Miscellanea

Projects

- IRB related issues
  - General guidelines for review
  - Points to consider
  - Best practice
    - Consent
  - Interaction with OHRP?
  - Why are IRBs giving different answers?
  - NHGRI fill gap?
  - Survey Wylie Burke
    - Use this as a tool to disseminate to the genomic medicine group
  - Case studies dissemination
    - Send to investigators and IRB chairs
  - Laura Rodriguez will take lead

Projects

- Clinic/Research interface
  - What is clinical care what is discovery research?
  - Blurring of issues
    - Logistics related to electronic medical records
      - Research data available to clinicians
      - Mixing of research with clinical data
      - Not new, but easier to access data
        - » Oncology clinical trial with genetic test no known use showing up in record
    - HIPAA treats family information differently that OHRP
      - Virginia Twin study
        - » Identified subject and 'relative of' identified subject is a research subject as they can be identified
    - Clinical characterization of novel variant (clinical laboratory)
    - Return of research results that are 'actionable'
    - Blurring of term consent (consent to clinical care vs. research consent)
  - Research study of effects of merging information
  - Evaluation/Inventory of different approaches
  - Consequences of 'blurring'
- Subject of panel to follow this presentation

Projects

- Variants for clinical use
  - Different groups are making recommendations about what's 'ready for prime time'
  - Mostly siloed
  - Can we develop criteria?
  - How can we facilitate consensus building?
- Propose working group from this group and ClinAction group to develop criteria

Projects

- Implementation consultants for systems wanting to implement in clinical practice
  - Future meeting with implementation, quality experts
- Develop ‘suite’ of validated methodologies to collect data to answer clinical/research questions
- Qualitative research to understand practitioner ‘experience’ with genomics