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

12 December 2022
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All of Us Research Program

National Institutes of Health

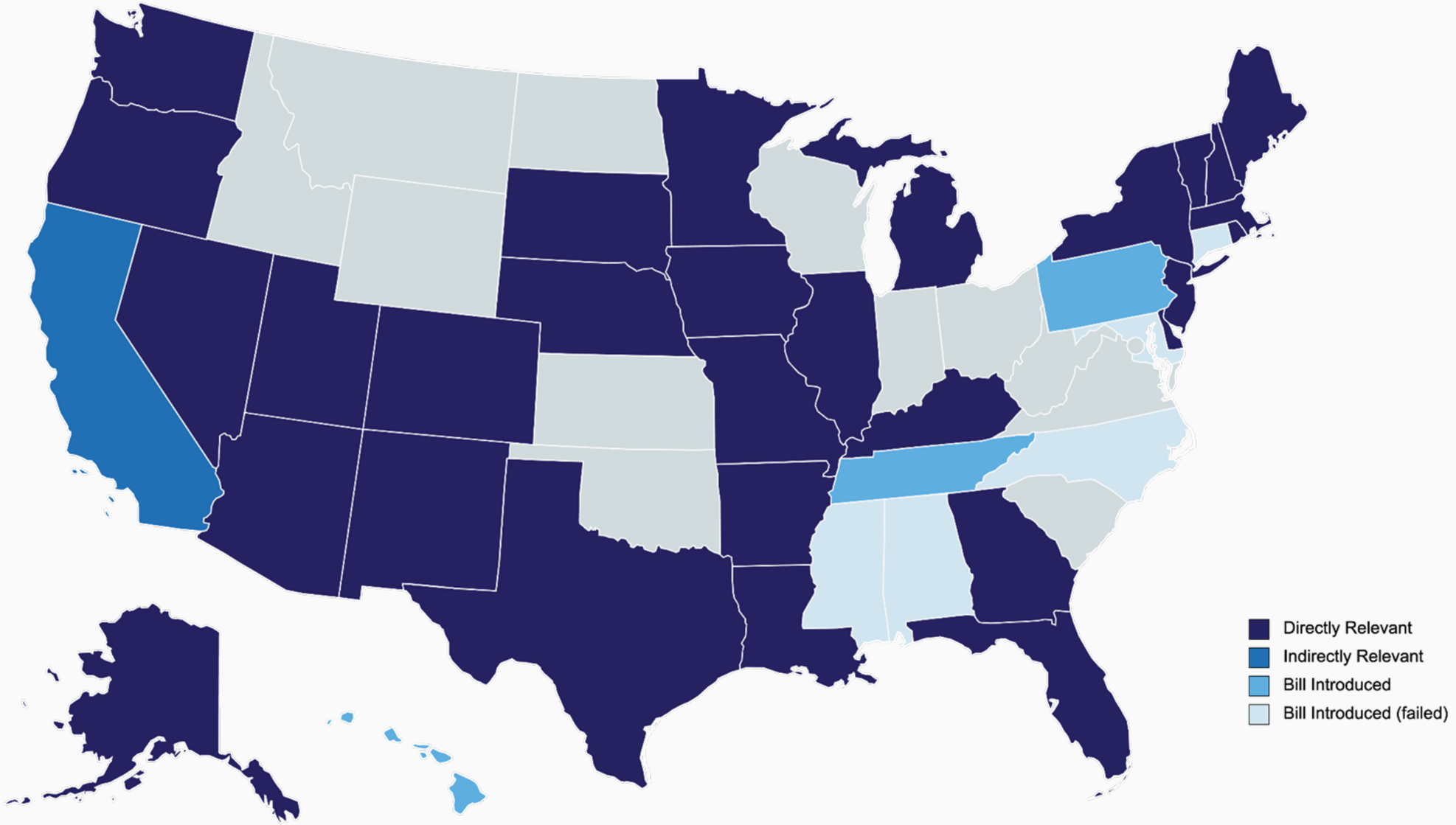
I am not an attorney

