



PROTOCOL FOR IRB SUBMISSIONS
Excerpt

February 26, 2008

8. HUMAN SUBJECT PROTECTIONS

The NCS will not include any interventions. Risks to the women and fetuses are not greater than minimal and the research will in no way affect medical decisions about pregnancy management and outcome.

Even though the NCS is primarily observational in nature and will have a low level of subject risk and reasonable subject burden, many human subjects issues are involved. These issues include the duration and complexity of the research; the diversity of the participants; the collection of biologic, environmental, social, and behavioral measures; and the creation of enduring data, as well as biologic and environmental sample repositories, with the potential for future studies not yet conceived. These issues were taken into consideration in the development of the informed consent plan.

The informed consent plan for the NCS accounts for the various types of participants and is tailored to address specific issues pertaining to each type. The types of participants who will require consent or assent include the following:

- Women at high probability of becoming pregnant (preconception women)
- Pregnant women (adolescents and adult women)
- Biological fathers
- Other caregivers (e.g., foster parents)
- Children (through the phases of young children, adolescents, young adults).

All consent materials will be available in English and Spanish and other translations will be available as warranted by local needs. The consent plan also recognizes that preconception women may become pregnant and at that time will need to provide additional consent for participation in the full NCS along with permission for their infant's participation. In addition, the assent–consent process for children will change as they grow from young children to adolescents and eventually reach the age of majority and legally become adults. The consent plan is described in greater detail in Section 12.

Most Study Centers will be part of an institution that has an IRB with a Federal-Wide Assurance for Human Subjects Research. At this time, a single, central IRB is not anticipated for the NCS. However, some of the Study Center institutions will be able to serve as Regional IRBs. Each Study Center will be expected to either obtain a human subjects review through their own institutional IRB or develop a cooperative agreement between their Study Center's IRB and another NCS Study Center IRB. In a cooperative agreement, one IRB in a multi-center study agrees to rely on the review of another qualified IRB to avoid duplication of effort and facilitate the process of review as described in federal regulations that govern human subjects research (§45 CFR 46.114). Individual Study Centers also are encouraged to develop cooperative agreements among local institutions, hospitals, and clinics within their study sites to decrease redundancy and facilitate the process of human subjects review. Similar types of cooperative

agreements also will be important in regard to HIPAA-consent procedures for obtaining medical information at the participating hospitals and doctors' offices in the region.

8.1. Rationale for Subject Selection

The NCS will employ a national probability sample. No exclusions are based on gender, race, or ethnicity. Women, children, men, and members of all of the racial and ethnic groups and economic strata represented in the United States will be participants in the NCS. The rationale for this approach is to accrue and follow a population of children that captures the range and diversity of exposures and outcomes experienced by children in the United States.

The primary procedures for recruitment will involve screening and recruitment from households located in neighborhoods targeted for inclusion in the NCS and through providers of prenatal care. A variety of materials and strategies will be used to increase public awareness of the NCS and to aid with recruitment of Study participants. These methods will include but will not be limited to messages transmitted through local media (e.g., newspapers, radio, and television), and distribution of various NCS materials, (e.g., Study brochures, question and answer sheets, and newsletters).

8.2. Evaluation of Benefits and Risks and Discomforts

8.2.1 Benefits

Although individual participants (women, men, and children) may benefit from participation, the NCS does not claim individual participants will have the "prospect of direct benefit" from the Study. There are likely to be collateral benefits of participation in the NCS, including information about individual examinations and tests performed during the course of the Study, increased awareness of medical and social services available in the communities studied, and serendipitous findings of clinical relevance or of predictive value to participants and their families.

8.2.2 Potential Risks

Each of the procedures, measurements, and assessments in the core NCS protocol is designed to fulfill the definition of *minimal risk* in the federal regulations (§45 CFR 46.102[i]) and to be reviewed by IRBs under §45 CFR 46.404 "Research Not Involving Greater Than Minimal Risk." In addition, NCS is committed to minimizing risks even when they are minimal.

Risks associated with the NCS are related to testing and storage of biologic specimens and environmental samples, reporting to authorities of observed possible child abuse or neglect, possible breaches of confidentiality, and informing participants of Study findings (which potentially could result in psychological effects, such as anxiety, or could have a financial effect, such as costs for additional testing). As described in the following sections, each of these potential risks has been considered by the NCS, and plans are in

place to minimize the risks to protect the welfare of participants and families involved in the Study.

8.2.3 Collection, Repository Storage, and Future Use of Biologic Specimens and Environmental Samples

Biologic specimens will be collected from women during the preconception period, during pregnancy, and after birth. Specimens also will be collected from biological fathers (during the pregnancy period) and from the child serially after birth. At the time of birth, collection of cord blood and placental material is planned. Appendix D2 includes details of the draft biospecimen collection plan for each Study visit.

NCS plans to obtain biologic specimens from participants including blood, urine, saliva, breast milk, vaginal swabs, nails, and small samples of hair. At birth, cord blood, umbilical cord, placenta, and meconium will be collected. These specimens will be used to measure various physiologic parameters (e.g., hematocrit, iron stores), to measure various environmental exposures (e.g., lead, chemicals), and to provide genetic information about each participant. Sample volumes will be kept minimal. Only experienced phlebotomists will collect the blood to mitigate risks. Specimens will be analyzed or stored in one or more repositories for future studies.

NCS also will periodically collect environmental samples of air, dust, and water from the homes of participants and other places where the child spends more than 30 hours a week. These samples will be analyzed to determine and measure environmental exposures or will be stored in one or more repositories for future studies. Appendix D3 includes details of the draft environmental sample collection plan for each Study visit.

Some biological specimens and environmental samples will be analyzed at the time of collection; others will be stored for future analysis. Strict guidelines on the use of specimens and samples will be followed to monitor these uses, maintain the quality and integrity of the specimens and samples, and protect the privacy and confidentiality of the participants. Under no circumstances will data, specimens, or samples relating to participants be distributed or used in any way that is inconsistent with their informed consent.

During the consent process, participants will be told that specimens and samples will be stored for future research as new research issues emerge or new technologies become available. All future uses of stored specimens will be approved by a multi-disciplinary Sample Oversight Committee that will be created and charged with assuring that the samples are used only for future studies consistent with the goals and mission of NCS (i.e., to better understand the effects of environmental influences on the health, growth, and development of children and their predisposition to adult disease). If the committee determines that the newly proposed research goes beyond the current scope of the goals and mission of NCS or that additional contact with participants is required, permission will not be given for the studies without new IRB review and additional consent.

Additional information about reporting results of future tests of stored biologic specimens and environmental samples and the role of the Sample Oversight Committee is provided in Section 8.2.5.a.

