

The Electronic Medical Records and Genomics (eMERGE) Network survey of perspectives toward broad consent and data sharing in biomedical research

Proposal Number:

900

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Description:

In 2011 the Department of Health and Human Services issued an Advanced Notice of Proposed Rulemaking (ANPRM) to modify the Common Rule in a number of ways, including requiring written informed consent for research on de-identified human data and specimens. The Electronic Medical Records and Genomics (eMERGE) Network's Consent, Education, Regulation, and Consultation (CERC) working group is conducting a survey to assess the potential impact of this proposed change on patients' willingness to enroll in biomedical research. The eMERGE network is a national consortium of 9 sites (10 separate institutions) supported by the National Human Genome Research Institute (NHGRI) that combines DNA biorepositories with electronic medical record (EMR) systems to perform large-scale, high-throughput genetic research. We first conducted a systematic literature review and identified constructs shown to characterize patients' and research participants' views about informed consent for the use of biospecimens for research. This literature search informed the development of the survey instrument as well as the sampling strategy. Patients will be randomized to one of three possible hypothetical biobanks with different consent and data sharing policies. They will then be asked about their perspectives on the consent model and data sharing of their

specimens and own data, as well as those of their children who are less than 18 years of age, given the hypothetical biobank they were randomized to. All three versions of the survey were pretested and refined through cognitive interviews in a convenience sample of up to 10 individuals per institution at 6 different institutions to ensure that all content within the survey was clear and comprehensible. A CERC survey subcommittee developed the single Institutional Review Board (IRB) survey protocol and coordinated the IRB submission for all of the institutions; the IRBs at all eMERGE institutions approved the survey. A geocoding and EHR-based sampling strategy was developed and is being used across all 10 institutions to maximize the sample diversity, and the population is stratified by age, gender, education, race/ethnicity, and location (geocoded). To further refine the survey instrument, a pilot survey is being offered to a random sample of 1,500 participants across all institutions (150 per institution), and will be followed by the full survey offered to 100,000 individuals (10,000 per institution) who have received health care at one of eMERGE institutions in the past 1 year. We expect at least 16,000 individuals to complete the survey. The data will be analyzed overall and stratified by multiple factors that may affect the results to address two key questions: 1) Are patients willing to provide broad consent for sharing of biosamples and data for future research? 2) Which biospecimen and biobanking-related research practices are likely to have the greatest impact on willingness to participate under broad consent? Knowledge from this survey will inform policy decisions on broad consent and will contribute to the ultimate success of the eMERGE Network.

Learning Objectives:

Describe approaches for the development of a survey across multiple institutions.

Learn how methods such as geocoding can be used to sample a wide range of under-represented populations for a survey.

Understand patient perspectives regarding biobank and biospecimen research consent and data sharing

Understand which biobanking-related research practices are likely to have the greatest impact on willingness to participate under broad consent.

Keywords:

Ethical, Legal and Social Issues

Methodology

Policy Issues

Psychosocial Issues

Primary Topic Focus:

Legal & Ethical Issues

Secondary Topic Focus:

Genetic Counseling

Each year an ACMG Foundation for Genetic and Genomic Medicine/ Signature Genomics, a PerkinElmer Company Travel Award is given to a selected student, trainee, or junior faculty ACMG member whose abstract submission is chosen as a platform presentation during the 2015 ACMG Annual Clinical Genetics Meeting. In recognition of their selected presentation, Signature Genomics, a PerkinElmer Company covers the travel costs for the recipient to the meeting. Would you like to be considered for the ACMG Foundation/Signature Genomics, a PerkinElmer Company Travel Award?

No

Would you like to be considered for the ACMG Foundation/Carolyn Mills Lovell Award for a Genetic Counselor?

No

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No

Please tell us what company or institution awarded a grant for your research? Please list all if more than one.

NHGRI