

NCS Policy and Practice on the Return of Research Results (excerpt)

Relevant consent language:

What about genetic information?

- If you agree, we would like to get information about your genes and those of your child from the blood, saliva, and other samples you give us. We will also ask you questions about your family medical history.
- Genetic information is collected to learn how genes affect our children's health and how our physical environment and experiences affect the way our genes work.
- Some people worry about how their genetic information will be used. We will protect your genetic information the same way we protect all your other information.
- Some people are sensitive about genetic information for cultural or religious reasons. If you don't want us to conduct genetic tests, let us know. You can still be in the Study.
- The Study won't do the genetic testing right away. We will do the testing of your stored samples in the future using state-of-the-art technologies.
- To answer the Study's research questions, we may also combine the genetic information that we receive from you with information from other research studies and information sources.
- We will not routinely share the results of genetic tests with you.

How can I find out about the results of the Study?

- We will share with you what we learn from the Study as a whole. We will keep in touch through newsletters, on our website, and in other ways.
- We will share with you some of the information we learn about you and your child when it becomes available.
- If we know the results from tests we do during a visit, we will share them with you during the visit. For example, we will tell you information about your height, weight and blood pressure.
- We plan to test most of your biological samples and samples from your home in the future.
 - ▶ At this time, we do not yet know exactly when these tests will be done, which tests will be done, and when information from the tests will become available.
 - ▶ Most of the tests that we will do on the samples we collect are to add to our knowledge of how the physical, social, and family environments, genes, and other factors affect health and disease and will not provide information about your personal health status.
 - ▶ A committee of doctors, scientists, and community members (the iSMOC) will advise the Study on which tests may provide information about participants' health.

- ▶ When test results related to your health and your child's health become available, we may contact you to see if you are interested in learning about these results.

Relevant language from the Vanguard Protocol (March 5, 2010)

1.1 Reporting Findings to Individuals

Revealing clinically relevant and actionable findings to individual participants is seen as an ethical obligation. Known environmental and health risks will be clearly communicated to respondents and participants throughout the course of the Study, planned tests will be communicated to them clearly, and means to limit exposure to known environmental and health risks will be conveyed to them at each visit. The NCS recognizes that lags and delays in receipt of test results may encourage participants to believe that test results failed to indicate health concerns and even discourage them from seeking regular healthcare.

The process of determining which, how, and when findings will be reported to affected individual participants and, in aggregate, to communities, will be made by the Independent Study Monitoring Committee (iSMOC). The iSMOC is charged with identifying, on an ongoing basis, those Study findings which are clinically relevant and actionable and advising the Principal Investigator and Study Team as to how such findings can be sensitively and effectively communicated to participants. For instance, the iSMOC will make recommendations as to how to: (1) ask participants whether or not they would like to receive particular Study results; and (2) how to explain to participants the consequences of learning such results. 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 results, basic information about the sources and risks, and guidance on where to find more information.

Participants will be informed of this approach through the informed consent process. The NCS approach to informed consent consenting approach uses Visit Information Sheets (VIS) to describe the specific research procedures to be conducted at a given visit or phone call and to obtain verbal consent from participants for the conduct of specific research procedures at each Study visit. The VIS also inform participants about which results the Study will and will not be able to share and, for those results that will be shared, a timeframe when participants may expect to receive them. For example, at the first trimester visit (T1) visit, the VIS tells the respondent that the NCS will report her height, weight, BMI, and blood pressure during the visit. The Study also tells the respondents which test results will not be given to them (for example, results of environmental analyses.) Consequently, the VIS allows all NCS participants to continue to make voluntary and informed decisions about taking part in specific NCS data collection activities throughout their participation in the NCS Vanguard Study.

1.1.1 Reporting of Results from Analyses of Biological and Environmental Samples and Genetic Analyses

Because of the nature of the NCS Pilot Study (which is designed to inform the Main Study in part by assessing the feasibility and effectiveness of Study data collection activities) we cannot be certain at what time during the duration of the Pilot Study biospecimens and environmental samples will be analyzed—if at all. Therefore we may not be able to return results that would be

clinically meaningful and actionable, as this would require return of results in a time frame what would not allow for timely medical or follow-up (if required). 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 10.5. 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.

At this time, the NCS Vanguard Study does not have a definitive list of the genetic analyses that will be conducted or the timing of these analyses. As the Study moves forward and the analytic plan is expanded, the NCS is committed to sharing information that is clinically relevant and actionable with participants in a timely manner. The iSMOC and Sample Oversight Group have the appropriate expertise to provide guidance to the Principal Investigator as to when and how findings should be shared with participants.

1.2 Reporting Aggregate Findings to Participants and Communities

NCS staff members are also committed to informing participants and communities of aggregate data, which will be done on a periodic basis as findings become available. The NCS was designed to yield nationally representative estimates, but not locally or regionally representative estimates. Nonetheless, because environmental findings may relate to local problems that could affect property values or other issues, potential risks exist in revealing aggregate information found by the NCS to individuals (participants and non-participants) and to the entire community. Therefore, revealing information to communities must be done responsibly and with sufficient preparation.

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 report some of the aggregate findings of interest to the local community.

The various NCS committees, including the iSMOC, the Sample Oversight Committee, and the Ethics Subcommittee of the Federal NCS Advisory Committee, and the Human Subjects/IRB Working Team will assist the Study directors in making decisions about sharing aggregate, national findings to communities. The iSMOC 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 national findings