8.2.4 Observing Participants in Serious Danger

NCS staff are cognizant of the fact that while research staff are in and around the homes of participants, they may observe or learn about environmental hazards or behaviors that place a child in imminent danger and investigators may be legally required to report such observations or information to specific authorities in some jurisdictions. Thus, the informed consent process will inform participants that one of the risks of participating in the NCS is that if a data collector observes that a child is in imminent danger of serious harm or is the subject of child abuse, the information will be reported to the proper authorities to obtain help for the child. Study procedure manuals and interviewer and supervisor training will describe the process that will be invoked to report such observations to the principal investigator or his or her designee at each site. Primary data gatherers will be trained to note such dangers to participants and to inform their supervisors immediately for evaluation as to the proper course of action. It will not be the sole responsibility of the data gatherers to report the observations to authorities; rather, it will be the responsibility of the professional staff under the supervision of the principal investigator to assure that reporting is performed in an appropriate and timely manner. Study Centers will have knowledge of local resources, including social service providers, for referral purposes. Each Study Center will work out a local mechanism for this reporting and referral process.

Primary data gatherers also will be trained to respond to observations of adults in danger, such as domestic violence between adults. While a responsibility exists to assist adults in dangerous situations, these situations will be dealt with differently. The adult victims will be involved in the process, and no reports will be filed with any authorities without the involvement and approval of the adult victims, unless required by law. Names of social service referral agencies will be provided upon request to adult victims of domestic violence.

8.2.5 Reports of Findings

Revealing certain relevant findings to individual participants is not only seen as an ethical obligation but also may be an important recruitment and retention strategy. Revealing local aggregate findings to the communities also may be an important strategy to maintain community engagement. The process to determine what findings to reveal will occur centrally at the national level—not locally at the Study Center level—to ensure that the process is consistent for all participants in the NCS. As part of the annual IRB review process, reports provided to IRBs will include a summary of findings that have been revealed to participants and communities. Draft materials associated with the reporting of findings are included in Appendix K.

8.2.5.a Reporting Findings to Individual Participants

Unless clinically relevant and actionable, NCS will generally not provide medical information to participants or family members. Available tests from NCS will be of uncertain relevance to the health or well being of individual participants and will be relevant for research purposes only. Participants will be informed of these standards during the consent process.

Some routine physical and laboratory test results will be revealed periodically as an incentive to participation. For example, results of routine physical measurements (e.g., height, weight, body mass index, and blood pressure), and routine laboratory tests performed on biologic samples (e.g., hematocrit and hemoglobin) will be provided to participants on a regular and recurring basis. These results will be presented in a context that will allow the participant to compare their individual results with normative data when appropriate (e.g., growth curves, normal range of hematocrit for age). Ultrasound images also will be provided to participants, and participants living in homes using well water will receive results of volatile organic compound (VOC) levels in their well water.

Most biospecimens and environmental samples will be stored and not analyzed for many years, until they are needed to address a specific hypothesis. All proposals for future use of specimens or samples to address a specific hypothesis will be reviewed by the Sample Oversight Committee, as described in Section 8.2.3. The Sample Oversight Committee will comprise of experts in the content area of the proposal, NCS Program Office staff, and people outside the program who are not involved in the NCS, including ethicists.

The Sample Oversight Committee will be responsible for determining the scientific value of the proposal given limited specimen resources, whether the proposal is consistent with the stated goals of the NCS, whether the proposed study is using procedures previously approved by an IRB, whether the proposed study is consistent with the information provided to participants during the informed consent process, and whether the proposed tests could yield results that would be clinically relevant and actionable and, therefore, reportable. If the new study is determined as valuable, is consistent with the NCS goals, is using previously approved procedures, and the results are not reportable, the proposal likely would be accepted and not require IRB review. If the study is using procedures not previously approved by an IRB or not consistent with the information provided to participants during the informed consent process, or it has new results that are deemed reportable, the study will go to each IRB for review and approval. The proposed new studies will be required to use procedures that include the signing of data and specimen-use agreements, confidentiality agreements, and non-disclosure agreements.

The Sample Oversight Committee also will consider the following:

- If there are state requirements to disclose.
- If federal or state standards or guidelines exist.
- If appropriate risk assessment has been conducted and published and are applicable to the community in which the samples were collected.

For those specimens that are analyzed in a timely manner, and for genetic analyses that are performed to address a specific hypothesis, participants will be informed that clinically relevant and actionable medical information exists and may be obtained upon request if it may affect their health. If participants request the information, Study Center staff will explain to the participants the consequences of learning such information, and if the participants still desire the information, Study Center staff will inform them in a sensitive and knowledgeable manner. When appropriate, participants will be encouraged to discuss results with their physician.

Results provided to participants will be accompanied by an explanation and context for the result, basic information about the sources and risks, and guidance on where to find more information.

Participants may opt out of any measurement, test, biological specimen collection, or environmental sample collection. However, if a test, measurement, or collection is performed, and the results indicate a known health effect or risk to the participant that is clinically relevant, timely, and actionable, the findings will be revealed to the participant.

The Information Management System will alert research staff at Study Centers and at the Coordinating Center of results that fall outside pre-determined normal ranges, including collected physical measures, as well as biospecimens and environmental samples that are analyzed. The principal investigator at the local site will be notified about each urgent, clinically relevant and actionable finding and will ensure that appropriate methods for informing the participant are in place.

8.2.5.b Reporting Aggregate Findings to Participants and Communities

NCS staff also are committed to informing participants of aggregate data, which will be done on a periodic basis as findings unfold. Because environmental findings may reveal local problems that could affect property values or other issues, potential risks exist in revealing information found the NCS to individuals (participants and non-participants) and to the entire community. Therefore, revealing information to communities must be done thoughtfully and with some level of preparation.

To help keep participants engaged in the NCS, all participants enrolled in the Study will receive periodic national updates on the progress of the NCS through newsletters, Web site postings, and other communications. This process of continuous informing will include updates on the progress of the NCS, health information appropriate for all participants, some insights into how large studies such as NCS analyze findings to make inferences about how an exposure might be related to an outcome, and, serially, information about the findings of the NCS.

It is anticipated that individual Study Centers also will integrate a local process to this national process to reveal some of the aggregate findings to the local community to

maintain contact with participants, give site-specific information to communities and participants, and to help maintain community engagement.

The various NCS committees, including the Data and Safety Monitoring Board, the Sample Oversight Committee, and the Ethics Subcommittee of the Federal NCS Advisory Committee, will assist the study directors in making decisions about revealing findings to communities. The Data and Safety Monitoring Board will determine the scientific validity of findings before they can be released, and community leaders will be engaged and informed before the information is disseminated. Community members will serve as consultants for issues related to informing communities about findings. Because there is a potential for conflict between the interests of individuals and the interests of the community, the advice of the community will be considered but need not be determinative of action.

8.2.6 Protecting Confidentiality

To protect the confidentiality of participants, only unique identification numbers, without personal identifiers, will be used for all data collected, including all biologic specimens and all information derived from those specimens. However, data that can be used to link the specimens to personal identifiers and other data obtained from individual subjects during the course of this longitudinal study will be maintained separately, securely, and confidentially.

To further protect participant confidentiality, the NCS will obtain a Federal Certificate of Confidentiality from the National Institutes of Health. The Certificate of Confidentiality protects data from forced release by court subpoena.

To further assure confidentiality of participant data, the NCS will employ rigorous methods such as a carefully designed computer Information Management System that protects personal identifying information and research staff trained and educated on issues related to privacy and confidentiality. All staff at the Study Centers and Coordinating Center must adhere to the security requirements implemented by NICHD, including the following:

- Completion of the NIH Computer Security Awareness Training.
- Completion of a Human Subjects Protection Training.
- Signing a legally binding Assurance of Confidentiality.

