JHS WORKSHOP ON RETURN OF RESULTS: BACKGROUND AND RECOMMENDATIONS

Report Outline:

1. Background/Rationale (Groups 1, 2, and 3)
    a. Increasing availability of information on roles of genetics and epigenetics in health and disease
    b. Extent to which current recommendations apply to research cohort studies
    c. ELSI questions and practical considerations for the return of results from cohort studies not addressed by current recommendations
    d. Need for practical standard procedures
    e. Need for delineation of resource needs and process(es) for procuring essential resources

2. Recommendations (Group 3)
    a. Stakeholders
        i. Researchers
        ii. Study participants
        iii. Labs
        iv. Genetic counselors
        v. Health care providers

    b. Ethical, Legal, Social Considerations (Group 1)
        i. How do CLIA regulations impact the return of individual-level research results to study participants?

    c. Procedures (Group 2)
        i. Selection of results to return
        ii. Re-consenting process
        iii. Process for contacting participants
        iv. Roles of
            1. Researchers
            2. Genetic counselors
            3. Labs
            4. Health care providers
        v. Lessons learned
            1. Clinical settings
            2. Cohort studies
        vi. Additional considerations

    d. Resource Needs (Group 2)
        i. Reconsenting study participants
        ii. Contacting study participants
        iii. Scheduling participants for diagnostic tests
        iv. Diagnostic tests
            1. CLIA certified lab

2. Costs

v. Pros and cons of alternate approaches for providing results of diagnostic tests to participants
    1. Letter
    2. E-mail
    3. Visit with genetic counselor and health care provider
vi. Genetic counseling
vii. Treatment