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?