Sensitive and confidential information on participants (e.g., identifiers, genetic information, and medical histories) will be collected by the Study Centers and will reside on the NCS Information Management System located at the Coordinating Center. This system will be used by the Study Centers as well as by the Coordinating Center. Participants will be contacted by the Study Centers and the Coordinating Center for a variety of purposes through in-person visits, telephone, and mail. For administrative purposes, sensitive and confidential information will be released back to the Study Centers only for participants that came from that specific center.

Photographs of participating children will be stored as digital images and will not be released or otherwise made available to anyone outside the NCS. The images will be observed by trained evaluators, and the evaluation data will be recorded and stored with other protected NCS data. The images will be retained and protected as sensitive and confidential identifying information. No photographs of participating children or any NCS participants will be used to promote the Study.

Identifying information from each Study Center will not be shared with other centers, unless an NCS participant moves to a location covered by another Study Center. Permission will be obtained from the NCS participant before releasing identifying information to a Study location other than the one that originally obtained the informed consent of the participant.

Study-wide data will be shared with Study Center investigators and other NCS investigators for data analyses. These data will be stripped of personal identifiers but otherwise minimally disrupted to protect the privacy and confidentiality of participants while preserving the integrity of the data. The data will be made available through secure systems with safeguards in place to limit access and protect the data.

Non-NCS investigators will have another level of data-sharing. These investigators will be required to sign data-use agreements to ensure and monitor appropriate use of all data, specimens, and samples. Data released to non-NCS investigators will be subject to a higher level of redaction. Variables that might enable individual participants to be identified will be removed, including some demographic data, outliers, dates, and study sites. Because it might still be possible to combine these data with other publicly available data (such as community-level environmental, safety, and educational data) and determine with reasonable certainty the identity of individual participants, these data are not truly anonymous. That is why these data will be shared only with investigators who agree to adhere to restrictive policies regarding the use of the data through signed data-use agreements prohibiting efforts to identify individual participants or otherwise misuse the data.

The third level of data sharing will be through public-use data files. Before being released to the public, these data will be maximally de-identified to remove personal identifiers, geographic identifiers, and other data that might reasonably lead to disclosure of participant identities. Careful and thorough methods will be used, including disclosure review analysis, to ensure that the data are protected from deductive disclosure (i.e., identification of participants through indirect means). Data also may be sub-sampled before release. Release of only a de-identified subset of the original records makes deductive re-identification of individual data even more difficult. Through these methods, the potential for disclosure will be minimized.

In addition to the core protocol for the NCS, adjunct studies are expected to be proposed and conducted by investigators associated with the NCS. Such studies may involve a subset of the NCS cohort at one or more Study Centers on all or a portion of the local

participants or their data. To protect the quality and integrity of the NCS, adjunct studies will be reviewed and approved through a defined process involving formal review and approval. The review will include the following criteria: scientific merit, scientific relevance and "fit" with the NCS, burden to participants and to the NCS, and other human subjects issues.

Because NCS participants may be asked to participate in these adjunct studies, the NCS consent process will include a statement that participants may be contacted for other studies connected with NCS as a result of their participation, but they are under no obligation to participate in any of these adjunct studies. All adjunct studies that involve additional interaction with human subjects will require separate informed consent and IRB review.

NCS data will be retained indefinitely, because the Study is a long-term cohort study.

Disclosure analysis for datasets released for analysis will be performed by the Coordinating Center according to disclosure plans and rules established by the Disclosure Review Board and the Data Access Committee.

The Data Access Committee is responsible for establishing policies concerning who may have access to data and at what point in the NCS. The Disclosure Review Board will report to the NCS Program Director and will oversee the specifics of the Disclosure Protection Plan to ensure that no individual can be identified at any of the various levels of data release. To do so, the board will approve disclosure control procedures and agreements for NCS data releases, review confidentiality analyses, review reports and publications for disclosure risk, and review the disclosure report for all data to be released.

8.2.7 Information Management System Security and Confidentiality

The Information Management System will provide administrative, computational, reporting and telecommunications support for the NCS. Information Management System applications are categorized into three primary groups:

1. *Data Capture and Management Systems.* These systems will include support for listing, sample management, data and specimen collection, shipping, forms and image receipt control and management, assignments and scheduling appointments, cash management, and correspondence.
2. *Support Systems.* These systems provide support in managing and tracking ancillary support needs, including tracking and shipping of supplies and assets, management of documents, training and certification management, IRB materials and approval tracking, and management of the review process for requests for the use of NCS specimens, data, adjunct studies, or other related publications.

3. *Quality Control and Data Delivery Systems.* These systems support the quality assurance reviews and general data management. Support includes monitoring reports (including Data and Safety Monitoring Board, Coordinating Center, and Program Office); tracking of data changes and issues; metadata maintenance; management of NCS protocol and analysis changes; management of survey weights; and full data cleaning, editing, and coding support. Creation and management of data releases as limited use, public use, and internal analytic files also are included. The NCS will supply all the necessary hardware, software, and training required by the Study Centers and their associated locations to use the capabilities of the Information Management System. The Study Centers will provide the necessary space, electrical power, high-speed connection to the Internet, and operate the equipment provided. Information Management System maintenance will be provided by the NCS. The Study Centers, however, are expected to designate an Information Management System Coordinator who will act as a part-time point-of-contact for Information Management System matters.

The NCS Information Management System will protect the confidentiality of personal identifying information and all other Study data. All Study Centers and associated locations, the NCS Program Office, the Coordinating Center, and participating laboratories and repositories will be connected through a secure network that will transmit encrypted data to assure adequate privacy and protect against unauthorized access. The Information Management System will meet all HHS and other privacy and security directives. The Information Management System consists of a number of integrated systems that will be used to support all NCS operational activities. Users of the Information Management System will include the NCS Program Office, Coordinating Center, Study Centers, and other stakeholders. A Mission Assurance Plan is being developed for the Information Management System to ensure the integrity and confidentiality of the system and all the data and other information contained therein.

A number of technical measures will be taken to protect NCS data confidentiality, including encrypted data communications; special firewalls and other network protections; and special segregated, encrypted storage of Protected Health Information (PHI).

Some of the specific layers of security include the following:

- All NCS data communications from the field to the NCS Data Center or to laboratories, repositories, or other Study entities will be encrypted using Secure Socket Layer (SSL) encryption.
- The NCS Data Center will be protected by multiple firewalls acting in layers to block intrusion. The first layer will consist of the standard border routers that protect all Coordinating Center network resources. Inside that firewall layer, the NCS Data Center will be placed in its own network zone, protected with its own set of firewalls and routers.

- Inside this protected zone, the actual NCS data and application servers will be protected by a set of proxy servers designed to filter all traffic and ensure that only authorized users can get to NCS data. No traffic will reach the NCS data servers without first being passed through the proxy servers.
- At the application or Web server layer, operating system and user ID and password controls form another barrier to unauthorized access.
- PHI requires special protection. The Information Management System will employ two general strategies for providing enhanced protection for identifier data stored at the NCS Data Center. First, the Information Management System will encrypt identifier data before storing it in databases at the Data Center and only decrypt the data to service requests for information from specially authorized users. Second, the Information Management System will store the identifier data separately from the research data using separate data tables and separate databases. Only staff with explicitly granted access will be able to access identifiers, and an even more restricted role will be required to access identifiers along with associated research data.

