Jackson Heart Study Workshop:
Return of Results from Genetic & Genomic Studies

UMMC Conference Center
Jackson Medical Mall
Jackson, Mississippi
April 4-5, 2017
Goal and Objectives

1. Goal
   To develop draft procedures and identify resource needs for the return of results (ROR) from genetic and genomic research studies.

2. Objectives
   a. To review general considerations, recommendations, procedures, resource needs, and perspectives from stakeholders regarding the ROR from genetic and genomic research in cohort studies; and
   b. To draft a white paper on rationale, procedures, and resource needs for the ROR from genetic and genomic research studies.
## Day 1
### TUESDAY, APRIL 4, 2017: Plenary & Breakout Sessions

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<tr>
<td>0730</td>
<td>Registration and Continental Breakfast</td>
<td>UMMC Conference Center Longwood Concourse</td>
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<tr>
<td>0800</td>
<td>Welcome</td>
<td>Dan Jones</td>
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<td>Workshop Objectives and Logistics</td>
<td>James (Jim) Wilson</td>
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<td>0815</td>
<td>TOPMed Overview</td>
<td>Adolfo Correa</td>
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<td>Mollie Minear</td>
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### Plenary Sessions – Dunleith Room

#### Plenary Session I: Recommendations & Considerations
**Moderator:** Malia Fullerton

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<td>ACMG Secondary Findings Recommendations</td>
<td>Sarah Kalia</td>
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<td>CLIA-HIPPA Considerations</td>
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#### Plenary Session II: Procedures & Resources
**Moderator:** Jonathan Berg

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<td>Multi-Ethnic Study of Atherosclerosis</td>
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<td>Framingham Heart Study</td>
<td>Joanne Murabito</td>
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<td>Andrew Johnson</td>
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<td>Empirical Data on Return of Genetic Results</td>
<td>Robert Green</td>
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#### Plenary Session III: Perspectives from Stakeholders
**Moderator:** Ebony Madden

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**BREAK**
# Day 1

**TUESDAY, APRIL 4, 2017: Plenary & Breakout Sessions**

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# Day 2

**WEDNESDAY, APRIL 5, 2017: Reports from Breakout Groups**

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<td>Finish Drafts of Written Reports and Materials for Presentations</td>
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<td>1100 General Discussion</td>
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Jackson Heart Study Workshop:
Return of Results from Genetic & Genomic Studies
Breakout Groups

1. Recommendations & Considerations
2. Procedures & Resources
3. Perspectives from Stakeholders
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?
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
Suggested References for JHS 2017 ROR Workshop:

Recommendations and Considerations


- Standards and guidelines for the interpretation of sequence variants: a joint consensus recommendation of the American College of Medical Genetics and Genomics and the Association for Molecular Pathology. Sue Richards PhD, Nazneen Aziz PhD, Sherri Bale PhD, David Bick MD, Soma Das PhD, Julie Gastier-Foster PhD, Wayne W. Grody MD, PhD, Madhuri Hegde PhD, Elaine Lyon PhD, Elaine Spector PhD, Karl Voelkerding MD & Heidi L. Rehm PhD; on behalf of the ACMG Laboratory Quality Assurance Committee. Genetics in Medicine (2015) 17, 405-423 doi:10.1038/gim.2015.30 http://www.nature.com/gim/journal/v17/n5/full/gim201530a.html


Procedures and Resources


Stakeholders’ Perspectives


Glossary

**ACMG:** American College of Medical Genetics and Genomics. Founded in 1991, the College represents providers of genetic services including clinical, cytogenetic, medical, and molecular geneticists, genetic counselors, and other health care professionals committed to the practice of medical genetics. The current mission of the ACMG is to establish a paradigm of genomic medicine through policy statements and evidence-based practice guidelines; to provide education in an effort to grow the genetics workforce; and, to work with policymakers and payers to support the application of genomics into medical practice.

**Allele:** An alternative form of a gene or genetic element such as an enhancer. Alleles have been created by mutations and can be responsible for variations in a phenotype.

**Chromosome:** A structure within a cell made up of DNA and proteins that stores genetic information. There are 23 pairs of chromosomes in the human genome. A chromosome abnormality is an extra and/or missing chromosome or part of a chromosome.

