

Revealing Findings: NCSAC Discussion and Recommendations (September 2005-January 2006)

Excerpt: NCSAC Ethics Subcommittee September 7, 2005

Background: Informing Participants, Families, and Communities of Information Learned

Dr. Fleischman outlined the background on informing Study participants, families, and communities of information learned. He explained that the Study Plan, which was issued on November 16, 2004, addresses the Study's intention to reveal findings and inform participants and their families. The Study Plan was presented and discussed during the NCSAC meeting on April 27 and 28, 2005. Dr. Fleischman read the paragraph verbatim:

The NCS is committed to revealing relevant and important information to participants and their families in order to inform participants of individually relevant findings and to protect the health and well-being of the children who are participants in the Study. Periodically, the NCS will provide individual-level data to participants' families concerning information on environmental exposures, physical and psychological examination findings, and routine laboratory test results. Some data obtained through the NCS will be of uncertain relevance to the health or well-being of individual participants. Such data will not be routinely reported to participants. Further guidelines regarding this topic will be developed as part of the final Study protocol.

Ms. Dubler and Dr. Genel agreed that the key word in this statement is "relevant" and that the key phrase is "protect the health and well-being of children."

There is an NIH policy concerning informing research subjects that came into existence in 1999. It states:

Occasionally NIH informed consent documents contain IRB-approved language which states that certain information will not be provided to research subjects. However, the Federal Privacy Act applies to the records of research conducted at the NIH when such records are retrievable by an individual identifier. This means that any language in a consent form that waives an individual's right to obtain access to his or her records is inconsistent with the Privacy Act.

Dr. Fleischman paraphrased other aspects of the NIH policy and said that, although the Study can inform subjects of the Study's intent to not tell them information, if they seek it, and the information is identified with their individual identifier, the Study has a legal obligation under the Federal Privacy Act to give it to them.

Ms. Dubler commented that under such circumstances, all subjects sign consent documents, but "savvy" individuals will know how to get their information anyway. Dr.

Genel noted that studies can agree to provide participants with data but may or may not necessarily provide an interpretation of the data. The Privacy Act stipulates only the legal obligation to provide the data. The data may be of uncertain value or validity, and if the data are not valid, then they may not be relevant. Dr. Fleischman noted that although the Privacy Act does not address issues of data interpretation, there are moral obligations to interpret an individual's data when relevant to the health and well-being of that individual. Legal and moral "gray areas" may arise when the data are of uncertain validity and uncertain relevance.

Dr. Fleischman said that the Study will have two internal mechanisms for monitoring the Study's data collection processes. A Data and Safety Monitoring Board (DSMB), which reports to the Study Director and the Director, NICHD, will review data provided by the Study's Coordinating Center and will provide a methodology to assess the validity of the science. The NCSAC Ethics Subcommittee will be available for consultation, should there be questions about whether and how to inform participants of aggregate and individual data. Dr. Fleischman clarified that the DSMB's roles and responsibilities have been clearly outlined and focus on the science of the data and information collected. If there are concerns about the data, the Study Director or the Director, NICHD, can query the NCSAC Ethics Subcommittee, which can report back to the NCSAC. The NCSAC can advise the Study on specific issues. Although the DSMB and NCSAC Ethics Subcommittee do not meet or communicate directly, they could be invited to do so at the behest of the Study Director or the Director, NICHD. Dr. Fleischman noted that details of how the various Study entities such as the Steering Committee, the ICC, and Advisory Committee will specifically interact have not been worked out. The NCSAC may be asked to give advice on how to best coordinate Study entities.

Dr. Fleischman concluded with three additional comments about the data and information collected for the Study:

- There is a distinction between clinical tests and observations, and research tests and observations. The intent of clinical research is different than the intent of clinical medicine; the settings may be different (for example, homes, schools, or childcare centers); and the utility of the information is different.
- Research tests and observations may or may not have clinical relevance, and research is sometimes conducted to establish the validity, reliability, and reproducibility of a test (for example, new methods to collect environmental samples, new neurodevelopmental measures of children, or new blood or urine tests for chemical exposures).
- Research tests and observations may influence individuals who are not participants in the research, such as members within a family, household, neighborhood, or community. A clinical observation occasionally has relevance to others, particularly within the realm of infectious disease.

Questions Under Consideration

Dr. Genel moderated a discussion that considered the following questions.

