



Alabama Genomic
HEALTH INITIATIVE

*Current Experiences with Barriers to Participation:
The AGHI Example*

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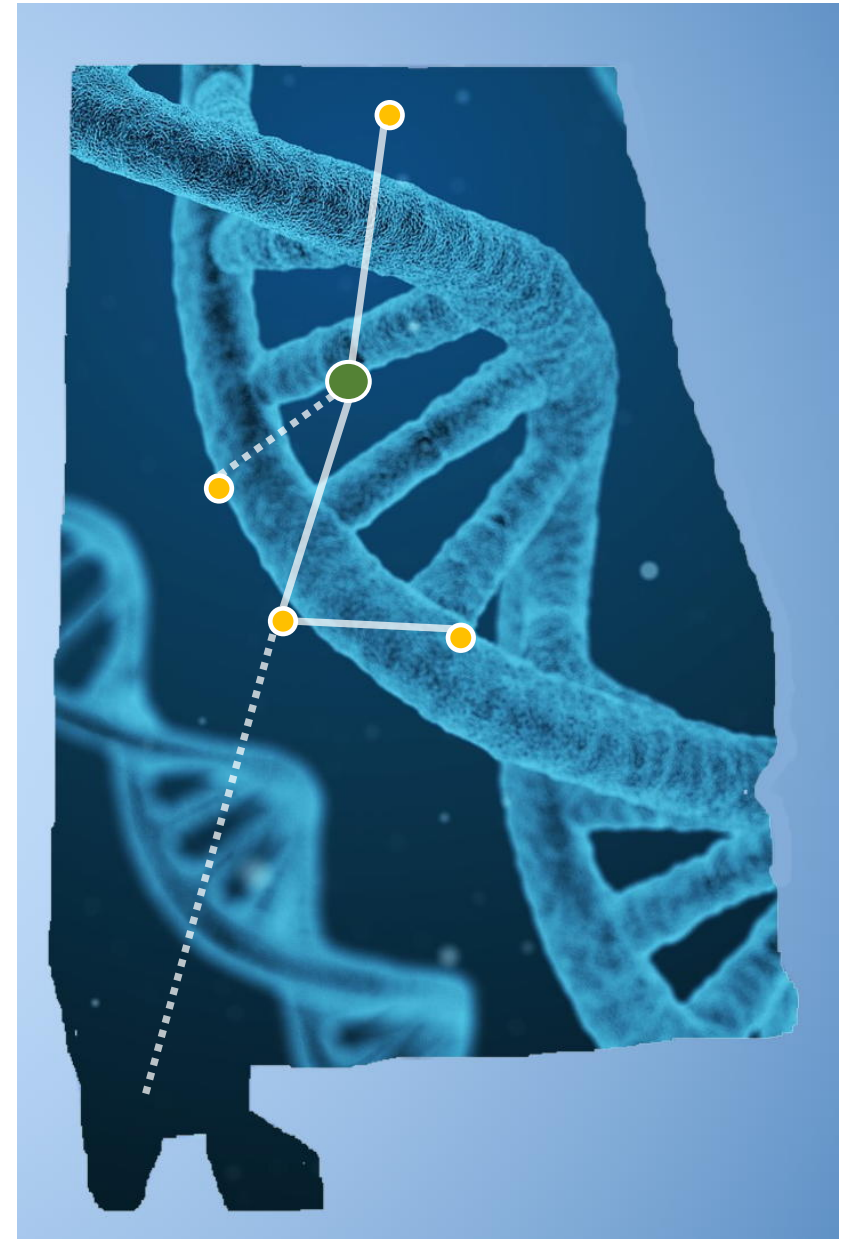
Angela Williams, Study Navigator

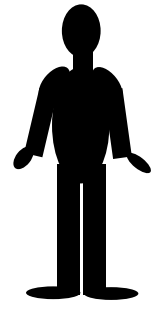
Alabama Genomic Health Initiative (AGHI) Enrollment 2017-



The program is aimed at preventing and treating disease, including certain types of cancer, heart problems, and genetic disorders. In collaboration with the **HudsonAlpha Institute for Biotechnology** in Huntsville, UAB Medicine will provide genomic testing, interpretation, and counseling free of charge to residents in each of Alabama's 67 counties. The AGHI also includes a major focus on research, through which data from test results will be used to advance scientific understanding of the role that genes play in health and disease.