**CLIA:** Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards on personnel and procedures that apply to all clinical laboratory testing performed on humans in the United States, except clinical trials and basic research. These standards require clinical laboratories to be certificated by their state as well as the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing. The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA).

**DNA:** Deoxyribonucleic acid is a chemical that carries genetic information and is usually present in a cell as two paired complementary strands. Each strand is a chemical chain made up of four chemical units (abbreviated A, C, T, and G). Genes are carried in the form of a genetic code in a strand.

**Gene:** A unit of inheritance, normally made up of a region of DNA, that codes for a protein or for an RNA chain. A gene mutation is a change in the region of DNA that makes up a gene. This change can be as small as a single chemical unit (A, C, G, or T) in the DNA.

**Genome:** The complete set of genetic information in an organism. The genome provides all of the information an organism requires to develop and function. A genome includes protein-encoding genes, genes that do not encode proteins, the regulatory regions of genes, and sequences of DNA whose functions remain to be determined. The study and analysis of genomes is called genomics.

**Genotype:** An organism’s collection of genetic information that determines its physical, chemical, and biological characteristics or traits. “Genotype” is often used more specifically to describe the form of a particular variant that an individual carries.
**HIPAA:** An acronym that stands for the Health Insurance Portability and Accountability Act, a US law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals and other health care providers.

**Penetrance:** The proportion of organisms that carry a particular variant of a gene that also expresses the associated trait or phenotype. In medical genetics, penetrance refers to the proportion of individuals carrying a genotype that manifest a related trait or the symptoms of an illness.

**Phenotype:** The set of individual’s biological and physical traits, such as skin color and eye color, as well as complex traits such as blood pressure. “Phenotype” can also be used to describe a specific trait or condition.

**Protein:** A chemical made up of a chain of amino acids that is created when a gene is translated. There may also be post-translational modifications such as glycosylation (addition of a sugar molecule) or other processing.

**RNA:** Ribonucleic acid is a chemical that performs several functions in the cells, including acting as an “intermediate” message for a gene to be translated into a protein. RNA is composed of a chain of chemical units (abbreviated as A, C, G, and U) connected along a sugar-phosphate backbone.

**TOPMed:** Trans-Omics for Precision Medicine. Trans-Omics for Precision Medicine (TOPMed), sponsored by the National Institutes of Health's National Heart, Lung and Blood Institute (NHLBI), is a program to generate scientific resources to enhance our understanding of fundamental biological processes that underlie heart, lung, blood and sleep disorders (HLBS). It is part of a broader Precision Medicine Initiative, which aims to provide disease treatments that are tailored to an individual’s unique genes and environment. TOPMed will contribute to this initiative through the integration of whole-genome sequencing (WGS) and other –omics (e.g., metabolic profiles, protein and RNA expression patterns) data with molecular, behavioral, imaging, environmental, and clinical data. In doing so, this program seeks to uncover factors that increase or decrease the risk of disease, identify subtypes of disease, and help to develop more targeted and personalized treatments.

The Whole Genome Sequencing (WGS) project is part of NHLBI’s TOPMed program and serves as an initial step for the larger initiative. In recent years, genetic research of complex disease using Genome-Wide Association Study (GWAS) and Exome-sequencing approaches has resulted in an unprecedented explosion of genetic discovery. However, a large portion of heritability in complex diseases remains elusive. Whole Genome Sequencing (WGS) will provide a comprehensive view of the genome, an opportunity to further understand the genetic architecture relevant to heart, lung, blood, and sleep (HLBS) disorders, and an unprecedented resource to the scientific community.
**Trait:** A physical, chemical, or biological feature of an organism, such as eye color and cholesterol levels. Traits are determined by genes, and complex traits may be modified by the environment.