- Should the Study inform participants and families about:

- All individual findings?
- All medically or clinically relevant individual findings?
 - Only those findings for which intervention is an option?
- Aggregate findings?
- What methods and frequency should be used to reveal information to participants and families?
 - Role of the Study Core versus role of individual centers in informing
- Should the Study inform “communities” about local findings?
 - What? How? Whom?

Aggregate Findings. At the suggestion of call participants, Dr. Genel agreed to first address the question of informing participants and families of aggregate findings and working back to considerations of individual findings. Dr. Genel noted that a key aspect of this discussion is defining “relevance.” Call participants discussed the following issues and concerns about the Study’s need to inform participants and families about aggregate findings:

- Use of the term “aggregate” without a modifier was discussed; the phrase “all aggregate findings that have scientific validity” was suggested.
- The notion of scientific validity needs to be linked with actual data to interpret aggregate findings.
- If aggregate data are provided to participants and families, then the Study is obligated to help participants and families understand the meaning of the data (how to interpret it).
- Data and information provided to Study participants and families need to be communicated in plain and common language.
- The public availability of aggregate results, once their validity was determined, was discussed. Findings would be, for example, posted on a Web site as they become available; findings would be continual and would be continuously made available; all valid findings would be shared publicly after a period of time.
- Aggregate findings could be shared through different mechanisms, from Web sites to newsletters and listservs.
- Although aggregate findings would be shared publicly, participants and families would have to be informed of aggregate findings and their meaning.

The call participants agreed that aggregate findings should be shared with participants and families as long as they are scientifically valid and clinically relevant and accompanied by an adequate explanation of the meaning of the findings. It was emphasized that the Study should help participants understand basic epidemiological data so they are able to interpret the aggregate findings. The call participants discussed whether the Study has a higher obligation to participants and families to make the aggregate findings available and interpretable. Scientifically relevant aggregate findings would be released to the general population as they become available, and the Study would do as much as it can to explain the meaning of all scientifically relevant aggregate data. The Study may be obligated to make an effort to facilitate awareness of the aggregate data’s availability to participants and families, but the aggregate findings would eventually be accessible to all.

Dr. Fleischman explained that focus groups had determined that parents are very interested in environmental and biological information and that there is a need to inform the public about such information. As an aspirational goal, all Study information should be made available in the public domain. The amount of this information, however, could be overwhelming. Therefore, the release of the data may need to be prioritized, and there may need to be processes for prioritizing data sets and determining how the information is released. Dr. Fleischman summarized the discussion on informing participants and families about aggregate findings:

- In general, the Study should inform participants and families about aggregate findings.
- The release of aggregate findings should be prioritized.
- This prioritization requires some boundaries and processes.
- There is an obligation to help participants and families understand and interpret the findings.

Medically or Clinically Relevant Individual Findings. Regarding the second part of this consideration (that is, “only those findings for which intervention is an option”), Dr. Genel asked Dr. Fleischman to elaborate on the definition of intervention in this context. Dr. Fleischman explained that the call participants could define intervention broadly, from personal interventions to environmental interventions. His primary concern was whether the subcommittee was interested in adopting language, for example, that is used for newborn screening. The call participants agreed that regardless of whether an appropriate intervention is available, parents must be informed of all medically and clinically relevant findings. They noted that although there may not be a current intervention for a particular finding, interventions may become available in the future. The Study should focus on how best to communicate this information so that it is useful to participants and increases knowledge without being unduly alarming.

Call participants discussed the following issues and concerns about the Study’s need to inform participants and families about all medically and clinically relevant individual findings:

- Involvement of a participant’s pediatrician, physician, or primary care provider to discuss medically or clinically relevant findings
- Release of medically or clinically relevant findings to a participant’s pediatrician, physician, or primary care provider
- The need for written communications
- The reading level at which Study findings are written; the need for communications to be written so that they can be interpreted by the greatest number of people
- Timeliness of informing participants and families about medically and clinically relevant findings, including urgent and emergency findings
- Some information may be confusing and misleading or not particularly useful to the participant.
- Should families be advised about the potential negative impact of being informed about findings?

- The processes for disseminating critical communications (telephone calls, written documents, face-to-face meetings)
- Written communications versus electronic communications
- Each measure or group of measures having parameters and criteria for “red flags” for individual findings (for example, clinical measures such as hematocrit or thyroid hormone that are dangerously too high or dangerously too low)
- Processes within the Study’s information management system for handling red flag alerts and triggering the communication of individual findings; these processes would be independent of the DSMB
- The need to perform a preliminary interpretation of individual findings before alerting participants and families.

