



Board of Scientific Counselors National Center for Health Statistics Centers for Disease Control and Prevention

September 4, 2012

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Edward J. Sondik, Ph.D.

Director, National Center for Health Statistics
Centers for Disease Control and Prevention
3311 Toledo Road, Room 7209
Hyattsville, Maryland 20782

Dear Dr. Sondik:

At its most recent meeting, the BSC considered actions relative to the current National Health and Nutrition Examination Survey (NHANES) DNA program. We regard this as an important piece of the NCHS portfolio of activities and encourage you to take action to ensure the continuation of the program. The NHANES program staff presented the issue that the changing techniques of DNA research and the changing standards regarding the reporting of DNA results to study participants has led to a requirement imposed by the NCHS Ethics Review Board to develop a plan to address the long history of DNA collected from NHANES respondents and the current policies regarding informed consent. The ERB approved a proposal outlining a plan to recontact previous respondents with reportable genetic results regardless of their expressed desire regarding future contacts. A process was outlined for determining the results to be reported.

Recontacting respondents regarding their genetic results

During discussion it became clear that there are likely to be large costs to NCHS involved in recontacting study participants and very few of those contacted are likely to have a genetic marker for a reportable condition. Furthermore, it is not known how respondents will react. Therefore, the Board of Scientific Counselors suggests the need for more deliberation regarding this issue to determine the necessity and potential harm of recontacting respondents.

Changing the current consent form to report genetic results

At this time the consent form specifically says that NHANES will not report genetic results to the respondents. A change in the form to include the option of providing genetic results requires pretesting. The pretesting of the new form could be done in such a way to shed light on best way to proceed with regard to recontacting respondents.



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We recognize that a good pretest will take time so we recommend that for the 2013-14 NHANES, the program modify the consent form based on best current knowledge or a small pilot test but continue with more extensive pilot work.

Meeting the “Dire Duty to Warn” criteria

We recommend that the program proceed with the plan to identify the most appropriate group currently working to “bin” the genome and present the result of that effort at the next BSC meeting. The BSC will set up a workgroup composed of at least two BSC members and other relevant parties, e.g. geneticists, clinicians, ethicists, to determine which of the genes that fall into Bin 1 meet the NHANES criteria of a dire duty to warn. We anticipate that the workgroup will make this determination once a year.

Outreach to other organizations

The issues raised by the DNA genetics program are not unique to this survey. We applaud the efforts of the program to involve other agencies and encourage further outreach. We would like to see a plan for additional broader discussion of the issues raised, e.g. recontacting respondents, the possible psychological distress, etc. Possibilities for accomplishing this could be through a conference, an National Academy of Sciences workshop or other means. We request that the DHANES program staff update the BSC on outreach activities at the next BSC meeting.

We appreciate the opportunity to provide input on this important topic affecting one of NCHS’ critical programs.

Sincerely,

/s/

Llewellyn Cornelius, Ph.D.
Chair, NCHS Board of Scientific Counselors