

National Children’s Study Federal Advisory Committee Meeting
Discussion Questions
July 2010

NCS Policy and Practice on the Return of Research Results:

Revealing clinically relevant and actionable findings to individual participants is seen as an ethical obligation. The NCS has operationalized the definition of “clinically relevant and actionable” as requiring the existence of a national or other widely recognized threshold or regulatory standard. This topic is much debated in the literature. At this time, there are not clear best practices for longitudinal cohort studies and biobanks.

The ability to link to individual records does exist within the NCS and is integrated into the current process; however, there is an unknown temporal lag between collection and analysis and an inability to define which potential analytic results may be relevant to participants. Due to this lack of certainty, the Independent Study Monitoring and Oversight Committee (iSMOC) was developed to independently review analytic plans and make recommendations regarding the advisability of reporting of specific results to participants.

Current NCS Policy and Practice on the Return of Research Results includes anthropometric measurements such as height, weight and blood pressure, would be shared immediately with participants. Other data such as analytes from environmental samples and biological specimens would be stored indefinitely. The iSMOC is charged with determining which analyses may yield analytically valid, medically relevant, and actionable research results. The planned mechanism for reporting of research results is direct communication of results to the Study Center principal investigator with a recommendation to repeat the evaluation with appropriate referral as needed.

NCS staff members are also committed to informing participants and communities of aggregate data, which will be done on a periodic basis as findings become available. Participants will be continuously informed of Study progress and aggregate findings via newsletters and other communications. It is anticipated that individual Study Centers also will integrate a local process to this national process to report some of the aggregate findings of interest to the local community.

1. Is the current NCS Policy and Practice on the Return of Research Results sufficient if real time analysis is instituted? What additional policies or clarifications, if any, should be incorporated into this NCS policy? Specifically, the NCS real time analysis would be performed in research laboratories with equipment dedicated to research, and would not be clinical grade or CLIA certified.
2. What are the possible downsides/risks of sharing research laboratory data in an observational study enrolling a broad population and how can we minimize those risks?
3. If the NCS policy for incidental findings follows other longitudinal study policies for incidental findings, health care providers would be informed. What recommendations would you make about the nature and extent of information provided to health care providers? In your opinion, how prepared are

health care providers to use research findings, particularly from environmental measurements or genetic analyses, in interactions with potential study participants? What recommendations would you make if a health care provider cannot be identified or contacted?

5. Under what circumstances, if any, would you recommend that community organizations or authorities be informed of environmental findings; for example if known toxins or carcinogens are found that appear to exceed allowable limits?

6. If genetic analyses are performed, under what circumstances, if any, should results be shared with participants? Should results be shared only for health related information, that is, no information about ancestry, physical traits, etc.? Should results be shared if requested by the participant? Should health related information be restricted to those conditions included for newborn screening?

7. For each scheduled visit, current NCS policy is to provide participants prior to the visit a Visit Information Sheet as a guide to the contents of the visit. As assays and analyses are identified as potentially yielding results that could be conveyed to participants and critical values are determined; should the NCS prospectively incorporate language within the Visit Information Sheets, in addition to the general language in the protocol and consent forms, to better communicate the possibility of sharing findings with either participants or health care providers?

Environmental Assessments:

1. Recent discussions suggest that questionnaires intended to assess environmental exposure have inconsistent or little predictive value.

a. Can you cite questionnaires that have been validated in pregnant women and children that have predictive value and should be considered for evaluation in the NCS?

b. Should the NCS initiate activities to develop and validate environmental exposure questionnaire instruments that would be consistent with the design, principles, rigor and precision used in domains that have validated questionnaire instruments?

2. Environmental contaminants of potential interest have multiple assay standards. Recent discussions suggest that consistent terminology and centrally accessible databases that exist in some research domains are absent for the environmental topics of interest.

a. Can you cite terminology and databases that have been vetted and validated for pregnant women and children that may be utilized for NCS environmental assessments?

b. Should the NCS initiate activities to develop consensus standards and a framework in conjunction with other partners to assure consistency, scalability, adaptability and interoperability for environmental assessments with other databases and data sources for future integrated analyses?