All Individual Findings. Dr. Schonfeld said that providing all of an individual’s findings might be overwhelming. Participants could, however, be informed that all of their individual findings, to the level they wish to pursue them, are accessible. The data may not be critical values, and they may not be perceived as relevant by the research team, but parents or family members may want to access certain findings because, for example, they may be concerned or worried about something that they have not disclosed to the Study. Dr. Genel noted that NIH policy requires this sort of notification as part of the Federal Privacy Act and that this notification will, in some fashion, be part of the consent process.

Call participants discussed the following issues and concerns about the Study’s need to inform participants and families about all individual findings:

- Access to data or measures that are not particularly relevant to an individual (such as classroom environmental assessment data)
- The reasons for having information and data available/accessible (for example, to prevent paranoia or a climate of suspicion)
- Whether all data should be available if requested, including raw, uninterpreted, and perhaps misleading data or information
- The nature of the data and the ability to provide meaning or proper interpretation
- The definition of “individual data” versus “group-level” data
- The ethical implications for providing access to group-level data
- Adding the following phrase to the consent form: “Individual findings are available *upon request.*”
- Processes for handling such requests.

Dr. Fleischman commented that there are three options for handling individual findings:

- Adding the phrase “available upon request”
- Findings are offered, with individuals stating whether they wish them
- Findings are told.

Offering individual findings then obligates the Study to not only “tell” the findings but also provides a process for interpreting the findings. This approach may, however, place a large burden on the Study. Dr. Rushton commented that “savvy” individuals will know

how to access findings regardless, but making the findings available upon request will put the individuals who are not particularly savvy at a significant disadvantage. Ms. Dubler said that individuals who do request findings might be inundated with a “snowstorm” of data that are not all that clinically relevant. Test results, environmental information, and other data may then require explanations to provide interpretations of what is normal for measures, results, information, and data.

Dr. Genel expressed some concerns with the Study making such offers if it does not have the capacity to respond to information requests. Dr. Fleischman suggested that the NCSAC Ethics Subcommittee craft a statement that encourages the Study to inform participants and families about individual findings but that acknowledges and is sympathetic to the logistical problems that would accompany this policy. The subcommittee should simply suggest that the Study further examine this issue. Dr. Schonfeld urged the call participants to carefully consider what is potentially relevant to individuals and not necessarily attempt to make all findings available to all participants. Dr. Fleischman commented that engaging the community at large might help to resolve some of these issues and that sharing information about the community might help with Study retention. He noted that there is a distinction between informing Study participants on the consent form and periodically reminding participants and their families that Study findings are available.

Continuing Discussion on Revealing of Information Concerning the Human Genome

Dr. Fleischman announced that the NCSAC will discuss genetic aspects of the Study during the second day of the NCSAC meeting on September 22. Part of that session will be a continuing discussion on the revealing of information concerning the human genome. Dr. Fleischman explained that it is the Study’s intent to gather genetic information from all participants and families, to the extent possible. Ms. Dubler and Dr. Genel agreed that, regarding privacy and consent issues, there is no difference between genetic data and environmental data, for example, and that the same principles hold. Dr. Schonfeld said that the Study should caution participants and families about sharing genetic information because it cannot be changed and it may not be as helpful as other information.

Ms. Dubler asked whether the sharing of genetic information will be a discrete process separate from the sharing of other information. Dr. Fleischman said that individuals may participate in the Study even if they do not wish to have their genetic information measured. The Study will examine population-based genetics. According to Dr. Fleischman, this genetic information may have little relevance in 2005, for example, but may be relevant in the future. Findings from other studies may make the Study’s genetic information more relevant. In such a case, a participant may be referred to his or her physician.

Because the Study cannot anticipate every potential impact of every finding, every bit of information, or every variable, there is a need for monitoring the findings and a process

for revision based on the findings. The call participants discussed privacy/confidentiality issues regarding genetic discrimination. Families would have to be advised about the potential negative impact of being informed of certain genetic information. The call participants agreed that the Study is obligated to inform participants and families that genetic information is available and potentially relevant to the participant. The call participants also agreed that the Study may need to have guidelines for every measurement on how and when to inform participants and families. A critical issue in the processes of informing participants and families is the role of the Study's central laboratory (the "Core") compared with the roles of the individual Study centers. Dr. Schonfeld commented that because the Study will essentially be looking at well children, any finding that requires immediate notification and intervention will be unanticipated. However, notification mechanisms will need to be established for timely notification to participants and families. Dr. Fleischman said that unanswered questions or unresolved issues will be addressed during the full NCSAC meeting.

