

Status Report
Begin to Develop Complete Operations Manuals
Prepare to Implement a Cohort Study of Children's
Environmental Health

Prepared for:

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**Deliverable: Status Report for Task 4, Begin to Develop
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**Prepare to Implement a Cohort Study of Children's
Environmental Health**

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1.0 Overview

As a precursor to the National Children’s Study (NCS), the North Carolina Cohort Study (NC Cohort Study) will provide the opportunity to field test procedures to better inform the implementation of the NCS. In order to test some of the study hypotheses, it will be important to obtain both pre- and post-conception measures of exposure. The NC Cohort Study will enroll 5,000 women who are either pregnant or planning to become pregnant, and follow the children born to them. This demonstration cohort will allow for testing both traditional and emerging technologies to recruit and survey these women and their families, as well as utilizing various methods to ensure high retention rates throughout the study. The experiences gained in the recruitment and data and biological specimen collection of the NC Cohort will inform these procedures for the NCS.

In order to be able to successfully plan, coordinate, and implement such a complex study, RTI staff will work closely with U.S. EPA to identify any supplemental materials and identify any gaps that need further development before specific study materials can be developed. The purpose of this task is to begin to assemble materials from the Program Office and other NCS reports that will be useful in the development of the OMB and IRB applications and operations manuals, and to identify the specific types of manuals that are likely to be required first for the NC Cohort Study, then for the NCS. This document identifies the current status of the preparations for materials to be developed.

2.0 Materials Development Schedule

RTI assumes that the development of Manuals of Operations (MOPs), Quality Assurance Procedures Plans (QAPPs), and Standard Operating Procedures (SOPs) will occur concurrently. Materials development will depend on the study team’s finalization of the study protocol for the NC Cohort. The materials development tasks also include ample time for finalization of each document, including time for the U.S. EPA and study team members to review and provide feedback on the materials, as well as time for RTI to incorporate feedback on the materials.

3.0 Development of Operations Manuals

Well planned and developed operations manuals are essential to the success of any research effort. Manuals are used as training tools and references by project staff and/or study participants throughout the implementation of the study as well as documentation of established protocols for historical record and for use during future waves of a study. The final study protocol and operations manuals serve as sources to document the protocol for both OMB clearance and IRB review.

Operations manuals cover all aspects of survey implementation, including procedures for sampling, recruiting and obtaining informed consent, data collection (instrument administration), biological and environmental sample collection and shipment, ensuring subject confidentiality, and

quality assurance. Detailed operations manuals documenting each major activity are necessary to coordinate and implement such a complex study as the NCS.

A typical operations manual begins with an introduction and overview of the research study that provides the foundation for the implementation. This background information should cover the need for collecting data, the intended use of the data, brief overview of the Program Office mission, and the contractor's role. Following the introductory sections, each manual begins to cover task-specific activities, describing how and when specific project tasks will be performed, and presenting a project schedule. The number of chapters required is dependent on the complexity and volume of tasks to be completed. Regardless of the type of manual, most operations manuals typically end with administrative details such as documentation of labor hours and expenses and other administrative issues required of contractor or subcontractor staff. Appendices are often used to depict data collection instruments, forms, supplemental materials, and other procedures that may not be easily included in the body of the manual.

For this Work Assignment Task, RTI has developed several examples of draft outlines of typical operations manuals. Example Tables of Contents for the following types of manuals have been included as appendices:

- Data Systems Development Manual, Appendix A
- Recruitment Manual, Appendix B
- Clinical Procedures Manual, Appendix C
- Field Interviewer Manual, Appendix D
- Participant Procedures Manual Outline, Appendix E
- Sample Logistics and Processing Manual, Appendix F

Once the study protocols have been established, RTI will utilize the appropriate sources of information to finalize the manual outlines and to develop these manuals in accordance with the U.S. EPA's specifications.

4.0 Assembling Documentation for Review

Documentation to support the development of operations manuals to carry out the NC Cohort Study began with a review of existing materials and documents developed as a result of the work of various NCS committees and working groups. We have identified materials under development that could be considered as potential sources of information for the operations manuals. In addition, we have begun to identify other studies that have data collection components similar to those proposed for the NCS (e.g., questionnaire administration, biospecimen collection) in order to develop broad outlines of the topics typically covered in the operations manuals. The next step will involve additional review of other supplementary materials provided by the Program Office, and under consultation with the WAM, we would use any relevant information to inform the materials developed for the study.

Since 2000, the NCS has generated planning information from a multitude of sources including the Interagency Coordinating Committee (ICC), the NCS Advisory Committee, more than 20 working groups of federal and nonfederal scientists, contract research organizations, universities, and other organizations and individuals. With this in mind, we have selected many potential sources of data to be used in developing the protocol, manuals, and OMB clearance package and IRB package that will be used to plan and implement the NC Cohort Study. *Table 1* provides a list of the different study components that may be included in the study, as well as a summary of the corresponding manuals and potential sources of information that could be used in their development. In addition to these materials, we expect that the draft protocol for the NCS—tentatively planned to be released at the end of 2004—will provide a wealth of information to guide the development and finalization of the operations manuals.

