NIH Award from the National Human Genome Research Institute

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- **Project:** Impact of Data Access Policies on Biobank Participation
- **Start Date:** September 22, 2009
- **Total Award Amount:** $378,975

**How the results of this project will benefit society:**
The goal of this study is to examine how the NIH data access policies for sharing genetic research information will impact participation in large-scale genetic research. The NIH data access policy encourages wide sharing of genetic research information among investigators to speed the translation of genetic research into improving human health. This policy has yet to be assessed for its impact on participation in genetic research nor the research participant’s understanding and preferences around this policy.

**The problem the project is trying to solve:**
The NIH data access policy for genetic research provides enormous opportunities for genetic investigators but also raises a number of challenges for educating and recruiting participants into large-scale genetic research studies. The NIH released a final data access and sharing policy for genome-wide association studies (GWAS) in August, 2007. The policy requires specific phenotypic and genetic data from GWAS be deposited into a government controlled, limited access database. In parallel with the emergence of GWAS, medical centers and research institutions worldwide are developing biobanks that house large numbers of participant DNA samples and data.

**How the project will work:**
We will ascertain novel educational strategies needed to help a patient population consisting of patients from a metropolitan Chicago hospital clearly understand the data access policy for genetic research, the role of the government as the holder of the data, the privacy protections included in the policy and the known and potential risks to privacy. Specifically, we propose to: (1) Investigate whether data access policies affect the willingness of patients to participate in a prospective hospital-based biobank, (2) Assess whether wide-spread data sharing policies for genetic research impacts participants’ preferences for two consent models: broad consent and opt-out approaches, and (3) Develop recommendations to help future patients to better understand GWAS and data access policies. To address these aims, we will conduct semi-structured interviews on a random sample of patients ascertained from Northwestern Memorial Hospital and affiliated outpatient clinics. The interviews will address in greater depth preliminary data obtained from focus groups on data sharing and genetic research and will be analyzed according to qualitative research methods. Interview results will inform development of a survey to test educational messages on data sharing and to address patients’ interest in participating in genetic research based on a presentation of the two consent models. The results of the survey will provide a basis for recommendations of educational messages and consent models for participants involved in studies in which data will be shared.

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