Excerpt: September 20-21, 2005 NCSAC Meeting Minutes

Ethical Considerations: Informing Participants, Families, and Communities of Information Learned

Myron Genel, M.D., Chair, NCSAC Ethics Subcommittee, Yale University School of Medicine

The mission of the NCSAC Ethics Subcommittee is to provide advice and recommendations concerning various ethical concerns. In a conference call prior to the meeting, the subcommittee (Dr. Genel; Nancy Dubler, LL.B.; Cynda Rushton, D.N.Sc., R.N.; David Schonfeld, M.D.; and Peggy Shepard) was asked to discuss and respond to specific questions derived from the following statements:

- The Study plan is committed to revealing relevant and important information to participants and families.
- NIH policy on reporting results specifies that:
 - Informed consent must include information on what will and will not be offered or told to participants.
 - Under the Federal Privacy Act, an individual may not waive his or her right to obtain access to research records.
- The Study's data and safety monitoring board (DSMB) will assess scientific validity of findings.

The subcommittee developed the following recommendations during its conference call:

- Should the Study inform participants and families about aggregate findings?
 - Findings must be scientifically valid and clinically relevant.
 - The Study should inform participants, families, and the greater community of findings.
 - The Study has an obligation to develop methods to help participants understand and interpret the meaning of the information.
 - A Web site can provide updated information, perhaps with access to some information for the general public, and secure access for individuals/families.
- Should the Study inform participants and families about all individual findings, or only those that are medically or clinically relevant, or only those for which an intervention is available?
 - The Study should inform participants and families about all medically or clinically relevant individual findings whether or not there is an available intervention.
 - The Study should focus on how best to communicate this information so that it is useful to participants and increases knowledge without being unduly alarming.
 - There is a need for a system to assure that each participant is informed of such information.
 - Written communication (paper or secure e-mail) should accompany any oral discussions.

The NCSAC reached consensus and agreed to these recommendations.

The remaining issues for discussion include:

- Some information may be confusing and misleading or not particularly useful to the participant; should it be shared?
- How should the Study determine which information is medically or clinically relevant?
- Should families be advised about the potential negative impact of being informed about findings?
- Should participants be “offered” or “told” the information, or should information “be available on request”?
- What methods and frequency should be used to inform participants of findings? (What method should be used for clinically “critical” versus “relevant” information?)
- Who should do the informing? The Program Office? The Coordinating Center? Participating local centers? Personal physicians?
- How should the Study treat genetic information?
- What information should be shared with local communities?

The NCSAC also reached consensus on the following issues:

- Those elements of aggregate data that are shared should be presented thoughtfully, and reasons should be provided as to why they are being shared; that is, there should be purpose to the informing of aggregate data.
- The concept of “clinical relevance” may not be uniformly applicable across geographic regions, across communities, and across time.
- The categories of aggregate data need to be the same across regions.
- The Study may not always be able to determine the meaning and clinical relevance of aggregate data.
- What may not be clinically relevant today may become relevant in the future.
- “Clinical utility” may be a more important concept than clinical relevance; that is, the aggregate data should be used for a specific purpose such as improving health outcomes in individuals and communities.
- Too much data can be dangerous. Community engagement may be helpful to determine what is useful to the community and what is not.
- The Study needs a clearly articulated process to define categories of information, and the participants need to understand what the categories are.
- The Study needs to offer information to participants, and communities need to be involved to help determine what information is offered.
- The Study should have methods to identify in a timely manner clinically critical findings, with appropriate “red flags,” and as best as possible, involve personal physicians and families in dealing with these clinically critical findings.
- When there is a reason to think that participants and families might wish to know clinically relevant but not clinically critical findings at the individual level, the participants should be offered the finding, with some element of interpretation of meaning, ideally in a face-to-face setting where participants and families can ask questions and discuss the meaning of the findings.

The NCSAC Ethics Subcommittee will continue to discuss these issues, and further recommendations will be presented to the NCSAC at future meetings.