8.2.8 Quality Control for Confidentiality

To protect the quality and confidentiality of the NCS data, as well as to achieve the goals of the Study, it is essential that a strong Quality Assurance and Quality Control (QA/QC) program be implemented so that data collected from many Study Centers can be combined into a comparable national data set. In a study of the breadth, complexity, and duration of the NCS, strong adherence to the Study protocol, Study procedures, and QA/QC program is very important. The QA/QC program begins with effective initial training, certification, and retraining of all NCS personnel at all Study Centers in the appropriate areas of the protocol and procedures, including confidentiality issues. Each Study Center will be responsible for ensuring that all NCS personnel attend and successfully complete all required training to be certified to collect data. All Study Centers also will keep the Coordinating Center informed when new personnel are hired and will arrange for the appropriate training and certification to be done. The QA/QC program includes periodic refresher training to introduce new procedures or sharpen data collection skills. Remedial training will be required for personnel who do not meet acceptable performance standards as identified by QA/QC measures and reports.

Another key component of QA/QC program will be field audits and observation of all recruitment–enrollment and data collection activities. QA/QC staff will accompany Study Center personnel as they do recruitment–enrollment and data collection visits at participants’ homes and clinic sites. They will observe adherence to NCS protocol and procedures and will initiate corrective action as needed. Examples of activities to be observed include building rapport with subjects of interviews, the recruitment and consent process, appropriate collection of biospecimens and environmental samples, appropriate collection of physical measures, appropriate processing of biospecimens, and appropriate shipping of biospecimens and environmental samples to the repositories or

laboratories. Field audits of labs and repositories will involve the sending and tracking of blank, standard, split, and spiked samples, as well as regular tracking of internal repository and laboratory QA/QC, such as equipment calibration and internal QA/QC audits.

Validation of data collection activities also will be performed, such as administering validation questionnaires by telephone for a sample of in-person interviews and replication of physical measurements. Monitoring a sample of all telephone contacts with participants will be performed, as well as verifying mailing procedures to be sure the correct materials are sent to the correct participants.

The Information Management System will serve as the central system for QA/QC activities. The Information Management System will perform many of the data QA/QC activities, including performing complex data edits and generating QA/QC reports on the data, activities, and findings. The Study Centers will be responsible for verification and correction of data as necessary, based on the findings of the Information Management System QA/QC procedures and reports.

A detailed Quality Assurance Plan is being developed for the NCS that will describe details of the QA/QC procedures to be performed at all the Study locations, including the Coordinating Center, Study Centers, site offices, repositories, and laboratories.

8.2.9 Compensation for Injuries

The general NCS policy on compensation for injuries is that the Study will not compensate for injuries except for immediate emergency situations. Medical expenses related to injuries will be covered by the participant's insurance company or by the participant if they are responsible for their own health-care costs. Some individual Study Centers may have their own policies on compensation for injuries. For that reason, compensation for injuries may vary between Study Centers depending on each one's individually determined policy. Each Study Center will need to determine whether the general NCS policy applies, or if it has its own policy on compensation for injuries. Either the general NCS policy or the specific policy at the Study Center will be specified in the consent instruments used at each center.

APPENDIX K.
REPORTS OF FINDINGS

REPORTS OF FINDINGS AND REFERRALS

1. Overview

Participants in the National Children's Study (NCS) will receive notification of the results of selected exams and tests that they participate in as part of the Study. The method and time frame for communicating the results to participants will depend on the medical findings and the time required for processing the results. In instances where the exam results are immediately available (e.g., blood pressure), the participant will receive the results at the end of the exam, in a Preliminary Report of Findings printed on a hard copy form.

Some reportable results will not be processed immediately but will be sent to participants eight to twelve weeks following the exam in a Final Report of Findings. The results that were reported on hard copy at the visit will be included in this report generated by the study management system.

In instances where exam results indicate further medical attention, participants will also receive a referral letter with information about the results and a recommendation regarding the time frame when they should contact their health care provider about these results. Referrals will be distributed during home or clinic visits for immediately available test results or via the mail and/or the internet for biospecimen results.

Study participants will receive an ultrasound at the first, second and third trimester visits. For each of the ultrasounds performed as part of the study, an image from the scan will be given to the participant at the end of the visit and a copy of the scan will be given to the participant's provider with the mother's permission. The process of reporting findings and referrals for ultrasounds is somewhat different from the measures mentioned above. The referral and report of findings procedures for ultrasounds are described in Section 5.

Most exam and test results in the NCS are done for research purposes and will not be reported to participants. However, some more common and familiar test results will be provided. The results that will be reported are outlined in Table 1.

National Children's Study: Report of Findings and Referrals

Table 1. Measures and Tests Reported by Visit

Measures and Tests by Study Visit						
Study Visit	P1	T1		T2	T3	B2
Participant Measured or Tested (M=mom; D=dad; C=child)	M	M	D	M	M	C
• Weight	P	P	P		P	P
• Standing height	P		P		P	
• Recumbent length						P
• Calculated body mass index	P		P			
• Blood pressure	P	P	P		P	
• Heart rate	P	P	P		P	
• Ultrasound image		P		P	P	
• Water – VOC	F	F				
• Measured hemoglobin		P	P		P	P
• Calculated hematocrit		F	F		F	F

P = Preliminary Report of Findings

F = Final Report of Findings

2. Preliminary Report of Findings

Participants will receive a Preliminary Report of Findings after completing a physical exam and phlebotomy, either at a home or clinic visit. The findings for those exam results immediately available (e.g., blood pressure and hemoglobin) will be written on a hard copy form. In addition to exam results, the Preliminary Report of Findings will include an interpretation of the results based on predetermined criteria. The interpretation will, in most cases, be different for adults and children.

The Visit Coordinator will be responsible both for giving the participant the Preliminary Report of Findings and verbally reviewing the results with the participant. The form will list an 800 number for participants to call should they have follow-up questions about the tests or results.

National Children’s Study: Report of Findings and Referrals

The tests and measures that will be reported in the Preliminary Report of Findings include blood pressure, heart rate, weight, height, body mass index, and hemoglobin. A brief description of the criteria and statements for these reported measures is outlined below.

2.1 Blood Pressure Report of Findings

Blood Pressure (adults): Systolic and diastolic blood pressure are categorized into specific ranges and assigned a statement indicating whether the results are within the normal range or in one of several ranges above the normal range. See Table 21 for Report of Findings statements for adults 18 years and above. The cells specify the blood pressure category (1-5) for the systolic and diastolic blood pressure combination. The category number defines the statement used for the report of findings. If the results are above the normal range, the participant will also receive a referral letter to give to their physician (See Section 4 for referral procedures).

Table 2. Statement by result category for blood pressure report of findings (adults 18⁺)

Category	Systolic	Diastolic	Report of Findings Statements: ¹ “Your blood pressure today is...”
1	<120	<80	...within the normal range.
2	120-139	80-89	...above normal and is in the pre-hypertensive range.
3	140-159	90-99	...high.
4	160-209	100-119	...very high.
5	>209	>119	...severely high.

