INFORMED CONSENT, EDUCATION & GOVERNANCE - ELSI RESEARCH IN THE EMERGE NETWORK

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What We've Accomplished

- Addressed issues related to biobanking and consent
  - Model consent language (http://www.genome.gov/27526660)
  - Pediatric model consent language *in process*
- Developed framework for addressing return of results within the network*

*Fullerton SM et al, Genetics in Medicine 2012

What We've Accomplished

- Engaged stakeholders to inform a variety of issues
  - Biobank governance/consent**
  - Data sharing and related privacy issues
  - Return of research results
  - Value of genomic research
  - Integrating genomic data into the EHR and clinical decision support***

**Lemke AA et al, Genomics Soc Policy 2010

***Hartzler A et al, Genetics in Medicine 2013

What We've Accomplished

- Developed educational methods for patients and physicians about genomic medicine
  - Implementation through EHR point of care tools, patient portals, patient website
- Assessed application of data sharing guidelines within the network*
- Compared institutional oversight across sites
  - Knowledge of genetics/genomic issues**
  - Reviews of consent for genetic research

*McGuire AL et al, Genome Research 2011

** GRRIP Consortium, J Empir Res Hum Res Ethics 2010

What We've Accomplished

- Obtained supplemental funding to conduct a survey across the 10 eMERGE sites related to the notice of proposed rulemaking, focusing on:
  - Acceptance of broad consent
  - Views on data sharing

What We've Learned

- There is a role for ELSI projects in eMERGE work at both pre-clinical implementation and the clinical implementation phases
- Community and stakeholder consultation is essential
- Consent for genomic research-many strategies required
- Educating stakeholders is a critical aspect of addressing the value of genomic medicine
- Oversight of consenting processes and genetic research varies greatly by institution
- Importance of interacting with external networks and investigators
- Our collective expertise, experience, demonstrated collaborations and participant populations can be utilized for continued exploration of questions related to genomic medicine

Future Directions

- Integrate bioethics aims into scientific studies
- Assess the impact of genomic medicine
  - Healthcare systems
  - Payers of healthcare services and tests
  - Patients and providers
    - What are the right outcomes?
- Engage stakeholders
  - Need to develop, evaluate and assess new models for consultation
  - Develop best practices
  - Examine role of stakeholder preferences in developing policies

Future Directions

- Consent
  - Assess use of model language
  - Develop and test new models for consenting process
- EHR and Clinical Decision Support
  - Assess point of care education of physicians, patients
  - Identify circumstances in which CDS is useful?
  - What policies and processes need to be in place for genomic data to be systematically entered into the EHR? How do the policies affect individuals?
  - Evaluate integration of family history data into the EHR

Future Directions

- Engage and educate IRB panel members, institutional officials and others charged with protecting patients and participants about genomic medicine & research
- Education
  - Explore new models for supporting physicians and other healthcare providers in clinical decisions around genetic tests
  - Models for public/patient education
    - Patient portals will become more common-how do we use them effectively?