This is not an exhaustive list


2. Examples
1.Overview
3. Solutions

Overview | The Legal Landscape around Genetic Information and Testing

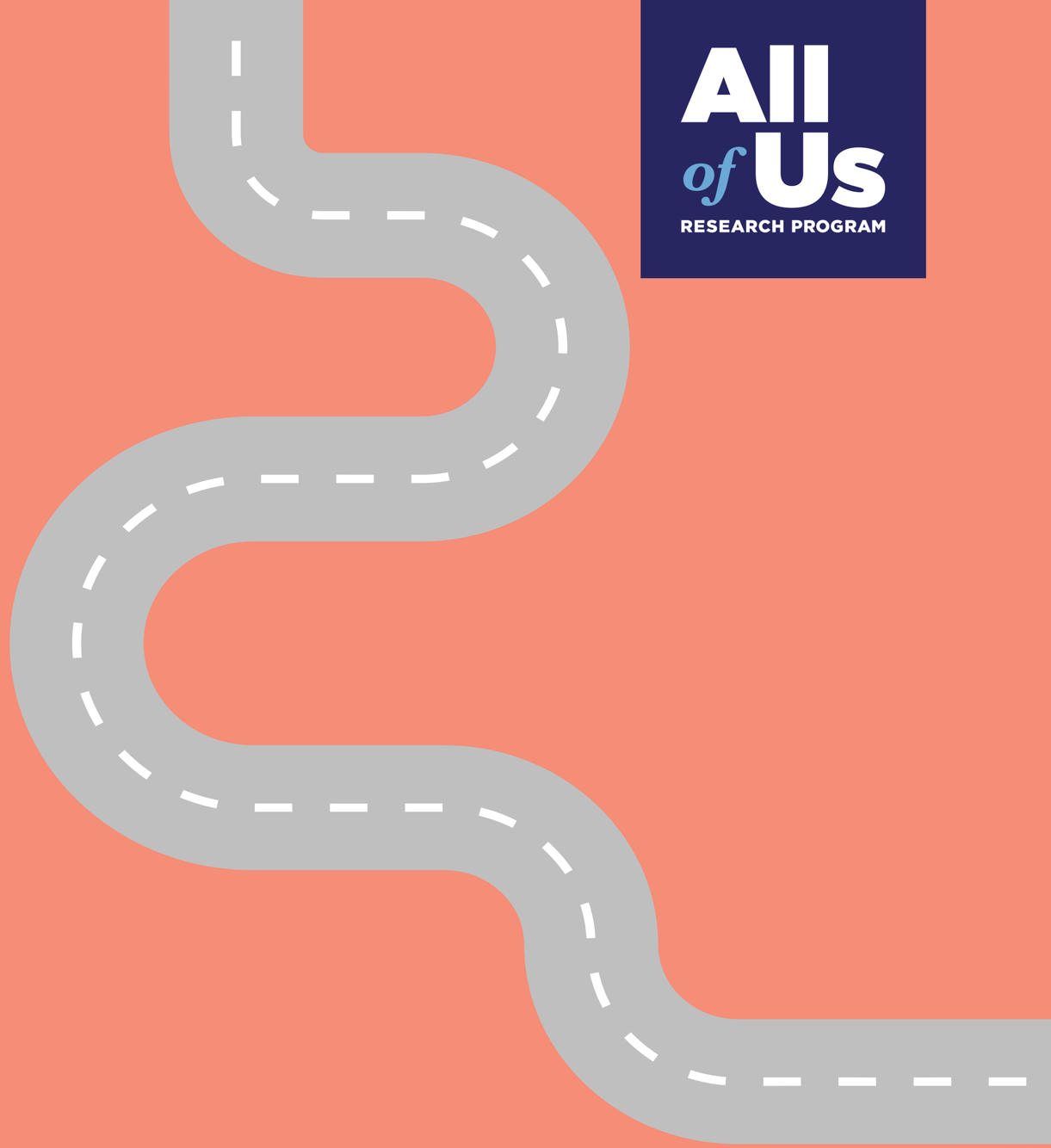
State Laws | Genetic Information and Testing



