

National Children's Study Federal Advisory Committee (NCSAC)
Discussion Questions (DRAFT)
October 14, 2010

Environmental Assessments:

Prior discussions of this committee endorsed an approach to perform "Real Time Analyses" of environmental samples and biological specimens collected during the National Children's Study. An alternative business model of collecting environmental samples and biological specimens and storing them until researchers and resources are identified at a future date was not endorsed due to risks of potential sample instability, missing scientific opportunities and delaying deliverables.

The NCS Program Office is exploring the development of environmental profiles- small panels of analytes- that may be informative regarding child health and general environmental conditions.

1. Do you have comments regarding the feasibility of such an approach with regard to technical challenges and opportunities, potential components, profiles, and sources (for example soil, water, air, blood, urine)?
2. Do you have experience or knowledge of how environmental profiles can relate to specific child growth and development parameters?

The NCS Program Office is also exploring the option of a hierarchy of environmental substances, using a subset of a larger class as index analytes that, if found to be outside identified parameters, would trigger additional analyses. For example if a standard panel contained four heavy metals and 2 or more of the heavy metals were above a threshold, the sample would be analyzed for additional heavy metals.

3. Do you have comments regarding the feasibility of such an approach with regard to technical challenges and opportunities, the linkages and correlations among substances of a particular class, preferred classes of substances and potential sources (for example soil, water, air, blood, urine)?
4. Do you have comments regarding preferred units or terminologies if environmental analytes are grouped into panels for profiles?

Data Acquisition and Management:

The Initial Vanguard Study utilized a centralized model of data management including case management systems and data capture systems. Based on the first year of experience with the centralized model and identification of multiple technical and logistical challenges in planning scale up, the NCS Program Office has implemented an approach to provide greater flexibility and permit exploration and innovation to determine preferred methods. The new approach is termed facilitated decentralization model. In this model, the NCS Program Office will develop evaluation questions and plans; data fields, tables and relationships; formatting and transmission standards; a central data archive; and specifications and guidelines for data security, participant confidentiality, and regulatory compliance. Distinct from the centralized model, however, the facilitated decentralization model allows study centers under contract with the NCS to select case management systems, data acquisition platforms, and as appropriate, data collection tools to acquire data whose content, format and security requirements have been established by the NCS Program Office. All data systems are certified and accredited per the Federal Information Security Management Act of 2002 (FISMA) and related regulatory compliance. All data specifications are intended to be consistent with international medical research standards such as those developed by the Clinical Data Interchange Standards Consortium (CDISC).

The facilitated decentralization model encourages the use of open-source, non-proprietary data capture and case management systems. It builds on local study center expertise with existing systems and supports adaptation or development of new systems.

1. Do you have any comments regarding the use of open source non-proprietary data systems as the basis for the NCS Informatics System?
2. Do you have experience with relevant data platforms or systems that the NCS should consider during the Vanguard Study?
3. Do you have architecture or process recommendations for the informatics systems?