



Advisory Committee Meeting

March 4, 2004

Program Office Report



# 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
  - Partnerships/project officer – Marion Balsam
  
- Scientists – part-time/detail
  - Kenneth Schoendorf
  - Carole Kimmel
  - Jim Quackenboss
  - Rebecca Brown
  - Randy Curtin
  
  - Tracy Thomas
  - Terry Cox
  - Terry Dwyer



# New Program Office Staff

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- Terry Cox, M.D., PhD – 1-2 d/wk
  - Neuro-ophthalmologist
  - Biostatistics, PhD
  - NEI
- Terry Dwyer, M.D., PhD – visiting scientist from Australia by contract for sabbatical
  - U. New S. Wales MD, Yale, MPH epi.
  - Dir. Menzes Cent. Pop. Health Research
  - Cohort & epi. Studies – cardiovasc. dis., genetics, cancer, SIDS.
  - Australian National Health and Medical Research Council
  - Chair of the WHO Western Pacific Advisory Committee on Health Research
- Tracy Thomas, MPH – EPA AAAS Fellow
  - Biomarkers



# Contracts

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- Technical Support – Battelle
  - Background for sampling strategies
  - Developmental Measures for the NCS
  - Sample protocol for the PBRN feasibility study
  - Power analyses for social environment hypotheses
  - Review of extant databases for the NCS
  - Review and white paper on measurement of housing quality



## Contracts (cont)

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- Development of Information Technology system for the NCS – Booz Allen Hamilton (lead), RTI, Battelle, Levine Fricke, Sanz
  - IT requirements for recruitment and enrollment
  - Mechanisms for questionnaire data collection
  - Electronic capture of clinical data



# Contracts – Anticipated Procurement

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- Clinical/data coordinating center
  - Concept clearance approved
  - Under development
- Repository
  - Sources-sought announcement & responses received
- Vanguard (initial) Centers



# Pilot Studies – Upcoming workshops

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- **Rurality Workshop** - March 2, 2004,
- **Sampling Design Workshop** - March 21–22, 2004,
- **Possible Roles for Inclusion of the Study of Cancer in the National Children's Study Workshop** - tentative: April 2004
- **Questionnaire and Diary-Based Methods for the Early Assessment of Asthma-Related Health Outcomes Workshop**  
Tentative: May 27, 2004,
- **Assessing Dietary Intakes and Patterns in Women and Young Children** - Tentative Spring 2004,



# Pilot Studies – Upcoming workshops (cont.)

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- Day-Specific Probabilities of Conception and Prospective Pregnancy Studies Workshop  
Tentative: May 2004
- Measurement of Maternal and Fetal Infection and Inflammatory Response - TBD
- Gene Expression and Behavior Workshop  
TBD,
- Social Environment Measures Workshop  
TBD



# Protocol Development

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- Ruth Brenner will discuss in more detail
- Entering a new phase
  - Elements of the protocol will become part of the scope of work for procurements
  - Potential problems with possible contractors or competitors regarding potential conflict of interest, inside track, procurement integrity



# Protocol Phase - Implications

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- Findings and proposals re study design and measures (protocol elements) from WGs & AC – OK
- Conversely, protocol elements cannot be shared with WGs & AC ahead of other potential contractors etc
- To protect Advisory Committee and Working Groups, communication about evolving protocol must be public.
- Decreased interaction with ICC and program office
- Reduced intensity of AC and WG activity.



# Partnership Development

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- Foundation for NIH
  - Memorandum of understanding in preparation
  - Implementation of specific partnerships will depend on funding for full study
  - Co-sponsor of Congressional briefing with ACC, CEHN and others



# Proposed Expansion of the National Children's Study

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- Proposal to expand the adult component of the NCS – still very much on the table, but...
- While decisions about funding with the administration and congress are still in process, the NCS will continue as is;
- NHGRI and other Institutes engaged with the adult component will continue to address conceptual questions and relationships with the other adult genetic studies;
- When funding for the NCS is clarified, more detailed consideration of the proposed three generational study will be given.



# Funding Status Up-date

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- FY 2004 – Needed \$26m, Have \$12m
- FY 2005 – We're ready to get the NCS launched and start collecting data beginning with participant enrollment in 2006. Our need for FY05 is \$27m to be able to do this. The President's Budget request to Congress for FY05 contains approx \$12M.
- Total projected cost - \$2.7 billion spread over 25 years



# About snacks

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We have not provided food along with drinks for AC meetings because:

- Available in relatively close proximity
- Very expensive when provided by hotels and bringing in food is prohibited
- For consistency with the many other working group meetings, workshops and the NICHD Council
- You can blame me