing and dissemination



Givens...

- Environmental influences on child health and development
- Environment broadly defined
- About 100,000 children
- Enrollment during or before pregnancy
- Follow-up 21 years
- National in scope

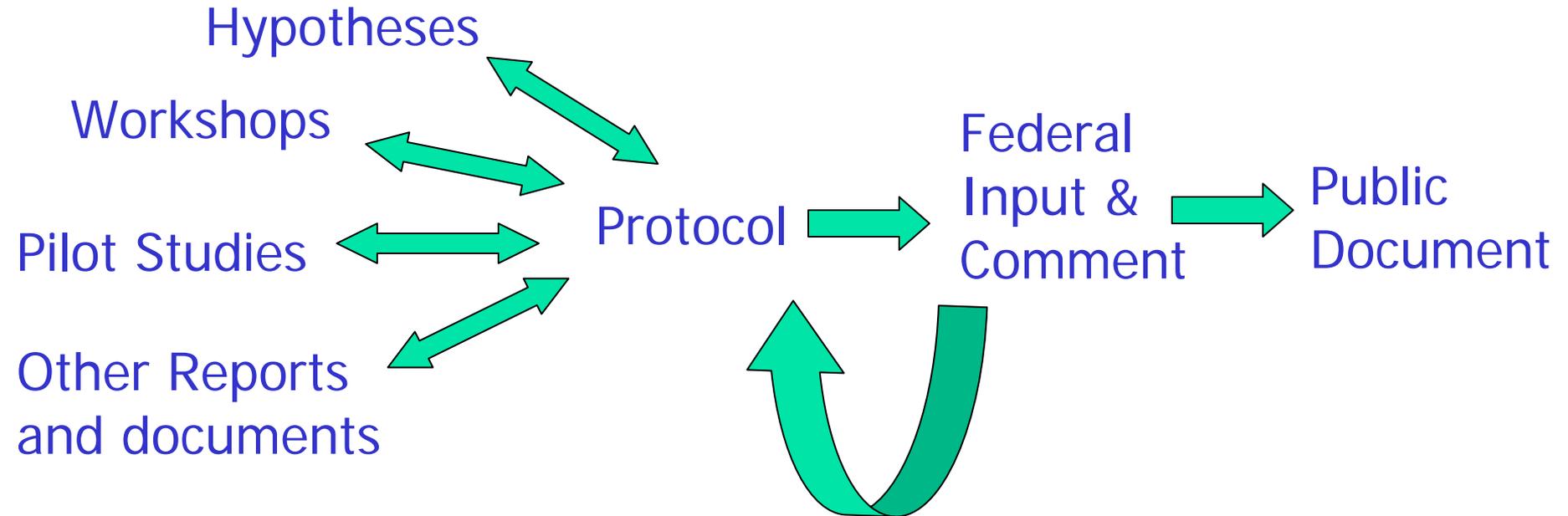


Guidelines

- Develop a unified study protocol that is:
 - Hypothesis driven
 - Focused enough to be a cohesive document
 - Broad enough to cover all relevant exposures and outcomes



Process





Major Issues

- Sampling strategy
 - Westat document
 - Batelle document
 - Workshop (March 21-22)
- Timing of enrollment
 - Above materials
 - Publications
 - Other documents



Major Issues

- Participant burden
 - Focus groups
 - Pilot studies (PBRN)
- Ethical issues
 - Workshop (June 2003)
 - Work group recommendations



Challenges

- Review, synthesize, and integrate all of the materials prepared to date
 - Solution: broken this down to manageable bites
- Limitations on who we can contact
 - Solution: rely heavily on expertise within the federal government



Strengths

- Voluminous study documents
- Expertise within the program office
 - Full time senior scientific staff
 - Marion Balsam- Pediatrics, Health Care Management
 - Ruth Brenner – Pediatrics, Epidemiology
 - Warren Galke- Environmental Epidemiologist
 - Sarah Knox – Behavioral Scientist
 - Peter Scheidt – General Pediatrics



Strengths

- Expertise within the program office
 - Part time senior scientific staff
 - Terry Cox – Neuro-Ophthalmologist, biostatistician
 - Carole Kimmel – Developmental Toxicologist
 - Jim Quackenboss – Environmental Exposure Specialist
 - Ken Schoendorf – Pediatric Epidemiologist
 - Temporary senior scientific staff
 - Terry Dwyer – Pediatric Epidemiologist



Projected Time Line

2004	Circulate draft protocol to federal experts
2004-2006	Ongoing public comment and revisions
2004-2005	Release initial RFPs
2005-2006	Selection of vanguard study sites
2006	Initial phase with vanguard sites
2007+	Additional sites added