**Transcription (of genes):** The process by which information in DNA is copied into RNA.

**Translation (of genes):** The process by which genetic information is converted from an RNA message into a protein.
### Biographies of Workshop Faculty

**Speakers, Moderators, and Breakout Leaders**

**Jonathan Berg, MD, PhD**

Jonathan S. Berg, MD, PhD, is an assistant professor in the Department of Genetics at the University of North Carolina at Chapel Hill (UNC). He also has a clinical appointment in the Department of Medicine, Division of Hematology–Oncology and the Lineberger Comprehensive Cancer Center. Dr. Berg graduated from Emory University with a BS in biology and completed the MD/PhD program at UNC in the curriculum in neuroscience. He subsequently underwent residency training in clinical genetics at Baylor College of Medicine. Dr. Berg is now a physician and researcher interested in the development and application of genetic tests in patients and their families. The recent revolution in genetic sequencing technology has led to an unprecedented opportunity to investigate the underlying etiology in families with genetic conditions, and yet it raises potential pitfalls that must be addressed in order to translate these new technologies into the practice of clinical genomics. Dr. Berg is particularly interested in the range of “incidental,” or “secondary,” findings that are discovered during the course of genome-scale sequencing, including the pre-test counseling and informed consent process; computational analysis required to determine the likely clinical relevance of variants; best practices for return of these findings to patients; and the impact of genomic findings on patients and their families. He is co-principal investigator of National Institutes of Health (NIH) grants to investigate the use of genome-scale sequencing as a diagnostic test in patients with suspected genetic disorders, as a potential screening tool in healthy newborns, and to develop a publicly available database of clinically relevant genes and variants through the “ClinGen” project. He is also an investigator in the UNC Center for Genomics and Society, which was recently renewed as a National Human Genome Research Institute (NHGRI) Center for Excellence in Ethical, Legal, and Social Implications Research to evaluate the prospect of using genomics to improve the health of adults in the general public. Dr. Berg has led the development of a novel semi-quantitative metric that evaluates several key aspects of “actionability” to score gene–phenotype pairs in a transparent, unbiased fashion. This approach was adopted by the Evaluation of Genome Applications in Practice and Prevention (EGAPP) Working Group as a means of approaching the problem of systematically evaluating the clinical utility of genomic information, and it is being studied as a way to guide the return of genomic findings in projects at UNC.

**Julie Cohen, ScM, CGC**

Julie Cohen is a certified genetic counselor from Baltimore Maryland. She received her Master’s degree from the Genetic Counseling Training Program at the Johns Hopkins Bloomberg School of Public Health and National Human Genome Research Institute. Julie is a senior genetic counselor at the Kennedy Krieger Institute in the Department of Neurology and Developmental Medicine, where she sees pediatric and adult patients with neurogenetic conditions and developmental disorders. Julie and her colleagues were early adopters of clinical exome sequencing, and she has extensive experience counseling, consent, and returning results to patients and families.
### Speakers, Moderators, and Breakout Leaders

#### Adolfo Correa, MD, PhD, MPH, MBA

Adolfo Correa is Director and PI of the Jackson Heart Study (JHS). He also serves as Professor of Medicine and Pediatrics at the University of Mississippi Medical Center in Jackson, MS. He has been affiliated with the JHS and UMMC since 2011, first as Chief Science Officer and interim Director and PI, and more recently (2015-present) as Director and PI.

A native of Mexico, Dr. Correa completed his training in medicine at the University of California San Diego, San Francisco General and University of California San Francisco; and in public health, epidemiology and preventive medicine at the Johns Hopkins School of Public Health. Before joining the JHS, Dr. Correa served as an Epidemic Intelligence Officer with the Centers for Disease Control and Prevention (CDC); as a member of the faculty in the departments of epidemiology at the Johns Hopkins School of Public Health, the University of Maryland School of Medicine, and Emory University School of Public Health; visiting faculty at Mexico’s National Institute of Public Health, and as a medical officer with the CDC. Dr. Correa’s research experience in preventive medicine includes studies of Reye syndrome and use of aspirin and of indoor wood smoke and respiratory illnesses in children; occupational exposures and cancer among nuclear shipyard workers and reproductive disorders among computer chip manufacturers; maternal periconceptional use of folic acid supplements and prevention of neural tube defects; chronic disorders among women of childbearing age and reproductive outcomes; and risk factors for and outcomes from cardiovascular disorders among African Americans. In the JHS, he serves as PI for the Coordinating Center and Field Center and as a liaison to JHS national research collaborations, including JHS Vanguard Centers, AHA Cardiovascular Genome Phenome Study, TOPMed, and other cross-cohort collaborations.

