



Advisory Committee Meeting

December 15, 2003

Program Office Report



# Director's Response to the Advisory Committee

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- Requests formal recommendations
- Liaison role to the Working Groups is critical
- Alignment of AC and ICC/PO timelines important
- Agree with recommendation for probability based sample as much as feasible and look forward to the reviews and conference that examines alternatives
- Look forward to seeing
  - Revised and updated hypotheses where needed
  - Inclusion of healthy development, social factors, race/ethnicity
  - Re-energized development and behavior WG
- Advisory committee will need to examine and re-evaluate structure and functions of AC and working groups as study evolves.



# Program Office Staffing

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- Scientists – full time staff
  - Protocol development leader – Ruth Brenner
  - Behavioral scientist – Sarah Knox
  - Data management/clinical coordinating center project officer – Warren Galke
- Scientists – part-time/detail
  - Visiting Scientist – Terry Dwyer, U. Tasmania



# Contracts

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- Technical Support Projects – Battelle
  - Advantages and Limitations of Probability Based Sampling for the NCS
  - Critical Data Collection Requirements for the NCS
  - Recruitment and Response Rates
    - Achieved in Other Relevant Studies
    - Projections for the NCS
    - Impact on sampling strategies
  - Sample design options for the NCS
  - Developmental Measures for the NCS



## Contracts (cont)

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- Development of Information Technology system for the NCS
  - Objectives
    - Information management system planning
    - Database development
    - Data collection systems
    - Operations systems
  - Duration – Award 12-'03 for up to 5 years
  - Team – Booze Allen (lead), RTI, Battelle, Levine Frickie, Sanz



# Protocol status

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- Starting with
  - Draft proposal by the ICC – 2001
  - Core hypotheses & “Study Areas” document
  - Measures database
- Protocol team at program office
- Definition at this phase, “define what is to be done in sufficient detail for IRB and OMB review and approval”.
- First rough draft for March 2004



# Partnership Development

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- Foundation for NIH
  - Approved the National Children's Study as a project for development of partnerships
  - Identify and broker for potential partnerships with Program Office
    - Adjunct and sub-studies
    - Financial support
    - Incentives
  - Memorandum of understanding in preparation



# Proposed Expansion of the National Children's Study

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- For the human genome to provide further understanding the the major adult diseases requires very large adult cohort
- Scientific consultation affirms that it is scientifically sound and advisable to incorporate with the NCS
- Proposed to combine longitudinal follow-up of the parents and all available grandparents
- Planning and details only just begun



# Timeline and coordination

<b>Time</b>	<b>Study milestone</b>	<b>NCSAC activity</b>
Ongoing	Pilot studies	Review and advise pilot study proposals, receive updates
Ongoing	Partnerships development, community engagement	Offer ideas and contacts
Through June 04	Preliminary protocol development	Propose hypotheses refinements, Propose specific measures
2003-2004	Information management system design and development	Advise on specified aspects as needed
2004-2005	Protocol refinement, OMB clearance, selection of measurement techniques	Advise on trade-offs of including/excluding major components
2004-2005	Contracting for coordinating center, pilot protocol, Vanguard centers, repository	N/A
2006	Enroll participants at initial sites	Continue advice on evolving pilots and protocol



# Perspective on Advisory Committee and Working Groups

From the Program office and ICC

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- Expertise and advice needed for planning the study
- Advisory Committee – broad overview, integrating findings, advice
- Working groups – focused science, findings needed for increased detail
- Working groups currently relatively inactive
- The pace will pick up over next 6 months and information from AC and WG's critical