



The National Children's Study

Data Access for the National Children's Study: Current Plans and Pending Issues

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Overview



- Sharing NCS data is an expectation, a necessity and a priority
- Sharing must be done in a way that preserves the integrity of the data, the privacy of the participant and his/her community, and transparency of study operations.
- The NCS has developed a management structure and policies to support these goals, and work toward these objectives is progressing.
- We are actively engaged in learning best practices from other studies.

Strategy



- Describe forms of data and materials to be made available to researchers, participants, and communities
- Describe policy considerations, current access plans, and pending issues
- Request feedback from NCSAC throughout

How do researchers access NCS data?



- Analytic data files (electronic)
- Image and audio data
- Biospecimens
- Environmental samples

Electronic data file access: Considerations



- Prompt access to data is required to answer scientific questions put forth in the Children's Health Act.
- Access must be clearly established for all members of the research community.
- The NCS design will present challenges to the protection of sensitive (identifiable) data.
- Preserving data integrity is vital.

Electronic data file access: Current plan



- Make NCS final data files available to all researchers, regardless of NCS affiliation
 - No early access to final data files for Study investigators
 - No “shadow data” collection or use permitted (including “extra” specimen collection at localities)
- Ensures equitable access to data
- Ensures monitored access and use of data

Electronic data file access: Current plan



- Prepare standard datasets for different purposes
- Purpose of the dataset determines extent of disclosure review, and degree of data coarsening and suppression
 - Public use files undergo strictest disclosure review and coarsening/suppression because use is not monitored.
 - Non-public use files undergo some disclosure review. Since users agree to terms of use and monitoring, minimal suppression used.
 - Controlled use materials are stored and accessed through supplemental agreements in “cold rooms.”

Electronic data file access: Pending issues



- Expand data access options available to researchers
 - Data use agreements (NCES)
 - Research data centers (NCHS, Census)
 - Image/audio archives (ICPSR, Murray Center)
- Develop web-based data access request tool (NCES, NCHS, NIST)
- Synchronize tracking tools used for data access, disclosure review, and scientific review for transparency, ease of use, and parsimony
- Input to these endeavors is most welcome.

Specimens and samples access: Considerations



- Maximize potential of finite material
- Use of finite material must
 - Balance between investigations for proximal or short term outcomes (such as perinatal event analysis) and later outcomes
 - Assure adequate samples for future, as yet unrecognized, analyses
- Gain efficiency and utility from ongoing advances in analytic technology

Specimens and samples access: Current plan



- Minimize immediate analyses on total NCS population
- Majority of specimens to be stored in repository
- Process, aliquot, store in flexible formats
- Focus on nested case-control studies
- Request access through Adjunct Study Review Group/Sample Oversight Group

Specimens and samples access: Pending issues



- Continue evaluation of
 - Collection feasibility and costs
 - Processing
 - Stability
- Prioritize among planned tests

How are NCS results shared with the public (not researchers)?



(apart from the peer review process)

- Participants
- Communities
- Everyone

Participants: Anticipated data needs



- NCS data will be gathered from participants through the informed consent process.
- The consent process is designed to tell the participant what we would like to collect, why, how we would collect it, how we would protect it, and when and how we can give them individual test findings.

Participants: Considerations



- Personal health information may be important to participants even if tests are conducted sometime in the future.
- Some tests for the evaluation of samples are known at the time of collection; others are not yet determined.
- Some tests require lab analysis, others can be reported immediately.
- Some tests could inform current medical care; others have unknown implications.
- The ease and salience of analysis for these tests can change over time.

Participants: Current plan



- Through informed consent process, identify tests results that can be reported during the visit. Report those findings to the subject.
- Inform participant that other tests have not yet been determined, and those results, in general, will not be reported to them.
- Advise participant that our independent Study Monitoring and Oversight Committee will review the testing process over time and make further determinations of how and when additional results could be reported to the participant.

Participants: Possible enhancements



- As study protocols are refined, identify those tests likely to be conducted by NCS.
- Among those tests, identify those with a well-understood evaluation process, time period, and critical values
- Prioritize among these tests to determine those which should be analyzed in a short time frame and reported

Summary



- Many uses of NCS data
 - Aggregated national data for analytic purposes by investigators and researchers
 - Individual health data of interest to participants
 - Aggregated local data of interest to communities and to the nation
- The intended purpose and intended user of the data will inform data access decision making process
- NCS principles of equity, integrity and transparency guide data access policy