#### Lynette Ekunwe, MPH

Lynette Ekunwe is currently employed as a Project Director/Research Associate with the Jackson Heart Study Field Center. She earned a BS and MS degree in Biology and a MPH (Epidemiology) from Jackson State University. Her research interests include the following areas: sleep, diabetes, genetics and cardiovascular disease epidemiology. She served as project manager and co-investigator for “Returning individual genetic results to participants in cohort studies” an ancillary study. The goal of this study was to get participants opinion on whether or not they would like to receive their individual genetic results from research studies that they participated in.

#### Barbara Evans, JD, PhD

Barbara Evans is the Alumnae College Professor of Law and Director of the Center for Biotechnology & Law at the University of Houston Law Center, a member institution of the Texas Medical Center. Her research interests include health information systems, genomic testing, gene editing, and precision medicine. She was named a Greenwall Foundation Faculty Scholar in Bioethics for 2010-2013 and is an elected member of the American Law Institute. Her recent activities have included service on the U.S. National Academies’ Committee on Future Biotechnology Products; the Institute of Medicine’s Committee on Accessible and Affordable Hearing Health Care for Adults; the U.S. Food and Drug Administration’s Sentinel System Privacy Panel, Patient Engagement Working Group, and National Evaluation System for Health Technologies Planning Board; and the U.S. National Committee for Vital and Health Statistics. She holds an electrical engineering degree from the University of Texas at Austin, an M.S. and Ph.D. in Earth Sciences from Stanford University, a J.D. from Yale Law School, and she completed a postdoctoral fellowship in clinical ethics at the University of Texas M.D. Anderson Cancer Center. She is licensed to practice law in New York and Texas.
### Speakers, Moderators, and Breakout Leaders

#### Malia Fullerton, DPhil

Malia Fullerton, DPhil, is Associate Professor of Bioethics and Humanities at the University of Washington School of Medicine. She is also Adjunct Associate Professor in the UW Departments of Epidemiology and Genome Sciences, as well as an affiliate investigator with the Public Health Sciences division of the Fred Hutchinson Cancer Research Center. She received a PhD in Human Population Genetics from the University of Oxford and later re-trained in Ethical, Legal, and Social Implications research with a fellowship from the NIH National Human Genome Research Institute. Dr. Fullerton’s work focuses on the ethical and social implications of genetic and genomic research, biobanking, and clinical genetic testing, including researcher and participant perspectives on data-sharing, secondary use, result return, and clinical implementation.

#### Robert Green, MD

Robert C. Green, MD, MPH is a medical geneticist and physician-scientist who directs the G2P Research Program in translational genomics and health outcomes in the Division of Genetics at Brigham and Women’s Hospital and Harvard Medical School.

Dr. Green is principal investigator of the NIH-funded REVEAL Study, in which a cross-disciplinary team has conducted 4 separate multi-center randomized clinical trials since 2000, collectively enrolling 1100 individuals in order to explore emerging themes in translational genomics. Dr. Green also co-directs the NIH-funded PGen Study, one of the first prospective studies of direct-to-consumer genetic testing services. He is principal investigator of the MedSeq Project, the first NIH-funded randomized trial to explore the use of whole genome sequencing in the clinical practice of medicine and co-directs the BabySeq Project, the first NIH-funded trial of sequencing in newborns. The MedSeq and BabySeq Projects apply genome sequencing both in patients who are affected with hereditary disease and in those who are healthy, in order to study downstream impact on health, behavior and health care costs.

Dr. Green is currently Associate Director for Research of the Partners Center for Personalized Genetic Medicine, a Board Member of the Council for Responsible Genetics and a member of the Informed Cohort Oversight Boards for both the Children’s Hospital Boston Gene Partnership Program and the Coriell Personalized Medicine Collaborative. He was the lead author of the recently published recommendations from the American College of Medical Genetics and Genomics for management of incidental findings in clinical sequencing.