Requirements for Testing

State Laws

- Knowledge/Informed Consent
- Valid Informed Consent



In almost all cases…

genetic testing requires knowledge and/or consent

… of the person being tested

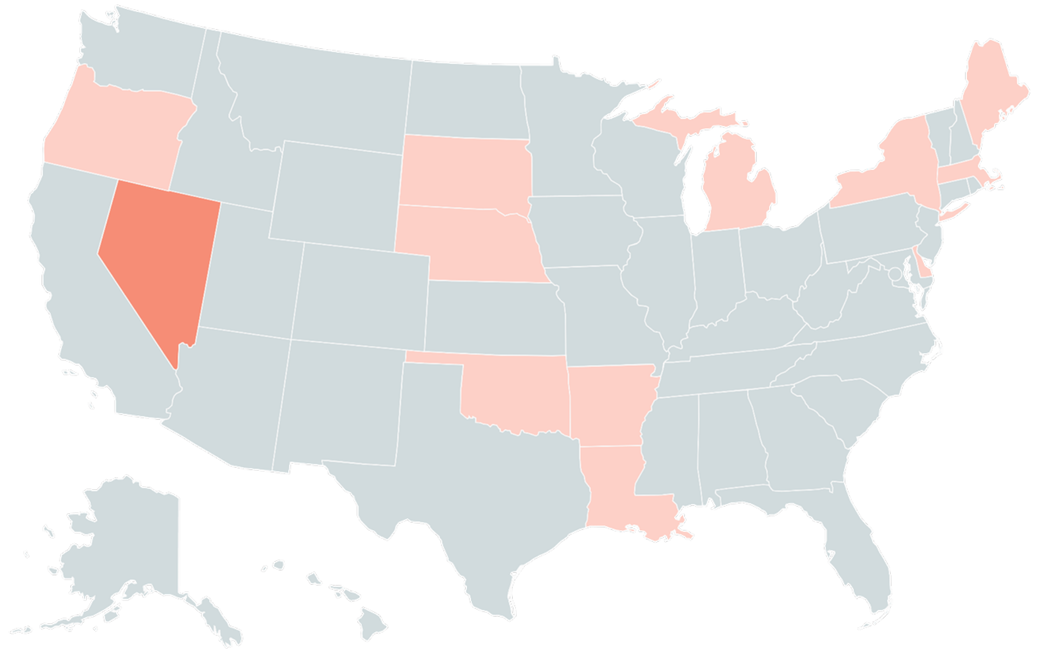
Valid informed consent…

… must be obtained in a certain way

… documentation must contain certain information

… must specify certain limits

NRS §71-551(1): Except as provided in section 71-519 and except for newborn screening tests ordered by physicians to comply with the law of the state in which the infant was born, a physician or an individual to whom the physician has delegated authority to perform a selected act, task, or function shall not order a predictive genetic test without first obtaining the written informed consent of the patient to be tested. **Written informed consent consists of a signed writing executed by the patient or the representative of a patient lacking decisional capacity** that confirms that the physician or individual acting under the delegated authority of the physician has explained, and the patient or his or her representative understands



Valid informed consent…

… must be obtained in a certain way

… documentation must contain certain information

… must specify certain limits

MCL §333.17520(2): … informed consent consists of… all of the following:

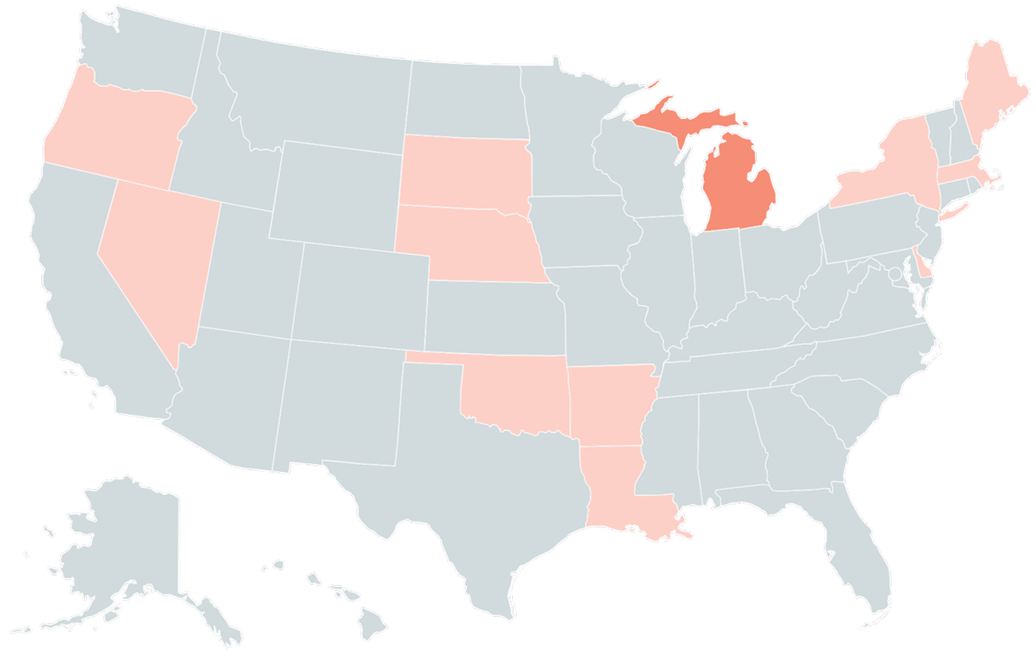
(a) The **nature and purpose** of the presymptomatic or predictive genetic test.

(b) The **effectiveness and limitations** of the presymptomatic or predictive genetic test.

(c) The **implications** of taking the presymptomatic or predictive genetic test, including, but not limited to, the **medical risks and benefits**.

…

(e) The **meaning** of the presymptomatic or predictive genetic test results and the **procedure for providing notice** of the results to the test subject.