Excerpt: NCSAC Ethics Subcommittee December 13, 2005

Dr. Genel opened the discussion, which focused on the role of communities in interpreting and disseminating Study data to individuals and communities.

Ms. Dubler asked who is defined as the community, who designates the community, and who gives the community the power to make decisions. In response, Dr. Fleischman first described the process of selecting segments in the Vanguard locations, which will be followed by household enumeration and determination of who in the households is eligible to participate. Some subjects will be Study participants and others in those neighborhoods and in the larger community will not be participants. The process of community engagement always involves defining who the community is, who to talk to, who the leaders are, and so on. Ms. Dubler clarified that she was comfortable with communities giving input about themselves and their neighborhood; however, she was not comfortable with “the community” making decisions.

Dr. Balsam explained that the Study will not be a community-based participatory research study, where the model is for the community to have significant input into what is studied. The community will not be making decisions about the research. The Study is focusing on how to engage the community to create interest and buy-in so that people will want to participate in the Study and will encourage others to do so. Dr. Genel noted that the Study has a Community Engagement Subcommittee.

Ms. Dubler said that her concerns were focused on involving the community in decisions about how data are logged, interpreted, and presented—which she feels would be very ethically problematic. Dr. Fleischman responded that the science cannot be determined by the community but must be determined by the scientists. However, community input will be valued. When the Study finds out something about a community, such as the presence of environmental toxins in air or water, the community may be helpful in finding ways to best present those issues. Dr. Genel agreed and suggested that if a subset of the population (such as a minority group) appeared to be uniquely vulnerable to an environmental insult, involving the community in determining how the data are shared would be beneficial.

Dr. Schonfeld noted that there will be situations in which the community might not act in the best interests of the individual and might want to restrict access to Study findings. For example, if radon levels are high, the community might be worried about a negative effect on property values and be less concerned about the effects on individuals. He stressed that ethically, individual data should be shared with the individual. He agreed that the Study could seek advice from the community but pointed out that not following the community’s advice could undermine the success of the project and suggested that seeking the community’s advice would have to be done on a case-by-case basis. Dr. Schonfeld added that he had concerns about the undue influence of the community in making decisions—or even advising—that would limit the access of individual families

to information that should be owned by them. Dr. Dubler said this was exactly what she was concerned about.

Dr. Schonfeld further elaborated that when information becomes available, the Study team must decide whether to present the information to the family and whether it is relevant to the community and should be acted on. In his view, the Study should engage the community before collection of data and consult with the community as questions arise, but the community should not determine the means by which the Study notifies and whether the Study notifies. Ms. Dubler said that she found this statement acceptable as a principle if community permission is not required before data are shared.

Dr. Fleischman said that community consultation can give advice without consent. He agreed that communities could be consulted without making their decision determinative of action for the Study. He gave an example of Native American communities that insist on at least knowing what is going to be told within their communities and would find it disrespectful if they were not informed first. However, they would not determine the Study's actions.

Ms. Dubler agreed that groups such as a Native American tribal council would have the strongest claim on hearing the data before the data are presented to the larger community. She noted the potential for discord if the Study acts against the advice of the community consulted.

Dr. Fleischman gave another example of the Salt Lake County Vanguard site, which includes as collaborators leaders of major community organizations as well as the health department and social service agencies. If the Study gathered data about that community, arranged a community meeting, and gave out information without first talking with those organizations, it would be troubling. Even if the commissioner of health and the Study disagreed about telling the community, it would be better to have had the conversation before releasing the information.

Dr. Schonfeld gave an example of a situation of community-level data that the community does not want released publicly. If there is information on risky behaviors collected on schoolchildren by community that shows, for example, a high level of cocaine use or sexual activity, the school may not want the information to go to the families or the public. There is an ethical problem of how to handle this. Dr. Fleischman responded that again, one must separate individual information (which the Study plans to give back to individuals and families) from community information. Dr. Schonfeld noted that consultation with the community can influence the process and behavior even if the community's opinion is not determinative of action.

Dr. Genel asked whether it was possible to define some general principles. Dr. Schonfeld suggested that the Study needs to say that there is an internal ethics group within the Study that will be consulted whenever necessary to address potential conflicts of interest. Dr. Fleischman said that the Ethics Subcommittee was that group and has authority to give advice to the Study through the NCSAC. The data and safety monitoring board

(DSMB) will look at the science, and the Ethics Subcommittee will make recommendations to the Study Director and the NICHD Director, who will ultimately be responsible for the decision.