Table 1. Study Requirements, Required Manuals, and Potential Sources of Information

Study Requirements	Required Manuals	Potential Sources of Information for Manuals
Survey Sampling	Sampling Protocol	<ul style="list-style-type: none"> • NCS Advisory Committee Meeting (June 28-29, 2004) • Gene Environment Interaction and the Regulation of Behavior Workshop (June 2-3, 2004) • Methods for the Assessment of Asthma-Related Health Outcomes in the National Children’s Study Workshop (May 27-28, 2004) • Maternal and Fetal Infection and Inflammation Workshop (May 20-21, 2004) • Expanding Methodologies for Capturing Day-Specific Probabilities of Conception Workshop (May 17-18, 2004) • Tingen C, Stanford JB, and Dunson DB. Methodologic and Statistical Approaches to Studying Human Fertility and Environmental Exposure. Environ Health Perspect 2004; 112:87-93. • NCS Sampling Design Workshop (March 21-22, 2004). Arlington, VA. • Strauss W, Lehman J, Menkedick J, Ryan L, Pivetz T, McMillan N, Pierce B, and Rust S (2004). Draft White Paper on Evaluation of Sampling Options for the National Children’s Study. Battelle Memorial Institute. Rockville, MD. • Sampling Strategies for the Proposed National Children’s Study (2002). Prepared by Westat for the National Center for Health Statistics Contract # HHS-100-97-0017
Web-based and Computer-Assisted Telephone Interviewing (CATI) Survey Data Collection	Telephone Interviewer Manual	<ul style="list-style-type: none"> • Methods for the Assessment of Asthma-Related Health Outcomes in the National Children’s Study Workshop (May 27-28, 2004) • WA 02-05, Chemical Exposures Workgroup White Paper, Section 5. • Study Process Area and Study Process Definitions (Booz Allen Hamilton) • Buck GM, Lynch CD, Stanford JB, Sweeney AM, Schieve LA, Rockett JC, Selevan SG, and Schrader SM. Prospective Pregnancy Study Designs for Assessing Reproductive and Developmental Toxicants. Environ Health Perspect 2004; 112:79-86. • Demonstration of Low Cost, Low Burden, Exposure Monitoring Strategies for Use in Longitudinal Cohort Studies (RTI Final Report, May 2003)

Table 1. Study Requirements, Required Manuals, and Potential Sources of Information (cont.)

Study Requirements	Required Manuals	Potential Sources of Information for Manuals
Computer-Assisted Personal Interviewing (CAPI) and Audio Computer-Assisted Self-Interviewing (ACASI) Data Collection	Field Interviewer manual	<ul style="list-style-type: none"> • Methods for the Assessment of Asthma-Related Health Outcomes in the National Children’s Study Workshop (May 27-28, 2004) • WA 02-05, Chemical Exposures Workgroup White Paper, Section 5. • Demonstration of Low Cost, Low Burden, Exposure Monitoring Strategies for Use in Longitudinal Cohort Studies (RTI Final Report, May 2003) • Study Process Area and Study Process Definitions (Booz Allen Hamilton) • Assessing New Technologies for Incorporation into the National Children’s Study (Landrigan et al, 2002)
Biologic Specimen Collection	Manual for FIs, Manual for participants (if self-collection), Laboratory SOPs QAPPs	<ul style="list-style-type: none"> • Measurement of Maternal and Fetal Infection and Inflammation Workshop (May 20-21, 2004) • WA 02-05, Chemical Exposures Workgroup White Paper, Sections 2 and 4. • November 2003 Placental Measurements Workshop • Workshop Psychosocial Stress in Pregnancy and Infancy, November 12-13, 2003. • Chapin RE and Buck GM. Our once-in-a-lifetime opportunity. Environmental Health Perspectives 2004; 112:67-68. • WA01-06, Technical Support for a Longitudinal Cohort Study: Estimating Subject Burden for Potential NCS Measurements (RTI Final Report, August 2003) • Demonstration of Low Cost, Low Burden, Exposure Monitoring Strategies for Use in Longitudinal Cohort Studies (RTI Final Report, May 2003)
Clinical Measurements	Clinical Procedures Manual	<ul style="list-style-type: none"> • Expanding Methodologies for Capturing Day-Specific Probabilities of Conception Workshop (May 17-18, 2004) • Demonstration of Low Cost, Low Burden, Exposure Monitoring Strategies for Use in Longitudinal Cohort Studies (RTI Final Report, May 2003) • Fetal and Neonatal Growth and Development Workshop, December 15-16, 2002. • November 2003 Placental Measurements Workshop. • Workshop Psychosocial Stress in Pregnancy and Infancy, November 12-13, 2003. • Rockett JC, Buck GM, Lynch CD, and Perreault SD. The Value of Home-Based Collection of Biospecimens in Reproductive Epidemiology. Environ Health Perspect 2004; 112:94-104. • WA 02-03, Testing Feasibility of 3-D Ultrasound Data Acquisition and Reliability of Data Retrieval from Stored 3-D Images

Table 1. Study Requirements, Required Manuals, and Potential Sources of Information (cont.)

