

Experience with IRB Review in Data Sharing for Genome Wide Association Studies: From the eMERGE (electronic medical records and genomics) Network.

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Problem/Issue Statement

The recent NIH policy outlining expectations for federally funded investigators to share research data from genome-wide association studies (GWAS) has moved the issue of “data sharing” to the forefront of genomic research. For many IRBs, the dialogue related to the ethical and regulatory issues surrounding data sharing has just begun. The eMERGE Network is a national consortium formed to develop, disseminate, and apply approaches to research that combine DNA biorepositories with electronic medical record systems for large-scale, high-throughput genetic research. Through this network, we have had the opportunity to interact with our IRBs to address issues of review of GWAS studies, including data sharing and being in compliance with the NIH GWAS data sharing policy. We report our preliminary experiences here.

Description of Program

The NIH Data Sharing Policy strongly encourages federally funded investigators performing GWAS to submit data for sharing with approved researchers worldwide. Procedurally, this requires IRBs from submitting institutions to review and verify that a study meets NIH requirements for data deposition into a federally controlled database called dbGaP. Institutional certification indicating compliance with the requirements must be obtained for all datasets submitted to dbGaP, including any limitations on use of the data. All eMERGE sites will submit phenotypic and GWAS results to dbGaP. Recognizing that many ethical and social issues surround large-scale genomic research and data sharing, eMERGE includes a focus on ethical issues through the Consent and Community Consultation (C&CC) Workgroup.

Interaction with IRBs: eMERGE Network researchers have interacted with their respective IRBs to review GWAS protocols, including consent forms and data use restrictions for depositing data into dbGaP. Our preliminary experience indicate that all IRBs have been supportive of working with researchers on GWAS studies and data sharing yet many are unfamiliar with the nature of GWAS and NIH policies related to data sharing. With the exception of one site, no specific process was in place for review of GWAS or obtaining institutional certification. In addition, we observed differences regarding IRB requirements for use of existing specimens and data. At one site, the use of specimens for GWAS was not considered human subjects research, while at another site IRB review determined that language specific to data sharing was inadequate and re-consent for dbGaP sharing was required.

Significance: Based on our preliminary experience we identified several opportunities to facilitate the interaction between GWAS researchers and IRB review, including education and development of consistent policies. We will present the various methods used to address the educational and procedural issues by eMERGE Network investigators and their ethics consultants.