

PANEL REACTION

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Approach to Communities

- There is no single correct way to approach the issues of consent/education, and the local community and the local research issues will influence how problems are solved
- However, major deficiency is that there is significant variability in IRBs and their knowledge/expertise around genomic issues leading to unnecessary variability in policies and decisions about similar research issues (eg return of results)
 - Opportunity to study why local IRBs come to different conclusions?
 - Opportunity to have central, deeper expertise?

Consent

- Consent for genomic studies can be quite complex. Standard written consents are not effective
- Opportunity to study effectiveness of alternative consenting strategies
- Use of video education materials to aid in education of participants and provide consistency in participant education
- Increasing use of staged consent to address new issues as they arise and provide participants with ability to consider their preferences in a more concrete context and in proximal time to relevance, but this requires increased infrastructure including portals

Return of Results

- Increasingly complex issues around return of results and needs to be addressed with the consent
- ELSI issues around policies for special populations (minors, deceased participants, participants without capacity)
- Coordination of return of all data from users with central data coordination. Secondary users are not as engaged with the communities and therefore central organization needs to assume leadership
- Mandatory list of results for return? How to define what results should be returned
- Need to educate providers as well, and the ability to eMERGE to have significant impact on best practices for education at time of medical decision making through the EHR

General Opportunities Unique to eMERGE

- Ability to disseminate and promote uptake of best practices and effective “products,” and use eMERGE as a showcase to implement and evaluate new approaches
- Studies are often lacking in the robust empirical design/power needed to move work in these areas forward
 - The collective expertise and resources of eMERGE provides an opportunity to carry out studies that overcome some of these limitations and address regulatory hurdles