#### Cassie Hajek, MD

Cassie Hajek is a Sioux Falls, SD native. She graduated from the University of Michigan with a Master’s degree in industrial engineering and went on to work for the Boston Consulting Group for two years before deciding to go to medical school. After graduating from the University of South Dakota Sanford School of Medicine and completing Internal Medicine residency at Montefiore Medical Center in Bronx NY, she practiced outpatient internal medicine at Sanford Adult Medicine in Sioux Falls. In 2014, she took a leave from her practice to pursue a medical genetics fellowship at the UCLA Intercampus Medical Genetics Program. Her training was focused on Adult Genetics and the genetics of common complex disease and genetic risk. She completed her training in June 2016, and now serves as the Clinical Director of Sanford Imagenetics. In her spare time, she enjoys spending time with her husband and 19-month-old son, Jack, doing just about anything.
### Speakers, Moderators, and Breakout Leaders

#### Frances Henderson, EdD

Dr. Henderson began her journey with the Jackson Heart Study (JHS) during the feasibility phase in 1998 as a consultant to the Principal Investigator (PI) of a study on facilitators and barriers to recruitment and retention for potential JHS participants. From 1998 to 2013, she served in several different roles, in part-time and full-time positions, including: Special Assistant to the PI of the JHS; Co-Director of the Examination Center; and Deputy Director. She continues to serve as a Consultant to the JHS on an as-needed basis. She also serves several constituents as an Evaluation Consultant and/or Qualitative Research Consultant. From 1988 to 2003 Dr. Henderson was Professor and Dean, School of Nursing, Alcorn State University in Natchez, Mississippi. She is a graduate of: Dillard University in New Orleans, Louisiana; University of California San Francisco Medical Center School of Nursing; and Nova University of Fort Lauderdale, Florida. Dr. Henderson is semi-retired and resides in Pasadena, California.

#### Nancy Jenny, PhD

Nancy Jenny is an Associate Professor in the Department of Pathology and Laboratory Medicine at the University of Vermont, Burlington, VT and, oversees the JHS biorepository at the University of Vermont. She received her PhD from the Rensselaer Polytechnic Institute, Troy, NY, and completed postdoctoral training in hemostasis, thrombosis and biochemistry at the University of Vermont, Burlington, VT. Her current research interests include associations of inflammatory and immune factors with development and progression of aging-related diseases like atherosclerosis, dementia and frailty. My research covers hypothesis-driven studies of relationships between inflammation and immune phenotypes with disease to genome wide association studies looking to identify new pathways linking inflammation and immunity with disease.

#### Andrew Johnson, PhD

Andrew Johnson, PhD, joined the Framingham Heart Study in 2007 after completing his doctoral degree at the Ohio State University College of Medicine.

Dr. Johnson is an Investigator with the National Heart, Lung, and Blood Institute and Head of Biomedical Informatics in the Population Sciences Branch. Dr. Johnson has published over 140 articles in leading journals. He is active on several national committees and a Fellow of the American Heart Association.