Valid informed consent…

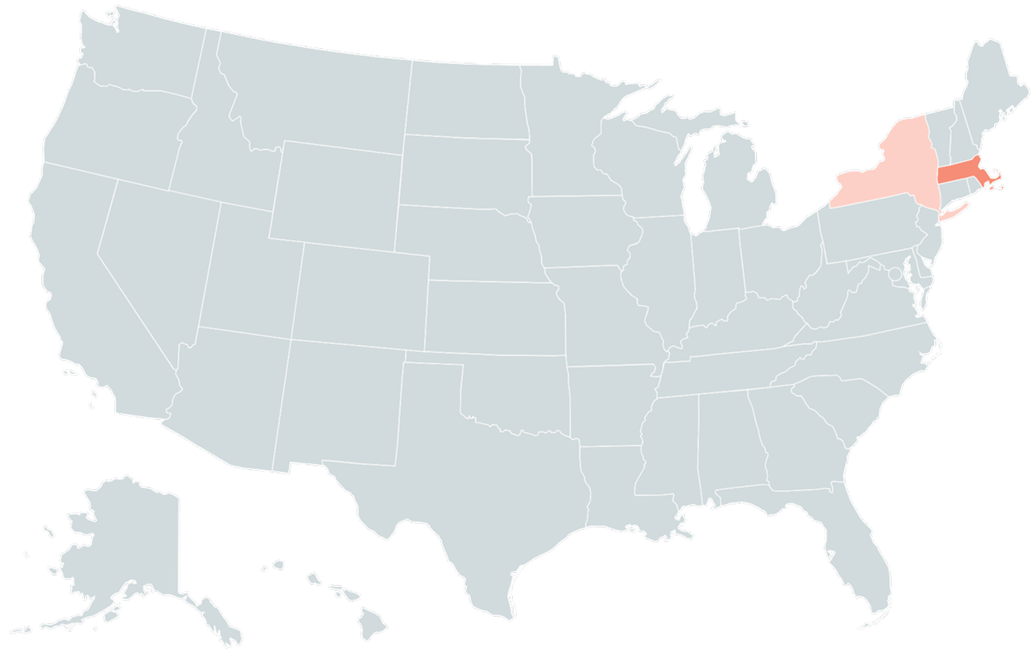
… must be obtained in a certain way

… documentation must contain certain information

… must specify certain limits

MGL Public Health 111 §70G(a): "Prior written consent", a written consent form… which shall include:

(3) a statement that the consenting person was **informed about the availability and importance of genetic counseling** and **provided with written information identifying a genetic counselor** or medical geneticist from whom the consenting person might obtain such counseling;



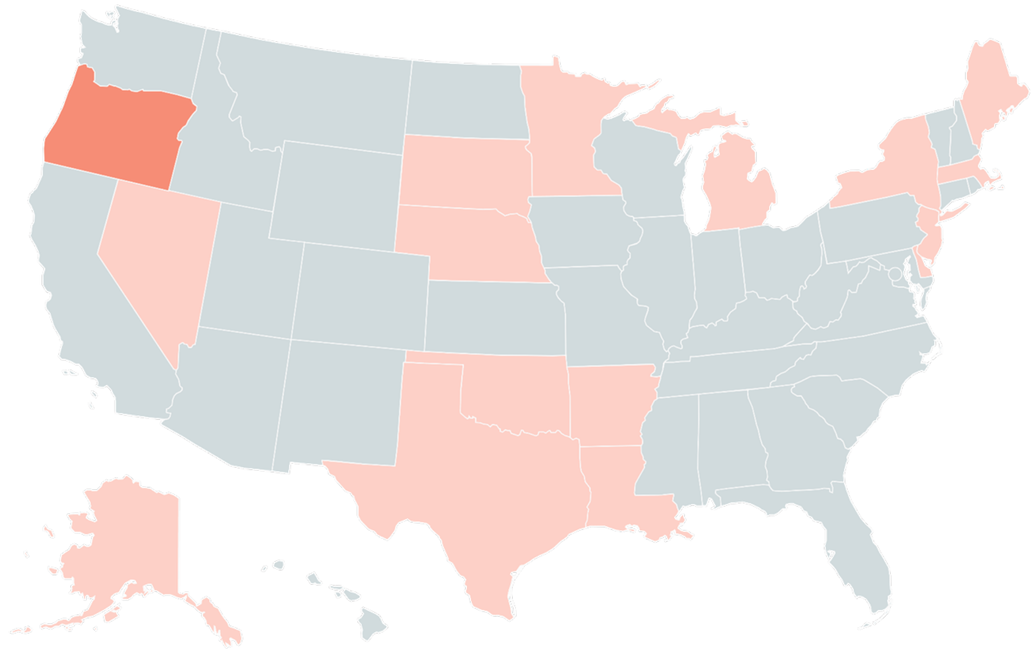
Valid informed consent…

… must be obtained in a certain way

… documentation must contain certain information

… must specify certain limits

ORS §192.538(5): A DNA sample from an individual that is the subject of a research project, other than an anonymous research project, shall be destroyed promptly upon completion of the project or withdrawal of the individual from the project, whichever occurs first, **unless the individual or the individual's representative directs otherwise by informed consent.**