Ms. Dubler suggested that one of the triggers for convening the Ethics Subcommittee might be the perception of some community interests that might be at odds with the interests of the subject families. In her view, the language of conflict of interest with the community that Dr. Schonfeld used was key. Drs. Fleischman and Genel agreed.

Dr. Schonfeld suggested adding as a principle that any clinically relevant information related to the individual child should be released to the individual family regardless of what the community thinks. Dr. Genel noted that the Ethics Subcommittee had already agreed on that. Ms. Dubler asked whether the knowledge that risky behaviors are going on in a high school is considered clinically relevant to the family of a teenager in the school. Dr. Schonfeld answered that it would not, and generally in that sort of research, the individual child's response is not known to the parent. "Clinically relevant" applies at the individual child level. In his opinion, the subject to be informed in the school example would be the school, and the school can decide how much information it releases and to whom. He noted that the only way to obtain that sort of sensitive information in schools is to have an agreement of confidentiality; schools will not participate otherwise. In response to a question about whether a national study has a different obligation, Dr. Schonfeld said that as a national study, the Study is supposed to look at what is representative of the country and at nationwide prevalence rather than trying to determine what percentage of children are engaging in risky behaviors in a given community.

After additional discussion, Dr. Genel summarized that there may be situations in which there are specific concerns about the impact the Study has on the community. Dr. Fleischman added that the Study has a structure in place (the DSMB and the Ethics Subcommittee) to assist the Study Director to obtain consultation. All Ethics Subcommittee members present said that they were comfortable with that approach.

Ms. Dubler suggested that it might be helpful in the future to collect anecdotes from various centers describing issues they face and to develop more specific and helpful guidelines.

Conclusions and Recommendations

- The Study has an obligation to share clinically relevant individual level data with individual participants/families.
- There is also an obligation to share community level data of importance with the broader community at each site.
- There may be potential risks to individuals (participants and non-participants) and to the entire community of revealing information found in the Study. Therefore, revealing information to communities must be done thoughtfully and with some level of preparation.
- Prior to revealing findings to a community, community leaders should be engaged and informed.
- Community members should serve as consultants for issues related to informing communities about findings.
- However, because there is a potential for conflict between the interests of individuals and the interests of the community related to reporting of findings, the advice of the community should be considered but need not be determinative of action.
- The Study should have a structure in place, including a DSMB and the Ethics Subcommittee, to obtain advice and assist the Study Director and the NICHD Director to make decisions about revealing findings to communities.

Excerpt: January 24-25, 2006 NCSAC Meeting Minutes

NCSAC Ethics Subcommittee Report: Informing Communities of Information Learned

Myron Genel, M.D., Chair, NCSAC Ethics Subcommittee, Yale University School of Medicine

Dr. Genel explained that the Ethics Subcommittee is still considering questions regarding the Study's commitment to revealing relevant and important information to participants and families. The specific remaining questions are:

- Should the Study inform "communities" about local findings? What? How? Whom?
- Who is the community?
- Who represents the community?
- How should the community be engaged?
- Should community permission be required before revealing findings?

Specific discussion issues are:

- The Study will not follow a strict community-based participatory research approach but is committed to engaging the community in a meaningful way.
- Engaging the community can benefit the Study.
- A community can be involved in consultation without being given the power of consent.
- Consultation with the community can influence the process of revealing findings even if the community's opinion is not determinative of action.
- Prior to revealing information to communities, the Study's data and safety monitoring board can determine the scientific validity of Study findings.
- The Ethics Subcommittee can give advice (through the NCSAC) to the Study concerning revealing findings to communities.

Dr. Genel listed the following conclusions and recommendations from the Ethics Subcommittee:

- The Study has an obligation to share clinically relevant individual-level data with individual participants and families.
- There is also an obligation to share community-level data of importance with the broader community at each site.
- There may be potential risks to individuals (participants and nonparticipants) and to the entire community of revealing information found in the Study. Therefore, revealing information to communities must be done thoughtfully and with some level of preparation.
- Prior to revealing findings to a community, community leaders should be engaged and informed.
- Community members should serve as consultants for issues related to informing communities about findings.