Dr. Johnson has been nominated for and received several awards including the NHLBI Claude Lenfant Fellowship Award. His main research interests include platelet genetics and genomics, RNA gene expression research, and the application of bioinformatics in genetics research.
<table>
<thead>
<tr>
<th>Speakers, Moderators, and Breakout Leaders</th>
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<tbody>
<tr>
<td><strong>Daniel (Dan) Jones, MD</strong></td>
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<tr>
<td>Daniel W. Jones, MD is the Sanderson Chair in Obesity, Metabolic Diseases and Nutrition and Director of Clinical and Population Science in the Mississippi Center for Obesity Research at The University of Mississippi Medical Center. He also serves as Professor of Medicine and Physiology and Interim Chair of the Department of Medicine.</td>
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<tr>
<td>He has a 24 year association with The University of Mississippi serving in a number of capacities including Vice Chancellor for Health Affairs and Dean of the School of Medicine from 2003-2009 and as Chancellor of the University from 2009 until September 2015.</td>
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<td>A native Mississippian, he graduated from Mississippi College in 1971, earned his MD in 1975 at the UM Medical Center and completed his residency in internal medicine there in 1978. He had a private medical practice in Laurel, then went to South Korea in 1985 to fulfill a passion for health care service to underserved populations. For more than twenty years, he has served as a medical education consultant to medical schools in North Korea. His research activities have focused on prevention of cardiovascular disease and racial and economic disparities in health outcomes. He was the first principle investigator for the landmark Jackson Heart Study, an NIH sponsored population study focused on identifying causes of disparate rates of heart disease in African Americans.</td>
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<td>Active in the American Heart Association (AHA), Jones was the 2007-2008 national president and for years has served as a national spokesperson on high blood pressure. Currently he serves as a member of the executive committee of the AHA Center for Precision Cardiovascular Medicine. He also represents the AHA on the ACC/AHA Guideline Writing Committee for the 2017 Hypertension Management Guidelines. He also serves as Chairman of the Advisory Board for the William Winter Institute for Racial Reconciliation and Chairman of the Advisory Committee for the Pyongyang University of Science and Technology’s School of Medicine.</td>
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<tr>
<td><strong>Sarah Kalia, ScM, LCGC</strong></td>
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<td>Sarah Kalia, ScM, LCGC is a certified genetic counselor and Director of Research Development with the Genomes2People (G2P) Research Program at Brigham and Women’s Hospital (BWH), where she develops research protocols and proposals for novel collaborations. As the only genetic counselor on the Partners Healthcare Biobank Return of Research Results Task Force, she contacts and counsels Biobank participants who are discovered to have an actionable genomic secondary finding. She is a member of the American College of Medical Genetics and Genomics (ACMG) Secondary Findings Maintenance Working Group and was first author on the updated ACMG secondary findings recommendations, co-author on the original recommendations, and co-author on an UpToDate article providing evidence-based clinical decision support for managing secondary findings. She also serves on the Practice Guidelines Committee of the National Society of Genetic Counselors. In her clinical role, she counsels patients in the BWH Adult Genetics Clinic and via video consultation for a variety of indications, including counseling about genomic secondary findings.</td>
</tr>
</tbody>
</table>
**Speakers, Moderators, and Breakout Leaders**

**Ebony Madden, PhD**

Dr. Madden is a Program Director in the Division of Genomic Medicine, National Human Genome Research Institute (NHGRI). Prior to joining NHGRI, she served as a research geneticist at the National Heart Lung and Blood Institute (NHLBI) from 2002-2006 and chief of staff of the Office of the Director, National Institute of Environmental Health Sciences (NIEHS) from 2006-2009. Her research portfolio includes Life After Linkage, Next Generation Association Studies, the Implementing Genomics in Practice (IGNITE) Network, and the H3Africa ELSI Program.

Dr. Madden received her BS in biology from the University of North Carolina at Chapel Hill, her MS in Genetic Counseling from Howard University, and her PhD in Genetics and Human Genetics from Howard University. Her research interests include population genomics, pharmacogenomics, complex disease and health disparities.

**Mollie Minear, PhD**

Mollie Minear PhD, is a health scientist administrator in the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute (NHLBI) of the NIH. She has a Ph.D. in genetics and genomics, and completed postdoctoral training in the ethical, legal, and social implications (ELSI) of genetics. Mollie came to the NIH as a 2015-16 American Association for the Advancement of Science (AAAS) Science & Technology Policy Fellow at the NIH, where she worked in the NHLBI’s Epidemiology Branch to address questions about the return of genetic data to participants in NHLBI cohort studies. After her fellowship, Mollie stayed at the NHLBI to continue working on return of results questions. She works with the NHLBI’s Trans-Omics for Precision Medicine (TOPMed) program, where she is the staff lead for ELSI concerns like informed consent and genomic data sharing.