Blood Pressure (children): Children’s normal blood pressures vary by age, weight, and height. The tables for children’s blood pressures are taken from the National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents.² The tables provide matrices of combinations of systolic and diastolic blood pressure results by percentile of height for males and females ages 6 through 17 years. The matrix cells specify the blood pressure category (1-4) for the systolic and diastolic blood pressure combination. The category number defines the statement

¹ Based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003

² National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents. Update on the 1987 Task Force Report on High Blood Pressure in Children and Adolescents: A Working Group Report from the National High Blood Pressure Education Program. *Pediatrics*. 1996; 11:649-658

National Children’s Study: Report of Findings and Referrals

used for the Report of Findings. See Table 3. If the results are above the normal range, the participant will also receive a referral letter to give to their physician (See Section 4 for referral procedures).

Table 3. Statements by result category for blood pressure report of findings (children)

Category	Report of findings statement ² “You child’s blood pressure today ...”
1	...is within the normal range.
2	...is normal but at the high end of normal range.
3	...high.
4	... very high.

2.2 Weight, Height and Body Mass Index Report of Findings

Children less than 3 years of age will be given results for weight and recumbent length. Body mass index will not be calculated for this age group. Although measurements are recorded in metric units for data collection purposes, the results for the Report of Findings will be converted to English units.

Weight and height measurements along with the calculated body mass index (BMI) from each visit will be given to participants ages 20 years and above at the end of the visit. These measurements along with a brief statement about the significance of the results will be printed on the hard copy report. The technician will check the appropriate statement based on the body mass index percentile. The statements for this age group associated with each body mass index category are displayed in Table 4.

Table 4. Statements by BMI categories for report of findings (≥20 years).

Body Mass Index	Report of Findings Statement for weight status based on BMI: “Body mass index (BMI), a number calculated from a person’s weight and height, is a measure of body fatness. Although it does not measure fat directly, research has shown that BMI is related to direct measures of body fat. Your weight status category can be determined from the table below.”
	Below 18.5
18.5 – 24.9	Normal
25.0-29.9	Overweight
30 and above	Obese

National Children's Study: Report of Findings and Referrals

Sample Preliminary Reports of Findings Forms for adults and children are displayed in Exhibits 1a, 1b, and 1c.

3. Final Report of Findings

The Final Report of Findings will be generated electronically and will include all reportable exam results, regardless of referral level or the time it takes to process the results. The information provided in the Preliminary Report of Findings at the end of the exam visit will be repeated in the Final Report for the convenience of the participant. This includes blood pressure, heart rate, weight, height, body mass index and hemoglobin. Hematocrit and water VOC will be included in the final report. An interpretation of the results will be included based on predetermined criteria.

The Visit Coordinator is responsible for ensuring that the Final Report of Findings is mailed to the respondent within eight to twelve weeks of the examinations. The report will include an 800 number that the participant can call if there are follow-up questions. An example of a Final Report of Findings is located in Exhibits 2a and 2b.

4. Referrals

Although the purpose of the NCS examinations is data collection, not diagnosis or treatment, physical exams and analysis of biospecimens and environmental samples may yield clinically significant findings that warrant further medical attention. In these situations, participants will receive same-visit notification of major medical findings for those exam results that are immediately available (e.g., blood pressure) and a referral letter will be issued to participants to give to their health care provider. Exam results are classified into three referral levels. Referral letters will be given for results that fall in Referral Levels 1 and 2.

4.1 Referral Levels

The Visit Coordinator makes decisions about generating a referral letter based on a system rated by three levels of urgency. This system was developed for use in the National Health and Nutrition Examination Survey and has been modified for use in the NCS. The three levels of referrals apply across all examinations and the action is defined for each level of referral based on predefined edit limits or

National Children's Study: Report of Findings and Referrals

ranges. These edit limits are set by the component specialist, followed by review and approval by the NCS Program Office. The referral levels are defined below.

4.1.1 Level 1 Referrals

These referrals are generated when there are major medical findings that warrant **immediate attention by a health care provider**, such as a dangerously high blood pressure, and life threatening emergencies. Participants determined to need a Level 1 referral will be strongly advised to get immediate attention by a health care provider. If the participant does not have a primary health care provider, the name and contact information for a doctor from the Study Center's health care provider referral list will be given to the participant.

4.1.2 Level 2 Referrals

Major medical findings that require **attention by a health care provider in the next two weeks** because they are expected to cause adverse effects over time require a Level 2 Referral. The participant may continue the remainder of the exam but will be given a referral letter indicating that a follow up clinical visit with their primary care provider is recommended. A high, but not dangerously high blood pressure is an example of a level 2 referral.

4.1.3 Level 3 Referrals

Level 3 referrals consist of either no out-of-range medical findings or minor medical findings that an examinee already knows about, is under care for, or **does not require prompt attention by a medical provider**. Level 3 findings do not necessarily generate referrals. Participants receive a report of the findings from many of the examination components at the end of the visit or in several weeks following the exam.

4.2 Timing of Referrals

Some referrals can be generated at the end of an exam if the results are immediately available while other referrals will be delayed until the results of the exam or test are obtainable, perhaps several weeks later.

National Children's Study: Report of Findings and Referrals

4.2.1 Immediate referrals

The only exam result available at the end of the exam to establish the need for a referral is blood pressure. (Ultrasound exams have a slightly different process. See Section 5 for referral procedures for ultrasound exams.) In the case of Level 1 findings, the Visit Coordinator will end the exam immediately and provide the respondent with a standard referral letter (Exhibit 3a) in addition to a referral form with specific information regarding the results Exhibit 3b (for adults) and Exhibit 3c (for children). The Visit Coordinator will provide verbal instructions to see their health care provider immediately. If the examiner believes the participant is in imminent danger, he or she will also call 911 for medical assistance. In the case of Level 2 findings, the Visit Coordinator will be responsible for providing the respondent with a referral letter and specific form and instructions to see their primary care provider within 2 weeks. If the respondent does not have a primary care provider, the name and contact information for a doctor from the Study Center's health care provider referral list will be provided. This information will be written on the referral form.

4.2.2 Later referrals

Referrals will also be issued for laboratory results that are processed after the exam (i.e., hematocrit) indicating Level 1 or Level 2 findings. The Visit Coordinator will be responsible for calling participants and notifying them of Level 1 findings within two days of the test results being finalized. The Visit Coordinator will also be responsible for mailing and/or emailing a standard referral letter (Exhibit 3a) and a specific referral form for Level 1 and Level 2 findings (Exhibit 3d) within 2 days of the test results being finalized. This will inform the participant of the need to see a physician about the results and include an 800 number that they may call to contact the Visit Coordinator with further questions. Where the results pertain to environmental samples, the participant will also receive a pamphlet on the potential risks of the environmental exposure in addition to a referral information page with space provided to insert free text (Exhibit 3e). The Referral Form will list an 800 number where the doctor can reach the Visit Coordinator should they have any questions about the study. A Referral Information Form will also be included with each Referral.

4.2 Blood Pressure Referral Levels (Adults)

Table 5 provides an overview of blood pressure referrals by the level of referral, category of blood pressure, and action required for adults (18 years and above). See Table 2 for the blood pressure values that determine the categories.