Participant Rights: Privacy

Certificates, FOIA, and State Laws

- Withholding
- Confidentiality
- Valid Disclosures

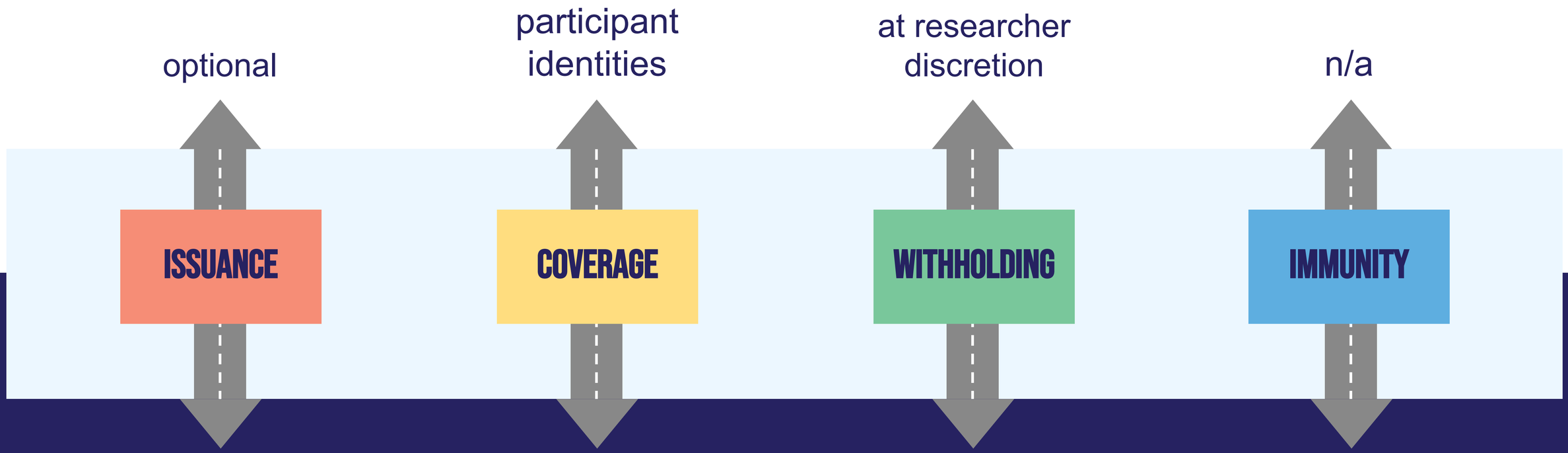
CERTIFICATES OF CONFIDENTIALITY

42 U.S.C. § 241(D)

- Applies to identifiable, sensitive information collected during the course of federally-funded research
- Ensures limited disclosures to protect participant identities

Overhauled by the 21st Century Cures Act

BEFORE



AFTER

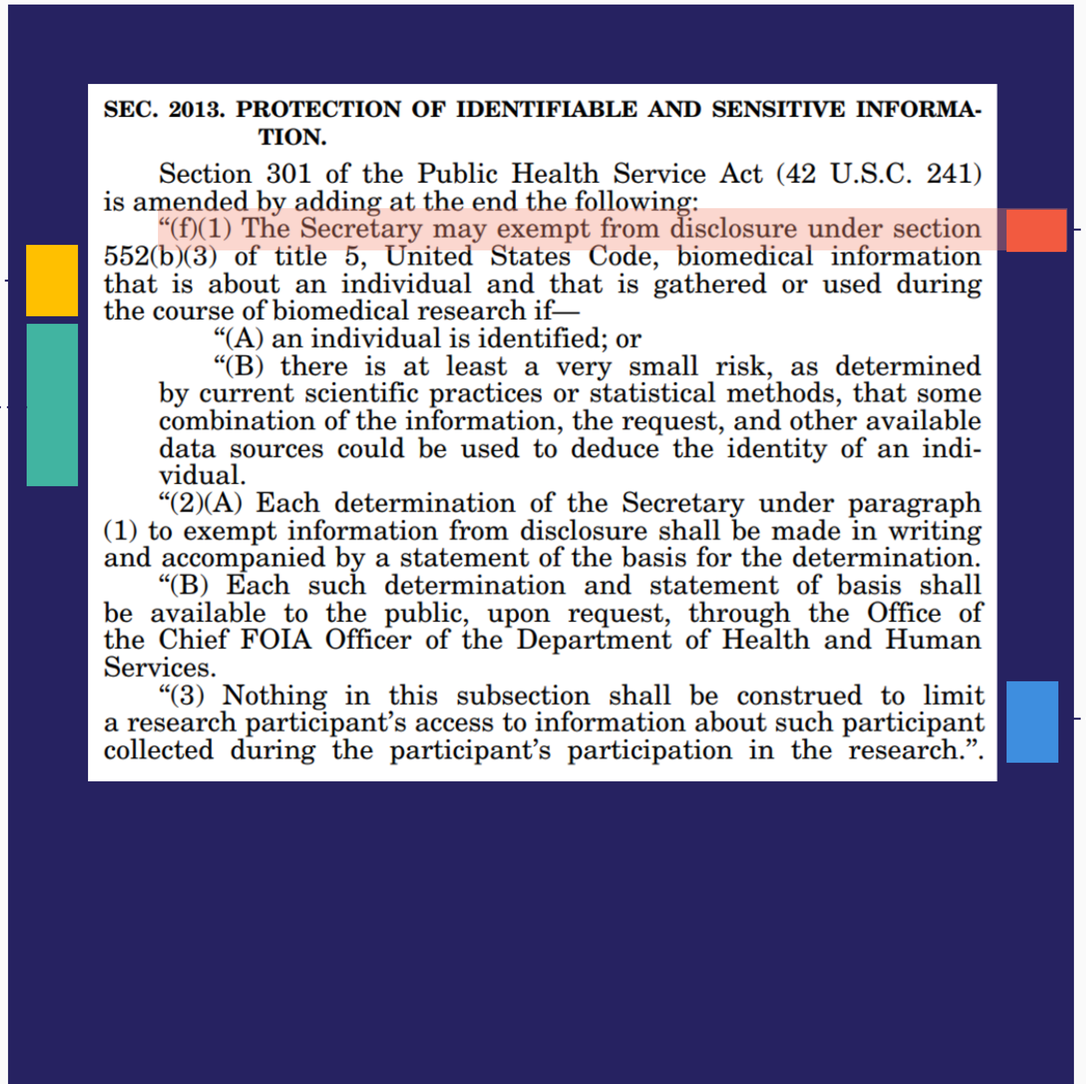
FOIA Type 3 Exemption Statute | 42 U.S.C. § 241(f)

