

**Workshop on Considerations for Returning Individual
Genomic Results from Population-Based Surveys: Focus
on the National Health and Nutrition Examination Survey**

December 2, 7, & 8, 2022

AGENDA

Population surveys collect information from participants by asking questions. Today, many surveys also collect biologic specimens that can be used to analyze a respondent's DNA and other biomarkers. The National Health and Nutrition Examination Survey (NHANES) administers a physical examination, collects biospecimens, and reports some test results (e.g., cholesterol levels) to the participant. Traditionally, NHANES participants have been told that they will not be contacted with personal genetic results. However, clinical science is evolving to encourage more return of individual research results. Therefore, NHANES will revisit the issue of if, when, and how to return genetic results to study participants.

This workshop is being sponsored by the Centers for Disease Control and Prevention (CDC).

**Meeting materials and recordings will be available via the [Project Website](#) on
NationalAcademies.org, Keyword= "Returning Individual Genomic Results"**

DAY 1: Friday, December 2, 2022

10:00 – 10:20 am ET

Welcome and Goals for Workshop

- *Brian Harris-Kojetin*, Director, Committee on National Statistics, National Academies of Science, Engineering, & Medicine
- *Brian C. Moyer*, Director, National Center for Health Statistics, Centers for Disease Control and Prevention (CDC)
- *Jeffrey R. Botkin*, Chair, Workshop Planning Committee, University of Utah

10:20 – 11:45 am ET

I. NHANES: Current Structure and Opportunities for Adding Genomics

10:20 – 10:35 am

Overview of the NHANES resource

- *Alan Simon*, National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC)

10:35 – 10:50 am

NHANES Biospecimen Program

- *Alan Simon*, NCHS, CDC

10:50 – 11:05 am

Types of research supported by the current survey data

- *Dana Crawford*, Case Western Reserve University (Member, Workshop Planning Committee)

11:05 – 11:20 am

Genetics 101/201: Understanding the current genetic testing landscape

- *Ingrid A. Holm*, Boston Children's Hospital (Member, Workshop Planning Committee)

11:20 – 11:45 am

Moderator/discussant questions and reflections

- *Leslie G. Biesecker*, National Human Genome Research Institute (NHGRI), National Institutes of Health (NIH) (Member, Workshop Planning Committee)

11:45 am – 12:00 pm ET

BREAK

12:00 – 2:00 pm ET

II. Return of Clinically Actionable Genetic Results

12:00 – 12:20 pm

What data is being generated? Implications for returning results

- *Matt Lebo*, Mass General Brigham

12:20 – 12:40 pm

Ethical arguments regarding the return of research results

- *Yvonne Bombard*, University of Toronto

12:40 – 1:00 pm

Current ACMG list, process, and alternatives

- *Marc S. Williams*, Geisinger

1:00 – 1:20 pm

Attitudes and outcomes of returning results to participants

- *Julie C. Sapp*, NHGRI

1:20 – 1:40 pm

Issues regarding data reanalysis for actionable variants

- *Natasha Strande*, Geisinger

1:40 – 2:00 pm

Moderator/discussant questions and reflections

- *Jeffrey R. Botkin*, University of Utah (Chair, Workshop Planning Committee)

2:00 – 2:15 pm ET

BREAK

2:15 – 3:30 pm ET

III. Regulatory Issues in the Return of Genetic Results

2:15 – 2:30 pm

CLIA lab certification and CLIA test validation

- *Benjamin Solomon*, National Institutes of Health (NIH)

2:30 – 2:45 pm

Potential FDA oversight and approval

- *Beth Collins*, All of Us Research Program, NIH

2:45 – 3:00 pm

Navigating Federal and State-specific Laws Governing Genetic Testing and the Return of Results

- *Katherine Blizinsky*, All of Us Research Program, NIH

3:00 – 3:30 pm

Moderator/discussant questions and reflections

- *Ingrid A. Holm*, Boston Children’s Hospital (Member, Workshop Planning Committee)

3:30 – 4:00 pm ET

General Discussion (30 mins)

4:00 pm ET

Adjournment

4:00 – 4:30 pm ET

Planning Committee Discussion (Closed Session)

DAY 2: Wednesday, December 7, 2022

12:00 – 2:00 pm ET

IV. Process for the Return of Genetic Results

12:00 – 12:20 pm

Infrastructure, expertise and other necessary resources to communicate results in a research setting

- *Anastasia Wise*, All of Us Research Program, NIH

12:20 – 12:40 pm

Communication strategies in a clinical research setting

- *Kathleen A. Leppig*, eMERGE, Kaiser Permanente of Washington

12:40 – 1:00 pm

Communication strategies in a direct-to-consumer context

- *Amy Sturm*, 23andMe

1:00 – 1:20 pm

Special issues for returns to participants in low-resource communities: Lessons from the Healthy Nevada Project

- *Joe Grzymalski & Gai Elhanan*, Healthy Nevada Project

1:20 – 1:40 pm

Special issues for returns to participants in low-resource communities: Lessons from the BioMe project

- *Noura Abul-Husn*, Icahn School of Medicine at Mount Sinai

1:40 – 2:00 pm

Moderator/discussant questions and reflections

- *Adam Buchanan*, Geisinger
(Member, Workshop Planning Committee)

2:00 – 2:15 pm ET

BREAK

2:15 – 3:30 pm ET

V. Informed Consent When Considering Returning Genetic Results to Survey Participants

2:15 – 2:30 pm

Community Engagement and Informed Consent in NHANES

- *Duong (Tony) Nguyen*, CDC

2:30 – 2:50 pm

Informed consent content for return of research results and biobanking

- *David Magnus*, Stanford University

2:50 – 3:10 pm

The informed consent process for return of results and biobanking

- *Michelle N. Meyer*, Geisinger

3:10 – 4:00 pm

Moderator/discussant questions and reflections

- *Amy McGuire*, Baylor College of Medicine

3:30 – 4:00 pm ET

General Discussion (30 mins)

4:00 ET

Adjournment

DAY 3: Thursday, December 8, 2022

1:00 – 1:10 pm ET

Recap of the Discussion Thus Far

- *Jeffrey R. Botkin*, University of Utah
(Chair, Workshop Planning Committee)

1:10 – 3:00 pm ET

VI. Considerations in the Return of Genetic Results: Lessons from Other Research Studies

1:10 – 1:30 pm

Genomics England

- *David Bick*, Genomics England

1:30 – 1:50 pm

Million Veteran Program

- *Jason Vassy*, Harvard Medical School

1:50 – 2:10 pm

Alabama Genomic Health Initiative

- *Bruce Korf*, University of Alabama at Birmingham

2:10 – 2:30 pm

All of Us

- *Stephanie Devaney*, All of Us Research Program, NIH

2:30 – 3:00 pm

Moderator/discussant questions and reflections

- *Leslie G. Biesecker*, NHGRI, NIH
(Member, Workshop Planning Committee)

3:00 – 3:15 pm ET

BREAK

3:15 – 4:15 pm ET

Panel Discussion: Key Themes and Considerations for Future NHANES

- *Jeffrey R. Botkin*, University of Utah
(Chair, Workshop Planning Committee)
- Workshop Planning Committee Members:
 - *Leslie G. Biesecker*, NHGRI, NIH
 - *Natasha Bonhomme*, Expecting Health
 - *Adam Buchanan*, Geisinger
 - *Dana Crawford*, Case Western Reserve University
 - *Ingrid A. Holm*, Boston Children's Hospital
 - *David Forster*, Western Institutional Review Board-Copernicus Group (WCG)

4:15 pm ET

Adjournment