

## **CONCEPT CLEARANCE**

### **Limited Competition for an Award to Support Continued Public Consultation to Inform the Design of a Possible Longitudinal Cohort Study on the Role of Genes and Environment in Health and Disease (U01)**

#### **BACKGROUND**

In September 2006, NHGRI awarded a cooperative agreement to the Genetics and Public Policy Center (GPPC) at Johns Hopkins University to conduct a pilot public consultation project to assess public attitudes about a proposed large longitudinal cohort study ( “Making Every Voice Count: Public Consultation on Genetics, Environment, and Health, U01 HG004206, K. Hudson, P.I.). The project was designed to investigate the attitudes of U.S. residents about the proposed study and addressed the kinds of information people would need in order to decide whether to participate, what protections they would expect to be in place, the kinds of personal health information and results they expect would be shared with them, and how they would view the contribution of such a large cohort study to U.S. public health or their own personal health. The two-year research project—which included 16 focus groups, 27 interviews, five town hall meetings, and a national survey of 4,659 U.S. residents—resulted in the collection of rich and detailed data on the public’s level of willingness to participate in such research, and the factors that influence these attitudes.

The results of the public consultation project revealed overall widespread public support for, and willingness to participate in, a large cohort study of the type described to them. However, because of the extensive number of topics and design issues covered in the pilot consultation project, there were a number of issues that the investigators were unable to explore in depth. The data obtained during the project also generated several new research questions that warrant further attention. For example, the initial public consultation demonstrated a remarkably high level of interest among participants in having research results returned. However, it is unclear what people understand a research result to be or how they would expect to use such information. These and other questions about returning results require further exploration. Other areas requiring follow-up study relate to such matters as (1) perspectives on the consent process and the consent form (e.g., preferences regarding blanket consent versus consent for certain categories of research or for each new project); (2) views on translation and benefits of a large cohort study and genomic research; (3) impact of the growing social networking phenomenon; (4) community outreach with particular populations (e.g., rural populations, particular racial and ethnic groups); and (5) additional variables influencing willingness to participate (e.g., convenience, educational vehicles, consenting options).

#### **PURPOSE OF THE RFA**

The purpose of the proposed RFA is to solicit a proposal for the further exploration of these and other areas of inquiry that leverages the efforts already undertaken by the

GPPC in connection with the original public consultation project. NHGRI Staff recommend that the solicitation be limited to the GPPC group because they have already developed the infrastructure and expertise to carry out such a study, and could get started immediately. For example, the GPPC team has a solid infrastructure in place for conducting follow-up focus groups and for continuing on-line public survey research with the Knowledge Networks web-enabled panel. Issuing this solicitation as a limited competition will make it possible to support the necessary research with a high degree of efficiency. The data to be gathered will have major practical implications for any large longitudinal cohort study that NHGRI, other NIH components, or other federal agencies may eventually decide to support.

### **MECHANISM OF SUPPORT AND AVAILABLE FUNDS**

This RFA will use the Cooperative Agreement (U01) award mechanism. The award will be made for a period of up to two years, with up to \$1 million per year made available.