

**Report of the NIH ACD Working Group on Participant and Data Protection for the Genetic Association Information Network (GAIN) and Genome Wide Association Studies (GWAS) for the December 2008 Meeting of the Advisory Committee to the Director, NIH**

The NIH ACD Working Group on Participant and Data Protection for GAIN/GWAS, which serves as a source of independent advice about participant and data protection management policies for GAIN/GWAS, has met six times since its establishment in February 2007.

On a September 12 teleconference, the Working Group discussed the privacy implications of a new bioinformatics method that allows the detection of an individual's single nucleotide polymorphism profile in a mixture of 1,000 or more individual DNA samples.<sup>1</sup> The Working Group concluded the NIH's response to the development by making aggregated data available through a controlled access process was swift, appropriate and sufficient.

At an in-person meeting on October 29, the Working Group was updated on GWAS oversight activities and on the status of recommendations made previously by the ACD. The NIH reported that a Certificate of Confidentiality will be obtained for dbGaP to protect against compelled disclosures and mechanisms will be established to issue Certificates to data users through the data use certification process. In addition, educational materials for participants and the public have been developed that will be made available shortly. The Working Group considered presentations from institutional representatives about the challenges being faced at the local level in meeting the expectations of the NIH GWAS policy.

The Working Group discussed questions raised by the panelists regarding the potential identifiability of GWAS data and the determination made by the Office for Human Research Protections (OHRP) in 2006 that the GWAS repository did not involve human subjects research<sup>2</sup>. The Working Group noted the need for an ongoing exploration of the identifiability of GWAS data, but concluded that this was not the time to recommend a reconsideration of the OHRP's determination.

The Working Group acknowledged the importance of providing general information about study findings to participants and noted that a more robust effort to do so could satisfy the concerns of participants and the public about GWAS and provide them with relevant health information. Deliberative processes may be an effective mechanism to develop best practices in this area. The Working Group noted the need for an ongoing exploration regarding the issues surrounding return of results from research based on data in the NIH GWAS repository.

The Working Group discussed whether the scientific community understands the role NIH is playing in protecting the privacy of participants and the confidentiality of their data. NIH staff acknowledged that data protection is a shared responsibility between the submitting institution and NIH and that further efforts could be made to clarify NIH's role in protecting participant data. The Working Group suggested that NIH develop informational materials to inform IRBs about the DAC process and what the DACs review when they consider requests from secondary users. Such information would help reassure

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<sup>1</sup> Homer, N. et al. 2008. Resolving individuals contributing trace amounts of DNA to highly complex mixtures using high-density SNP genotyping microarrays. *PLoS Genet.* 2008 Aug 29;4(8):e1000167.

<sup>2</sup> OHRP determined that the repository does not involve human subjects because it involves only coded, de-identified information, the repository will not have access to identifying information, and the specimens and data were not collected specifically for the NIH GWAS repository. See OHRP Guidance on Research Involving Coded Private Information or Biological Specimens, October 16, 2008 <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.htm>

submitting institutions and IRBs that the DACs include concerns about participant and data protection in their consideration of data use requests. The Working Group also discussed the importance of consistency and uniformity among the NIH DACS and requested additional information about data access requests that have been disapproved or raise difficult issues in order to better understand the role of the DACs in protecting participants.

The Working Group also suggested that additional guidance or best practices would be helpful regarding the responsibilities of data submitters and their IRBs and data users with regard to risk assessment for GWAS; the return of research results to participants; and the issues surrounding submission of pediatric data and whether re-consent is needed when the child reaches the legal age of majority. NIH has a number of efforts underway that will help address these issues.

### **Conclusion**

From an in-depth exploration of the data access request review process, the Working Group reaffirmed its assessment that the participant protections in place are appropriate. Since the scientific community does not appear to understand all the steps being taken by NIH to protect participant data, more information regarding NIH's role in protecting participant data, particularly the DAC process, would probably be helpful in reassuring the community of the sufficiency of participant and data protections.