National Children’s Study: Report of Findings and Referrals

Table 5. Blood pressure referral levels, categories, and action required (≥18 years)

Referral level	Category (From Table 2)	Action
Level 1	Category 5	Indicates major medical findings that warrant immediate attention by a health care provider.
Level 2	Categories 3 & 4	Indicates major medical findings that warrant attention by a health care provider within the next 2 weeks. These findings are expected to cause adverse effects within this time period and they have previously been undiagnosed, unattended, nonmanifested, or not communicated to the participant by his or her personal health care provider.
Level 2	Category 2	Indicates prehypertensive blood pressure, minor medical findings that a participant already knows about and is under care for, or findings that do not require prompt attention by a medical provider within a month.
Level 3	Category 1	Indicates no abnormal medical findings.

4.3 Blood Pressure Referral Levels (6 through 17 years)

Table 6 provides an overview of blood pressure referrals by the level of referral, category of blood pressure, and action required for children and adolescents (6 through 17 years). See Appendix X for the set of tables of the blood pressure values that determine the categories for this age group.

Table 6. Blood pressure referral levels, categories, and action required (6 through 17 years)

Referral level	Category (From Table 1)	Action
Level 1	Category 4	Indicates major medical findings that warrant immediate attention by a health care provider.
Level 2	Category 3	Indicates major medical findings that warrant attention by a health care provider within the next 2 weeks. These findings are expected to cause adverse effects within this time period and they have previously been undiagnosed, unattended, nonmanifested, or not communicated to the participant by his or her personal health care provider.
Level 3	Categories 1&2	Indicates no abnormal medical findings, minor medical findings that an examinee already knows about, and is under care for; or findings that do not require prompt attention by a medical provider.

National Children's Study: Report of Findings and Referrals

5. Ultrasound Report of Findings and Referrals

Participants in the National Children's Study (NCS) will receive an ultrasound at the first, second and third trimester visits. If a clinical ultrasound was performed for gestational age in the first trimester, the results of this scan will be requested for study purposes. If no clinical ultrasound was performed, a scan will be scheduled as part of the study data collection. Details of the timing of scans, measures taken, and procedures for data collection will be outlined in the ultrasound procedure manual. The purpose of the ultrasound scans in the NCS is to collect an estimate of gestational age and measures of growth. No attempt will be made to detect or diagnose medical conditions. These scans are intended for research purposes only and do not take the place of a clinical scan.

An image from the ultrasound scan will be given to the participant at the end of the visit. The process for providing this study information to the participant and provider is described below. This process is detailed for two scenarios. The first is for routine scans and the second is for a scenario where the ultrasonographer notices an abnormality.

Participants will be provided with an image from their ultrasound scan along with an Ultrasound Report of Findings Form with a statement that indicates the scan is part of a research study and is not intended to take the place of a clinical scan. The information page includes the name of the local study coordinator and a phone number to the local study center if there are any questions about the scan or the image. See Exhibit 4a.

5.1 No Abnormality Noted by Ultrasonographer

The sonographer will complete the ultrasound scan, record the required measurements on a hard copy form, and save the scan to a CD. In most circumstances, the scan will not be read or reviewed at that time. The CD will be sent to the Coordinating Center and will be used at a later date for quality control review. The sonographer will print an image from the scan and give it to the participant along with an Report of Findings Form with a statement that indicates the scan is part of a research study and is not intended to take the place of a clinical scan. The form includes the name of the local study coordinator and a phone number to the local study center if there are any questions about the scan or the image. See Exhibit 4a.

In addition to giving the image to the participant, a copy of the scan and an Ultrasound Information Letter (for providers) will be sent to the participant's provider. The participant will be asked to

National Children's Study: Report of Findings and Referrals

sign a medical release form to provide permission to give this information to the provider. See Exhibit 4b for the release form and Exhibit 4c for the letter to the provider. If the participant refuses to sign the release form, no information will be sent to the provider.

5.2 Abnormality Noted by Ultrasonographer

The ultrasound scans for the NCS are not intended for detecting abnormalities and the ultrasonographer will not be doing that as part of the study scan. However, if an ultrasonographer notices or suspects an abnormality on the scan, this scan will be reviewed by a physician at the Study Center. The Study Centers will make arrangements for this scenario and will have physicians who will be available to review the scan. This review may not be possible while the participant is in the clinic but should take place within 24-48 hours of the scan.

If the reviewing physician does not confirm the abnormality, the participant will be given an image and will go through the usual steps outlined above for women with no abnormality detected. If the reviewing physician confirms the presence of an abnormality on the scan, the participant will not be given an image from the scan. She will be asked to sign a medical release form to provide permission to send a copy of the scan and an Ultrasound Referral Letter to the participant's provider. See Exhibit 4b. The Referral Letter will include a statement that indicates the scan is part of a research study and is not intended to take the place of a clinical scan. The name of the local study coordinator and a phone number to the local study center will be included if there are any questions about the scan or abnormality. In addition to the standard letter, an Ultrasound Referral Page will be provided to allow the physician to describe the abnormality noted and write additional comments to the provider. See Exhibit 4e.

If the participant refuses to sign the medical release form to release the information to her provider, she will be given the scan and Ultrasound Referral Letter and Referral Page. She can choose how she will use this information.

If the participant does not have a provider, she will be given a list of names of physicians who have agreed to accept referrals from participants who do not have providers. Each Study Center must maintain a current list of physicians who have agreed to provide this service. The participant will be given the scan, referral letter, and a list of providers from which to choose. Copies of referral forms, information pages and medical release forms will be kept for study purposes.

Exhibit 4f displays a flow chart of the process the Ultrasound report of findings and referrals.

National Children's Study: Report of Findings and Referrals

Exhibit 1a: Sample Preliminary Report of Findings (18 years and above)

**National Children's Study
PRELIMINARY REPORT OF FINDINGS
(18 years and above)**



Date of Examination: ___ / ___ /20 ___

Participant Name: _____

BODY MEASUREMENTS

Height: ___ feet ___ inches

Weight: ___ pounds

Body Mass Index (BMI): ___

Body mass index (BMI), a number calculated from a person's weight and height, is a measure of body fatness. Although it does not measure fat directly, research has shown that BMI is related to direct measures of body fat. Your weight status category based on your body mass index can be determined from the table below:

Body Mass Index	Weight Status
Below 18.5 - 24.9	Underweight
18.5-24.9	Normal
25.0-29.9	Overweight
30 & above	Obese

BLOOD PRESSURE AND HEART RATE

Systolic Blood Pressure: ___ mmHg

Diastolic Blood Pressure: ___ mmHg

Resting Heart Rate: ___ beats per minute

Your blood pressure today is*
 ___ within the normal range
 ___ above normal and is in the pre-hypertensive range
 ___ high
 ___ very high
 ___ severely high

*Categories are based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.

† The purpose of the study examinations is data collection, not diagnosis or treatment. The study examinations are not intended to substitute for a clinical exam. Adults should see their doctor once a year for an annual exam.

Should you or your physician have any questions about this report, you may contact the <Local Study Center>. The phone number is <Study Center 1-800 Phone Number>.