Specific to biomedical research information

RELEVANCE

COVERAGE

Covers identifiable and ***potentially*** identifiable information



SEC. 2013. PROTECTION OF IDENTIFIABLE AND SENSITIVE INFORMATION.

Section 301 of the Public Health Service Act (42 U.S.C. 241) is amended by adding at the end the following:

"(f)(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5, United States Code, biomedical information that is about an individual and that is gathered or used during the course of biomedical research if—

"(A) an individual is identified; or

"(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

"(2)(A) Each determination of the Secretary under paragraph (1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

"(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

"(3) Nothing in this subsection shall be construed to limit a research participant's access to information about such participant collected during the participant's participation in the research.".

DISCRETION

Leveraged **at the discretion** of the Secretary of HHS

EXEMPTION

Does not interfere with individual's access to information about themselves

Privacy and Confidentiality | Additional Protections in State Laws

ARS §12-2802(A): Except as otherwise provided in this article, genetic testing and information derived from genetic testing are **confidential and considered privileged to the person tested**…

Privacy and Confidentiality | Additional Protections in State Laws

NRS §629.181(1): Except as otherwise provided in subsection 2, the State Board of Health shall by regulation:

…

(b) Prescribe a form for use in obtaining the informed consent of a person. The form must include:

(1) **Information relating to the use and confidentiality of the genetic information** of the person set forth in NRS 629.101 to 629.201, inclusive;

Privacy and Confidentiality | Stipulations for Valid Disclosures

Certificates of Confidentiality

42 U.S.C. § 241(d)(1)(C): The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

Privacy and Confidentiality | Stipulations for Valid Disclosures

State Laws

LRS 22:1023(C)(2): To be valid, an authorization for disclosure of genetic information shall:

…

(f) State the **date upon which the authorization will expire**, which in no event shall be more than sixty days after the date of the authorization.

…

(h) Include a statement that the authorization **shall be invalid if used for any purpose other than the described purpose for which the disclosure is made**.

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Privacy and Confidentiality | Stipulations for Valid Disclosures

State Laws

FS §760.40(3): A person who performs DNA analysis or receives records, results, or findings of DNA analysis must provide the person tested with notice that the analysis was performed or that the information was received. The notice must state that, **upon the request of the person tested, the information will be made available to his or her physician.**