<https://www.uabmedicine.org/aghi>





Healthy
Volunteers

Affected
Individuals



- Patient Navigator
- Recruitment
Comm. Engagement
- Communications
- Administration
- Bioethics
- Biobank
Bioinformatics
- Genomics
- Education

Consent
Genotyping
Medical Information

Consent
Whole Genome Sequencing
History and Exam

Return *Medically Actionable* Results
(currently ACMG59)
Genetic Counseling

Return Diagnostic Results
Genetic Counseling

OnCore
Specimen
metadata

Biorepository
Plasma, DNAs,
buffy coats

i2b2
Health data

Research
Community

AGHI Recruitment and Enrollment Team



Bioethics Study Navigator Training

- Led by Bioethics Working Group
- Established relationship between Bioethics and Recruitment *before* the study launch
- Information on Transparency/Honesty, Respect, Confidentiality and Fairness
- Definitions of Bioethics and the importance
- Historical information and responses
- Detailed Consent overview by Bioethics
- Chance to ask questions and address concerns



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Assistant Professor
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Bioethicist & Professor
of Allied Health
Sciences, National
Center for Bioethics in
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AGHI Bioethics Consent Highlights

- Navigators highlight the Bioethics Working Group Leaders
- Certificate of Confidentiality
 - Researchers can legally refuse to disclose information that may identify participants in any federal, state, or local civil, criminal, administrative, legislative or other proceedings.
- Genetic Information Nondiscrimination Act (GINA)
 - Generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against participants based on genetic information

Power of Participant Choices:

Please initial your choice below:

_____ I agree to allow my specimens and specimen-associated data to be kept and used for future research on genes and diseases, disorders or other health-related conditions. I also give permission to be re-contacted in the future.

_____ I do not agree to allow my specimens and specimen-associated data to be kept and used for future research.

Power of Choices_Results Consent:

As stated in item (iii) of Section “**Explanation of Procedures**” of this document, you can choose whether the genotyping results will be returned to you or your medical provider by us.

Please initial your choice below:

(A) _____ I would like to know results about “medically actionable” genes **AND** I want my medical provider to know results about “medically actionable” genes.

(B) _____ I would like to know results about “medically actionable” genes but I do **NOT** want my medical provider to know results about “medically actionable” genes.

(C) _____ I do **NOT** want to know results about “medically actionable” genes and I do **NOT** want my medical provider to know results about “medically actionable” genes.

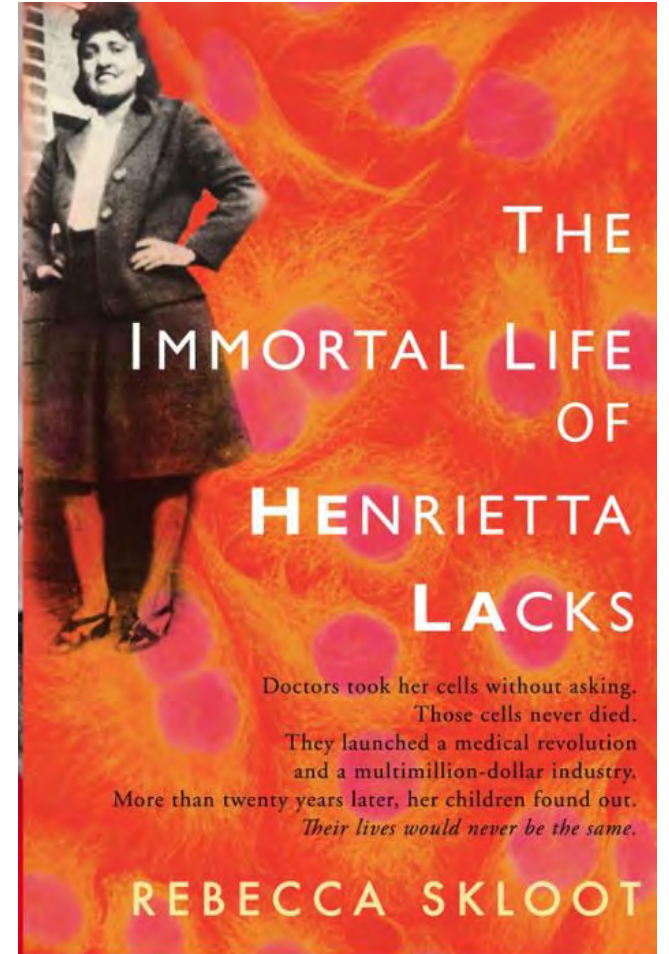
AGHI Frequently Asked Questions

- Privacy, Confidentiality, and Participant Re-contact Information
- Reconfirms transparency of AGHI
- Henrietta Lacks
- Working document
- Published on AGHI.org and given to each participant at enrollment



Participant Bioethical Concerns at Enrollment

- Henrietta Lacks
 - Payment for “super cells”
 - Oprah’s HBO Movie, April 2017
- Re-Contact
 - Fear that something was positive
- Biobank Access
 - Concern of who may gain access





On the Horizon for FY18 in Recruitment and Bioethics

- Continue dialogue between working groups
- Update Bioethics Working Group as we expand through the state
- Update FAQ's as needed
- Harmonize bioethics training of navigators across all sites with Standard Operating Procedures

Questions and Discussion