Version 1
12-07-07

National Children’s Study: Report of Findings and Referrals
 Exhibit 1b. Sample Preliminary Report of Findings (6 through 17 years)

National Children’s Study



**PRELIMINARY REPORT OF FINDINGS
 (6 through 17 years)**

Date of Examination: ___ / ___ /20 ___

Participant Name: _____

BODY MEASUREMENTS

Height: ___ feet ___ inches

Weight: ___ pounds

Body Mass Index (BMI): ___ .__

Body mass index (BMI), a number calculated from a person’s weight and height, is a measure of body fatness. Although it does not measure fat directly, research has shown that BMI is related to direct measures of body fat. Your weight status category based on your body mass index can be determined from the table below:

Body Mass Index	Weight Status
Below 18.5 - 24.9	Underweight
18.5-24.9	Normal
25.0-29.9	Overweight
30 & above	Obese

BLOOD PRESSURE AND HEART RATE

Systolic Blood Pressure: ___ mmHg

Diastolic Blood Pressure: ___ mmHg

Resting Heart Rate: ___ beats per minute

Your child’s blood pressure today is*
 ___ within the normal range*
 ___ normal but in the high end of normal *
 ___ high*
 ___ very high*

** Categories are based on the National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents. Update on the 1987 Task Force Report on High Blood Pressure in Children and Adolescents: A Working Group Report from the National High Blood Pressure Education Program. Pediatrics. 1996; 11:649-658. (These blood pressure categories are relevant for participants 6 through 17 years.)*

† The purpose of the study examinations is data collection, not diagnosis or treatment. The study examinations are not intended to substitute for a clinical exam. Adults should see their doctor once a year for an annual exam. Should you or your physician have any questions about this report, you may contact the <Local Study Center>. The phone number is <Study Center 1-800 Phone Number>.

Version 1. Date: 12-07-08

Exhibit 1c. Sample Preliminary Report of Findings (Birth to <6 years)

National Children's Study

**PRELIMINARY REPORT OF FINDINGS
(Birth to <6 yrs)**



Date of Examination: ___ / ___ /20 ___

Participant Name: _____

BODY MEASUREMENTS

Recumbent length: ___ . ___ cm. (Birth up to 36 months)

Height: ___ feet ___ inches (36 months and above)

Weight: ___ pounds

BLOOD PRESSURE AND HEART RATE (12 months and above)

Systolic Blood Pressure: ___ mmHg

Diastolic Blood Pressure: ___ mmHg

Resting Heart Rate: ___ beats per minute

† The purpose of the study examinations is data collection, not diagnosis or treatment. The study examinations are not intended to substitute for a clinical exam. Adults should see their doctor once a year for an annual exam.

Should you or your physician have any questions about this report, you may contact the <Local Study Center>. The phone number is <Study Center 1-800 Phone Number>.

National Children's Study: Report of Findings and Referrals

Exhibit 2a. Sample Final Report of Findings (Page 1)

National Children's Study**FINAL REPORT OF FINDINGS**

Date of Examination: <Exam Date>

Participant Name: <Participant First and Last Name>

(A copy of your blood pressure, heart rate, weight and height results was given to you at the end of your visit. For your convenience, those results are listed again on this report)

LABORATORY

Measured Hemoglobin: <Insert Measured Hemoglobin>

Measured Hematocrit <Insert Measured Hematocrit>

Normal Values for Hemoglobin:

Adult Males: 13.0 – 17.0 g/dL

Adult Females: 12.0 – 15.0 g/Dl

Infants, after neonatal period: 11.0 – 14.0 g/dL

Children, 2 years to teenage: Gradual increase to adult normals

BODY MEASURES

Height: <Insert Height>

Weight: <Insert Weight>

Body Mass Index (BMI) <Insert BMI>

Body mass index (BMI), a number calculated from a person's weight and height, is a measure of body fatness. Although it does not measure fat directly, research has shown that BMI is related to direct measures of body fat. Your weight status category can be determined from the table below.

Body Mass Index	Weight Status
Below 18.5 - 24.9	Underweight
18.5-24.9	Normal
25.0-29.9	Overweight
30 & above	Obese

National Children's Study: Report of Findings and Referrals

Exhibit 2b. Sample Final Report of Findings (Page 2)

Final Report of Findings

Page 2

Blood Pressure and Heart Rate

Your Measurements

Systolic Blood Pressure:	<Insert Systolic BP>
Diastolic Blood Pressure:	<Insert Diastolic BP>
Resting Pulse Rate:	<Insert Pulse Rate>

Your blood pressure result is* ___ within the normal range
 ___ above normal and is in the pre-hypertensive range
 ___ high
 ___ very high
 ___ severely high

Your blood pressure today is based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.

Environmental Samples

Water VOCs <Insert Water VOC>

{insert statement to explain the significance of the results}

† The purpose of the study examinations is data collection, not diagnosis or treatment. The study examinations are not intended to substitute for a clinical exam. Adults should see their doctor once a year for an annual exam.

Should you or your physician have any questions about this report, you may contact the <Local Study Center>. The phone number is <Study Center 1-800 Phone Number>.

Version 1. Date: 12-07-07

National Children's Study: Report of Findings and Referrals

Exhibit 3a. Sample Standard Referral Letter for Physical Measures and Laboratory

National Children's Study

REFERRAL LETTER



Participant's Name: _____

Physician's Name: _____

Physician's Address: _____

Date: _____ / _____ / 20 ____

Dear Doctor:

<Respondent Name> has voluntarily participated in the National Children's Study conducted by <Local Study Center> and the National Institute of Child Health and Human Development. The objectives of the National Children's Study are to obtain information on the health and development of U.S. children, including the health of their parents. As a result of the testing that was done, it was noted that on <Exam Date>, a finding was revealed that was outside the survey's medically acceptable range. This finding is described on the attached Referral Information Form page.

This examination is intended to collect health measures for research. It is not a complete physical exam. No attempt has been made to diagnose or treat medical conditions of the participants. The findings disclosed to you are done so with the participant's permission.

Should you have any questions, you may contact me at <Local Study Center>. The phone number is <Study Center 1-800 Phone Number>.

Cordially,

<Study Center Coordinator>
<Insert Local Study Center Name>

Version 1. Date 12-07-07

National Children's Study: Report of Findings and Referrals

Exhibit 3b: Referral Information Page – Blood Pressure (≥ 18 years)

National Children's Study

**REFERRAL INFORMATION PAGE
BLOOD PRESSURE (≥ 18 YEARS)**



Participant's Name: _____

Blood pressure was measured in a seated position after resting quietly for several minutes. Three measurements were taken, the first measure was discarded and the average systolic and diastolic blood pressures were calculated from the remaining readings. The results are recorded below.

Systolic Blood Pressure: _____ mm Hg
Diastolic Blood Pressure: _____ mm Hg
Heart Rate: _____ beats per minute

The participant's blood pressure is: within the normal range*
 above normal and in the prehypertensive range*
 high*
 very high*

It is highly recommended that your child see their physician:
 immediately
 within 2 weeks

Additional comments:

* Categories are based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003

National Children's Study: Report of Findings and Referrals

Exhibit 3c. Referral Information Page - Blood Pressure (child)

National Children's Study

REFERRAL INFORMATION PAGE
BLOOD PRESSURE (child)



Participant's Name: _____

Blood pressure was measured in a seated position after resting quietly for several minutes. Three measurements were taken, the first measure was discarded and the average systolic and diastolic blood pressures were calculated from the remaining readings. The results are recorded below.