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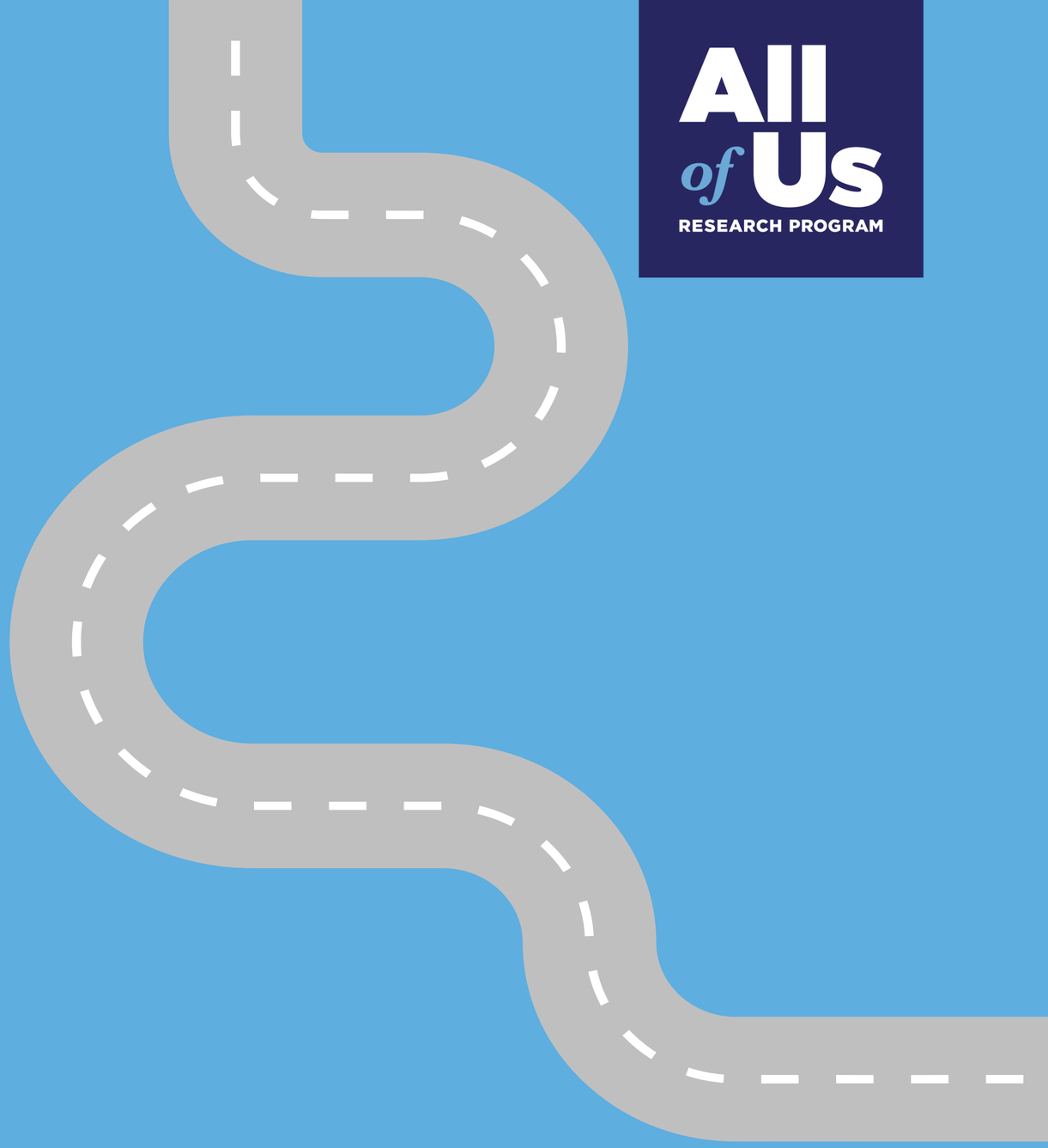
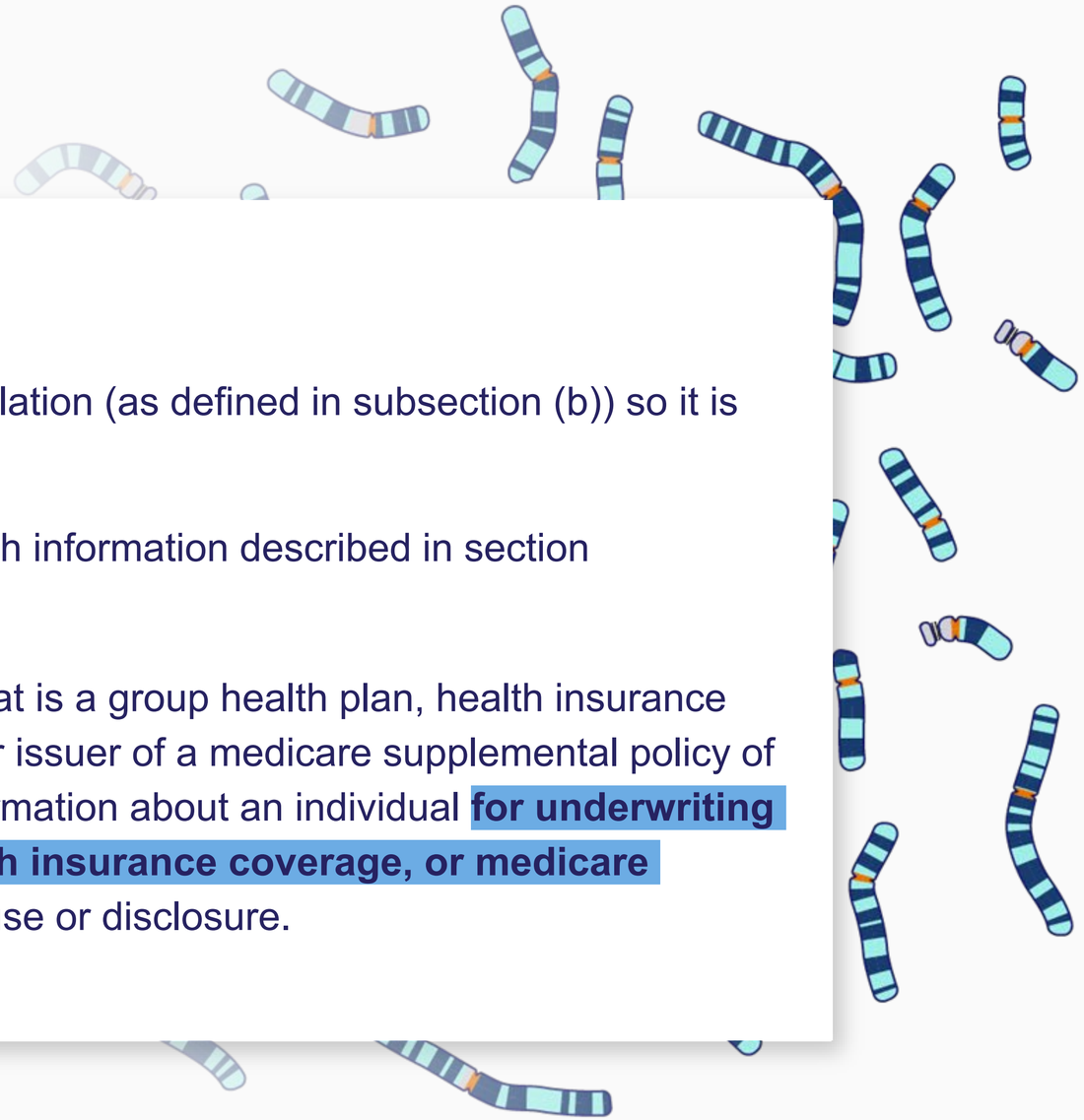
Participant Rights: Nondiscrimination

