JHS 2017 ROR Workshop: Discussion Questions for Consideration for Breakout Groups

- **Considerations and Recommendations**
  - How do CLIA regulations impact the return of individual-level research results to study participants?
  - Do/should HIPAA direct access rights factor in to the decision to return research results?
  - Is there an ethical obligation/responsibility for researchers to return results to participants in long-running cohort studies like JHS?
  - How could/should the consent process be modified to adequately inform and prepare participants for the possibility of receiving (potentially harmful) genetic results?

- **Procedures and Resources**
  - Which type of results should be returned?
    - No results
    - All variants
    - Only ACMG/medically actionable variants
    - Create a study-specific list of variants to return, which might include:
      - medically actionable, significant findings from that study (e.g., novel CVD risk factor identified in JHS), and/or
      - conditions more frequent in that population (e.g., sickle cell disease/trait for African American studies like JHS)
    - Allow participants to select categories of interest (e.g., carrier status, cancer risk)
  - Who should determine which results are returned?
    - Research investigators
    - Advisory board with community representatives, clinicians, investigators, bioethicists, IRB members, etc.
    - Participants decide individually which results they want to receive
  - CLIA confirmation process – who pays (participant, study, research institution, participant's insurance if applicable)? Is this the responsibility of the study, or should this be done by the participant during clinical follow-up with their primary care provider?
  - Variant interpretation: Should the research team handle this task vs. send it out to a clinical lab to handle (i.e., "outsource" the interpretation)? How should interpretations be validated (since interpretations can vary between labs)? How much time and staff effort will interpretation require, and are funds available to pay for this as a part of the research study (e.g., salary support)?
  - How frequently should variant interpretations be assessed (e.g., annually, never)? Should reinterpretation occur after the study ends? If so, how would this be handled?
  - Genetic counseling: should the study pay for this vs. the participant vs. participant insurance (if available)? How should uncertainty be conveyed (e.g., variants of unknown significance, inconsistency in variant interpretation between labs)? Does a genetic counselor automatically need to be involved, or could some results be returned via a paper report or an educational web portal (e.g., like 23andMe or My46)?
  - Participant re-contact: should study investigators do this vs. a genetic counselor vs. someone familiar to the participant like their primary care provider? How is re-contact handled so that re-contact does not automatically convey there is a "bad result" to report (i.e., since you're asking about interest in receiving results it means there's something to return)? How frequently should a participant's preference to receive results be assessed

(e.g., only once - during consent, at consent + when results are ready to return, at consent + annually thereafter like during annual follow ups)?

- **Perspectives from Stakeholders**
  - How best can a study support participants through the process of receiving results, some of which may be harmful (e.g., cancer risk) or traumatizing (e.g., Alzheimer's) to receive? What has worked in other studies, and what would work in JHS?
  - Which results do participants want to receive? How do they want to receive them? From whom (e.g., study investigator, genetic counselor, healthcare provider)?
  - Should studies automatically return a participant's results to their healthcare provider vs. let the participant decide whether to share with provider?
  - Does a research study have an obligation to help healthcare providers, who would provide follow-on clinical support for genetic variants, understand the significance of a clinically relevant finding? If so, how can studies help educate healthcare providers about genomics?
  - How should a study format the "report" that might be provided to a participant/healthcare provider? Would separate reports be needed for participant vs. healthcare provider? What content should be in such reports?