**Joanne Murabito, MD, ScM**

Dr. Joanne Murabito is an Associate Professor of Medicine in the Division of General Internal Medicine at Boston University School of Medicine. Dr. Murabito currently serves as Co-PI and Research Center Director of the Framingham Heart Study. She conducts both traditional epidemiologic research and genetic epidemiologic research in the areas of longevity, healthy aging and reproductive aging. She is an active member of the Cohorts for Heart and Aging Research in Genomic Epidemiology (CHARGE) Consortium and the Long Life Family Study. A goal of these projects is to identify genes and pathways that contribute to aging biology and risk for age-related disease. Framingham Study participants have dense genotyping, whole exome sequencing and FHS is a participating cohort in the NHLBI TOPMed project. Dr. Murabito serves on the FHS Genetic Results Reporting Committee.
**Michael Murray, MD**

Dr. Mike Murray is board certified in Internal Medicine and Medical Genetics and he joined Geisinger Health System as the director of clinical genomics over four years ago after serving on the faculty at Harvard Medical School and as the clinical chief of genetics at Brigham and Women’s Hospital in Boston for nine years.

Mike was born and raised in Philadelphia PA. He earned his medical degree at Penn State Hershey, and went on to do additional training at Cleveland Clinic, University of Pennsylvania, and Harvard Medical School.

At Geisinger he is leading the GenomeFIRST return of results program for the over 125,000 patient participants who undergo Genomic Sequencing as part of the MyCode Community Health Initiative. This project builds on the collaboration between Geisinger and Regeneron Pharmaceuticals, but is funded outside of that research collaboration through internal Geisinger support, external grants, and generous donations.

The GenomeFIRST return of results program expects to deliver important risk information based on genetic sequence back to between 2-4% of MyCode participants in its initial phase. These risks primarily fall into the categories of either risk for cancer or cardiovascular disease. Geisinger is the first institution in the world to build the necessary infrastructure at the scale needed to deliver this kind of genomic results to this many patients and their providers, and to then assist the patients in getting their at-risk family members tested too. This program is expected to help define a best practice model for doing this new 21st century approach to care within healthcare systems everywhere.

Mike was one of the principal investigators on the Boston-based MedSeq project, and is an investigator in both the ClinGen and eMERGE project. He is also the lead editor of a genomics textbook for practicing clinicians, “Clinical Genomics: Practical Applications for Adult Patient Care” (McGraw Hill 2014 [http://www.mheducation.ca/professional/products/9780071622448/]).

**David Peloquin, JD**

David Peloquin is an attorney at Ropes & Gray LLP where he practices in the firm’s health care group. He focuses his practice on advising academic medical centers, life sciences companies, and information technology companies on issues related to human subjects and animal research, Medicare/Medicaid reimbursement, and data privacy. He also serves as a member of the Institutional Review Board at Boston’s Brigham & Women’s Hospital.

David graduated from the Yale Law School, after which he spent one year as a law clerk to the Honorable Diana E. Murphy of the United States Court of Appeals for the Eighth Circuit. Before attending law school, David worked as a project manager for Epic Systems, a leading provider of electronic medical records.
Jerome Rotter, MD

Dr. Rotter’s research is in the genetics of common, complex diseases, i.e. the earliest determinants of what are for the most part adult diseases but with the origins of their pathophysiology in childhood. He has contributed to our knowledge of the genetic basis of cardiometabolic disorders (atherosclerosis, coronary artery disease, valvular heart disease, arrhythmias and EKG variation, blood pressure and hypertension, lipid disorders, nonalcoholic fatty liver diseases, diabetes, diabetic kidney disease, diabetic eye disease, and insulin resistance), autoimmune/inflammatory disorders (type 1 diabetes, inflammatory bowel disease, systemic lupus, coeliac disease), eye diseases (diabetic retinopathy, keratoconus, glaucoma, macular degeneration, myopia), and pharmacogenetics (genetic determinants of response to a therapy). His work (which is intensively collaborative) has utilized a variety of paradigms, from family based, to case-control, to cohort, to pharmacogenetic studies, and from candidate gene, to family based linkage, to genome-wide association, to large scale specialized genotyping and sequencing. Dr. Rotter and colleagues have been especially active in multiethnic studies including those in Caucasian, Hispanic, African-Americans, Chinese, Armenian, and Jewish populations. In the process, they helped delineate the genetic architecture of diabetes and insulin resistance, and of blood pressure and hypertension, and of lipid disorders, in multiple ethnic groups. Dr. Rotter has published some 630 peer reviewed articles and over 150 other publications (reviews, chapters, editorials, letters), and 5 books, the most notable being the two editions of King, Rotter, and Moltulsky’s Genetic Basis of Common Diseases. The ultimate goal of this work is to identify the optimal therapy and prevention for cardiometabolic and ocular disorders as a function of an individual’s genetic predisposition. Thus this is the basis for precision/personalized medicine, especially in minority populations. Dr. Rotter serves on the External Advisory Boards of the Precision Medicine programs of two health systems, in Nevada (Nevada Institute for Personalized Medicine), and South Dakota (Sanford Imagenetics). He serves on the Steering Committees of TOPMed (PI of MESA WGS TOPMed and the TOPMed Multi-Omics projects; also a convener of the diabetes and lipid working groups, respectively), CHARGE (Cohorts for Heart and Aging Research in Genomic Epidemiology; chair, Genotyping Committee), and MESA (Multi-Ethnic Study of Atherosclerosis; chair, Genetics Committee; PI of MESA Family and MESA SHARE GWAS studies).