- However, because there is a potential for conflict between the interests of individuals and the interests of the community related to reporting of findings, the advice of the community should be considered but need not be determinative of action.
- The Study should have a structure in place, including a data and safety monitoring board (DSMB) and the Ethics Subcommittee, to obtain advice and assist the Study Director and the Director, NICHD, to make decisions about revealing findings to communities.

After the presentation by Dr. Genel, additional thoughts from and issues discussed by the Ethics Subcommittee and NCSAC included the following:

- *The need to have ethicists who are not part of government agencies advise the Steering Committee on a range of issues.*
- *The need to create clear expectations about the boundaries of disclosure from the beginning of a relationship with a community.* It was noted that the Study should be clear concerning who makes decisions and how the Study and the community can work together to think about how the information is communicated. Having a way to understand what the community thinks is important and what the community may view as risky or nonrisky information will be important.
- *When the DSMB will have the authority to take action and to what entity it will report.* Dr. Fleischman said that the present plan is that the DSMB would report to the Director, NICHD.
- *Whether findings will be reported at the county, Census tract, or Census block level and the implications for community representation.* Dr. Fleischman replied that the data will be available in various ways, and there will be an iterative process to think about that as the data become available. The Study will aggregate data regularly for all communities to see, but the DSMB will play a role when there is a question of the meaning of some local data, for example. If the findings are real, then community people would be involved at the appropriate level concerning how to reveal the findings. However, community members may disagree about revealing findings.
- *Women of diverse income levels and race/ethnicity will be participating in the Study.* Dr. Fleischman agreed and noted that there will be a broad spectrum of socioeconomic status and that ethical concerns may differ among different groups.
- *The need to be cautious about the release of data at the local block level that could pose a confidentiality problem.* Dr. Fleischman suggested that biostatisticians and ethicists would assist the Study to protect individual confidentiality of data.
- *The meaning of “clinically relevant” individual data and who decides what data are clinically relevant and how they are reported.* Dr. Genel noted that this question was discussed at the September meeting and that clinically relevant data would include finding something of importance that would potentially need some medical or other intervention or that the person should know about. Dr. Fleischman explained that

there are several levels of information using the concept of clinical relevance, including clinically critical levels, in which the Study would have an obligation to inform participants and families in a timely manner about findings that could have immediate health implications. Most people agree that there is an ethical obligation to assure there is a system in place to inform and help families deal with clinically critical findings. A second level of findings might not need to be dealt with immediately but ought to be dealt with. Then there will be information of lesser importance that may be optional for participants to receive and that would be available upon request. Some findings may be given to families directly or through their clinicians, and the participants will likely be responsible for telling the Study how they want that information revealed.

- *The role of the DSMB in assessing the meaning of Study findings.* An Ethics Subcommittee member commented that the DSMB's role would not be to look at individual test values but to look at patterns that suggest a community risk, for example. The researchers would use cutoffs for test values to decide what to report to a provider or family. Dr. Fleischman added that the DSMB would help determine the meaning of elevated biomarkers in a group, and if the meaning is not known, then the Study should not create unintended negative consequences. A member commented that there are many gray areas where the meaning of an individual test result is not clear.
- *Making resources available to help communities change environmental factors, even if that means changing Study outcomes.* Dr. Fleischman commented that the NCSAC had previously discussed the obligation to intervene at the community level even if it meant changing the outcomes for the children. The NCSAC has said that it wishes to help in developing strategies at the national and local level for empowering communities to make change, since that might not solely be the job of the centers.
- *The importance of working with community health care providers and the need to educate primary care providers about the Study.* Dr. Fleischman noted that embedded in this comment was the creation of a strategy of obtaining permission to inform primary care providers of study results. The centers cannot share health information with a participant's primary care providers without the participant's permission. Dr. Scheidt commented that the RFP for the Vanguard Centers stipulated that the centers convey plans to refer to and access primary care providers and how they would deal with serious circumstances, such as fetal death, as well as straightforward clinical referrals—and not just plans to refer but also to follow through and make sure the problem has been addressed.
- *A suggestion that the centers be required to meet some minimum Study standards on the transfer of information.* An Ethics Subcommittee member suggested that critical values need to be determined at the national level before the first participant is enrolled. When critical values are not known, results can be reassessed as the Study goes forward and more information is available. Dr. Fleischman said that this fits in with the QMP and the IMS system described earlier in the meeting.

The NCSAC concurred with the report of the Subcommittee . . .