



Advisory Committee Meeting

March 4, 2004

Program Office Report



Program Office Staffing

- 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

- 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

- 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)

- 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

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



Pilot Studies – Upcoming workshops

- **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.)

- 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

- 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

- 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

- 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

- 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

- 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

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