Vikki J. Taylor, JD

Vikki is Managing Partner of Taylor Jones & Associates, PLLC, a Ridgeland, MS law firm. Her diverse practice includes representing businesses and individuals in complex civil and commercial litigation. Vikki has extensive experience in the areas of employment law, banking litigation, personal injury, medical malpractice, air quality, and bad faith insurance cases. During her legal career, Vikki has litigated hundreds of cases and participated in numerous mediation proceedings. She conducts workplace investigations and develops training programs for HR professionals, managers, and other employees on a variety of employment law topics. Vikki earned a Bachelor of Science degree in Paralegal Studies from the Mississippi University for Women and a Juris Doctorate degree from the University of Mississippi School of Law. After completing law school, she began her legal career as defense attorney with the law firm of Campbell DeLong Hagwood & Wade in Greenville, MS. She later became a Partner in the law firm of Watkins Ludlam Winter & Stennis in Jackson, MS. Vikki’s professional activities are too numerous to mention. Some highlights include recognition by Super Lawyers® in 2006 and 2015 as one of Mississippi’s top litigation attorneys; a nomination by the Mississippi Bar Association as Outstanding Woman Lawyer of the Year; and a finalist for the Leading Business Woman award by the Mississippi Business Journal. Vikki has traveled extensively in the United States and internationally in her capacity as a member of Meritas’ Board of Directors. She lives in Madison, MS and has one daughter and one granddaughter.
Speakers, Moderators, and Breakout Leaders

James (Jim) Wilson, MD

James Wilson, MD was born in Jackson, MS and attended Murrah High School. He did undergraduate work at Rice University and then returned to Jackson for medical school at the University of Mississippi Medical Center (UMMC). Thereafter completed residency and fellowship training in internal medicine and rheumatology at Duke University, with additional training at Brigham and Women’s Hospital in Boston, where he remained on the faculty of Harvard Medical School for several years. He returned to the UMMC faculty in 1986, initially working at the V.A. Medical Center and then moving full-time to UMMC. Throughout his career he has been active in medical research, first in immunology and more recently in genetic epidemiology. He has served as genetics coordinator of the Jackson Heart Study since the beginning of participant recruitment, and has directed the study’s involvement in a series of national and international genetics projects. He chairs the Steering Committee of NHLBI’s Trans-Omics for Precision Medicine (TOPMed) project, which will complete deep-coverage whole genome sequencing in more than 70,000 study participants in 2017. Extensive analysis of genomic features and association with medically important traits will be conducted in 2017 and the years that follow. Dr. Wilson is widely published, with a particular focus on inherited factors that affect the health of African Americans.

Joon-Ho Yu, PhD

Joon-Ho is an ethicist and translational researcher at the University of Washington (UW). He received his MPH and PhD in public health genetics at UW and was a trainee of the Center for Genomics and Healthcare Equality. He currently holds a K99R00 career development award from the National Institutes of Health, National Human Genome Research Institute, focused on the return of genome sequencing results to underserved minority populations. Before academia, he worked for over a decade in the non-profit sector on minority health issues. His interests span the ethical, legal, social implications (ELSI) and clinical translation of genomics, including the translation of genomic technologies in the context of underserved populations, minority participation in research, and the use of race and ancestry in biomedical research.
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