Study Requirements	Required Manuals	Potential Sources of Information for Manuals
Environmental Sampling	Manual for Environmental Sampling Field Interviewers, Lab SOPs/QAPPs	<ul style="list-style-type: none"> • WA 02-05, Chemical Exposures Workgroup White Paper, Section 3. • Demonstration of Low Cost, Low Burden, Exposure Monitoring Strategies for Use in Longitudinal Cohort Studies (RTI Final Report, May 2003) • WA 02-06, Preparing Issue Papers on the Use of 1) Sensors and 2) Radio Frequency ID (RFID) for the National Children's Study
Neurobehavioral or Cognitive Assessments	Field Interviewer Manual	<ul style="list-style-type: none"> • Measurement of Maternal and Fetal Infection and Inflammation Workshop (May 20-21, 2004) • Workshop Psychosocial Stress in Pregnancy and Infancy, November 12-13, 2003. • Assessing New Technologies for Incorporation into the National Children's Study, Landrigan et al, 2002. • WA 02-04, Measurement of Spontaneous Motor Activity for Behavioral Assessment in Human Infants
Data Management and Information Technology	Study Protocol	<ul style="list-style-type: none"> • NCS Workshop on Innovative Technologies for Remote Data Collection (Boston, MA, May 12-13, 2003) • Assessing New Technologies for Incorporation into the National Children's Study, Landrigan et al, 2002 • Study Process Area and Study Process Definitions (Booz Allen Hamilton)
Ethical Considerations	IRB Package	<ul style="list-style-type: none"> • NCS Ethics Resource Guide (Draft, 2002) • Coughlin, SS and Beauchamp TL. 1996. Ethics and epidemiology. Oxford University Press: New York. • Beachamp, DE and Steinbock, B (eds). 1999. New ethics for the public's health. Oxford University Press: New York.

5.0 Further Development of Operations Manuals

As described above, there are a variety of sources available to begin development of operations manuals for the NC Cohort Study. Although RTI has identified these documents mainly from the NCS website and applicable work performed under the Longitudinal Cohort Study, we expect that additional input from the WAM and other study team members will be necessary to identify materials that are still under development or planned for release. Additionally, the draft NCS protocol will help to flesh out some of the details required in the operations manuals.

Appendix A

Example of Data Systems Development Manual

Develop Participant Identification System	1
Develop Sample Identification System.....	1
Develop Computer-assisted Personal Interviews (CAPI).....	2
Draft Specifications, Program, and Test Background Questionnaire	2
Draft Specifications, Program, and Test Health Questionnaire	2
Draft Specifications, Program, and Test Dietary Questionnaire.....	3
Develop Computer-assisted Telephone Interview (CATI) for Recruitment.....	3
Draft Specifications, Program, and Test Screening Mechanism.....	4
*Electronic Calendar for Scheduling	4
Draft Specifications for Web-Based Case Management System (CMS).....	5
Program and Test CMS.....	5
Load Data into CMS	5
Train Staff with CMS.....	6
Draft Specifications for Sample Tracking System.....	6
Program and Test	7
Barcode Readers	7
Draft Specifications for Supplies Inventory Tracking System	8
Program and Test	9
Barcode Readers	9
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Example of Recruitment Manual

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National Children’s Study.....	4
U.S. Environmental Protection Agency.....	4
RTI International.....	5
Participating Clinical Sites.....	5
Project Video	6
Hospitals (contact info for all involved)	6
County Health Departments	7
Other Health Organizations	7
Participants of the NC Cohort.....	8
Females pre-conception	9
Male spouse/partner pre-conception	9
Females prenatal	10
Males prenatal.....	11
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Mothers postnatal.....	12
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*Outline modified from the Venipuncture Study, a substudy to the National Long Term Care Survey (NCTLS)	
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Appendix C

Example of Clinical Procedures Manual

*Assumes most biospecimens collected at clinic site.

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National Children’s Study.....	4
U.S. Environmental Protection Agency.....	4
RTI International.....	5
Project Video.....	6
Participating Clinical Sites.....	6
Hospitals (contact info for all involved).....	7
County Health Departments.....	7
Other Health Organizations.....	8
Participants of the NC Cohort.....	8
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* Given to participants in a 3-ring binder.

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