Systolic Blood Pressure: _____ mm Hg
Diastolic Blood Pressure: _____ mm Hg
Heart Rate: _____ beats per minute

The participant's blood pressure is: within the normal range*
 normal but in the high end of normal *
 high*
 very high*

It is highly recommended that your child see their physician:
 immediately
 within 2 weeks

Additional comments:

* Categories are based on the National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents. Update on the 1987 Task Force Report on High Blood Pressure in Children and Adolescents: A Working Group Report from the National High Blood Pressure Education Program. *Pediatrics*. 1996; 11:649-658.

National Children's Study: Report of Findings and Referrals

Exhibit 3d. Referral Information Page for Laboratory

National Children's Study

**REFERRAL INFORMATION PAGE
LABORATORY**



Participant's Name: _____

Measured Hemoglobin: _____ g/dL

Calculated Hematocrit: _____ g/dL

Normal Values for Hemoglobin

Adult Males: 13.0 – 17.0 g/dL

Adult Females: 12.0 – 15.0 g/dL

Infants, after neonatal period: 11.0 – 14.0 g/dL

Children, 2 years to teenage: Gradual increase to adult normals

Action Limits for Hemoglobin*:

	Low	High
Male & female (<6years)	<6.5 g/dl	>14.5 g/dL
Female (>6years)	<6.5 g/dL	>16.0 g/dL
Male (>6.5 g/dL)	<6.5 g/dL	>18.0 g/dL

It is recommended that <you/your child> see their physician within 2 weeks.

Additional comments:

* Categories are based on data from the National Health and Nutrition Examination Survey (NHNAES).

National Children's Study: Report of Findings and Referrals

Exhibit 3e. Referral Information Page - Other

National Children's Study

**REFERRAL INFORMATION PAGE:
OTHER**



Participant's Name: _____

Date: ____ / ____ / 20 ____

Comments:

Version 1. Date: 12-07-07

National Children’s Study: Report of Findings and Referrals

Exhibit 4a. Report of Findings –Ultrasound (Participants)

National Children’s Study

**REPORT OF FINDINGS - Ultrasound
(Participants)**



Date of Examination: ___ / ___ / 20 ___

Participant Name: _____

ULTRASOUND IMAGE

As part of your participation in the National Children’s Study conducted by <Local Study Center> and the National Institute of Child Health and Human Development **an ultrasound was performed today for research purposes only to obtain specific measurements of your baby. No attempt has been made to diagnose medical conditions and this scan is not considered a substitute for a clinical ultrasound.**

We have printed an image from your scan for you to take with you today. Should you have any questions, you may contact the Study Coordinator at <Local Study Center>. The phone number is <Study Center 1-800 Phone Number>.

Version 1. Date:12-07-07

National Children’s Study: Report of Findings and Referrals

Exhibit 4b. Authorization Form to send Ultrasound Scan to Provider

National Children’s Study



**AUTHORIZATION FORM
TO SEND ULTRASOUND SCAN TO DOCTOR**

As part of your participation in the National Children’s Study conducted by <Local Study Center> and the National Institute of Child Health and Human Development **an ultrasound was performed today for research purposes to obtain specific measurements of your baby. No attempt has been made to diagnose medical conditions and this scan is not considered a substitute for an ultrasound your doctor may do.**

If you are seeing a doctor for this pregnancy, s/he may be interested in seeing a copy of your ultrasound scan. With your permission, we will send a copy of the scan along with a letter to him/her. If you agree and give us the name and address of your doctor, we will send him/her a copy of your ultrasound scan along with a letter about the study.

Permission to send ultrasound scan to your doctor:

I agree that you may send a copy of my ultrasound scan to my doctor named below.

Date: ___ / ___ /20 ___

Name of participant

Signature of participant

Doctor’s Contact Information:

Name: _____

Address: _____

Phone: _____

I do not have a provider

I do not agree

Version 1. Date 12-07-07

National Children's Study: Report of Findings and Referrals

Exhibit 4c: Sample Ultrasound Information Letter (for Providers)

National Children's Study

**ULTRASOUND INFORMATION LETTER
(For Providers)**



Date of Examination: ___ / ___ /20 ___

Participant Name: _____

Physician's Name: _____

Address: _____

Phone: _____

Dear Doctor:

<Respondent Name> has voluntarily participated in the National Children's Study conducted by <Local Study Center> and the National Institute of Child Health and Human Development. The objectives of the National Children's Study are to obtain information on the health and development of U.S. children, including the health of their parents. **As part of the data collection for this study, an ultrasound was performed today for research purposes only to obtain specific measurements. No attempt has been made to diagnose medical conditions and this scan is not considered a substitute for a clinical ultrasound.** We are sending you a copy of the scan taken for this study. We have obtained a medical release form from the participant to send this information to you.

Should you have any questions, you may contact me at <Local Study Center>. The phone number is <Study Center 1-800 Phone Number>.

Cordially,

Study Center Coordinator

<Insert Local Study Center Name>

Version 1. Date 12-07-07

National Children's Study: Report of Findings and Referrals

Exhibit 4d: Referral Letter - Ultrasound

**National Children's Study
ULTRASOUND REFERRAL LETTER
(For Providers)**



Date of Examination: ___ / ___ / 20 ___

Participant Name: _____

Physician's Name: _____

Address: _____

Phone: _____

Dear Doctor:

<Respondent Name> has voluntarily participated in the National Children's Study conducted by <Local Study Center> and the National Institute of Child Health and Human Development. The objectives of the National Children's Study are to obtain information on the health and development of U.S. children, including the health of their parents. **As part of the data collection for this study, an ultrasound was performed today for research purposes only to obtain specific measurements. No attempt has been made to diagnose medical conditions and this scan is not considered a substitute for a clinical ultrasound.** We are sending you a copy of the scan taken for this study. As a result of the testing that was done, a finding was revealed that may indicate the presence of an abnormality. This finding is described on the attached Referral Information Form page. We have obtained a medical release form from the participant to send this information to you.

Should you have any questions, you may contact me at <Local Study Center>. The phone number is <Study Center 1-800 Phone Number>.

Cordially,

Study Center Coordinator

<Insert Local Study Center Name>

Version 1. 12-07-07

National Children's Study: Report of Findings and Referrals

Exhibit 4e: Referral Information Page - Ultrasound

National Children's Study

**REFERRAL INFORMATION PAGE
ULTRASOUND**



(Included with Ultrasound Referral Letter)

Participant's Name: _____

Date of Examination: ___ / ___ /20 ___

Ultrasound Images:

This ultrasound was intended to collect information for research purposes and is not and is not a substitute for a clinical ultrasound. No attempt has been made to diagnose medical conditions.

Additional comments:

<Name of physician writing the referral>

<Insert Local Study Center Name>

Version 1. Date 12-07-07

NCS Ultrasound Report of Findings Process

01-03-08

Most women will follow this path.