GINA and State Laws

- Insurance



Genetic Information Nondiscrimination Act



42 U.S.C. § 1320d-9:

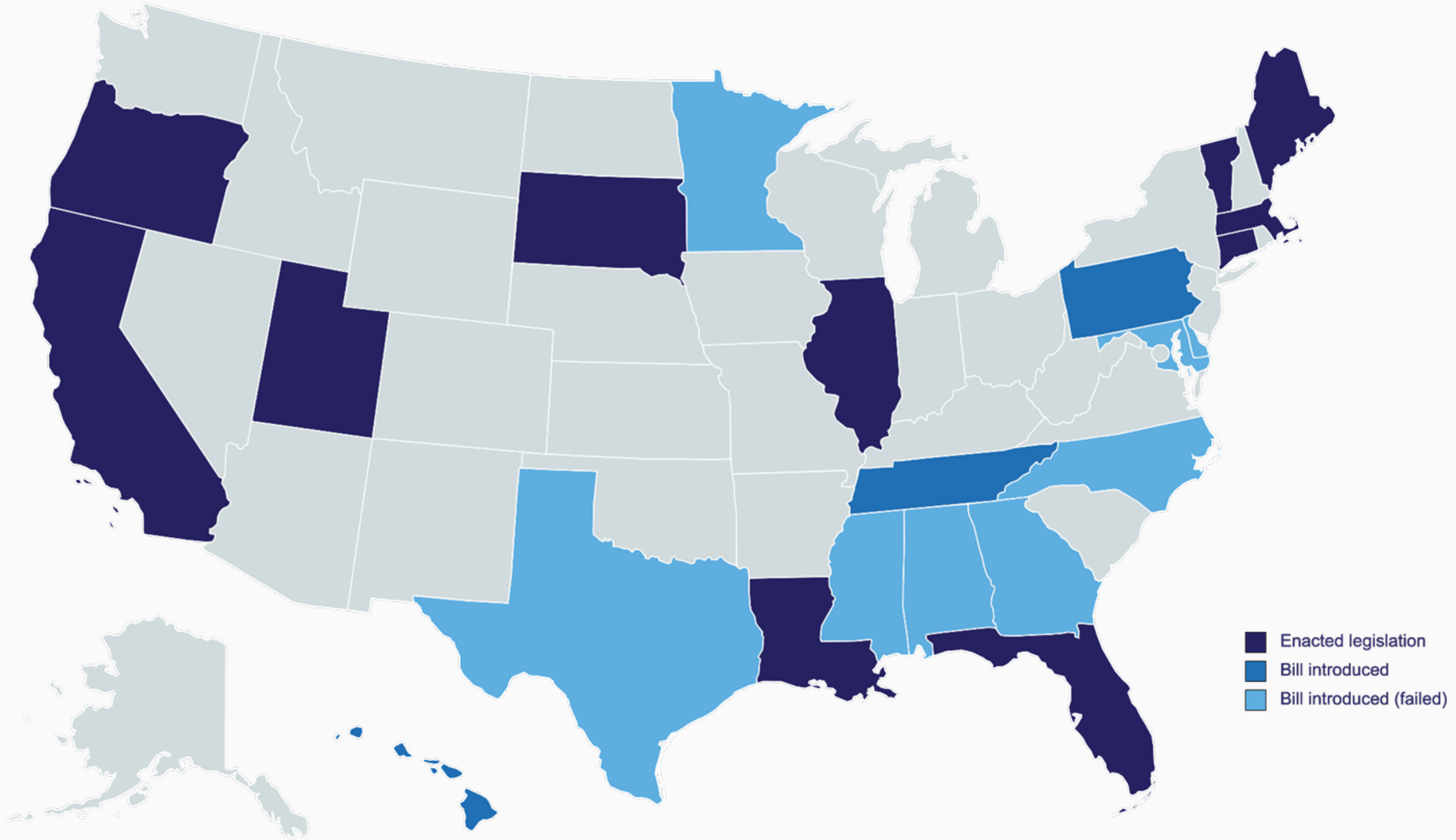
(a) In general

The Secretary shall revise the HIPAA privacy regulation (as defined in subsection (b)) so it is consistent with the following:

(1) Genetic information shall be treated as health information described in section 1320d(4)(B) of this title.

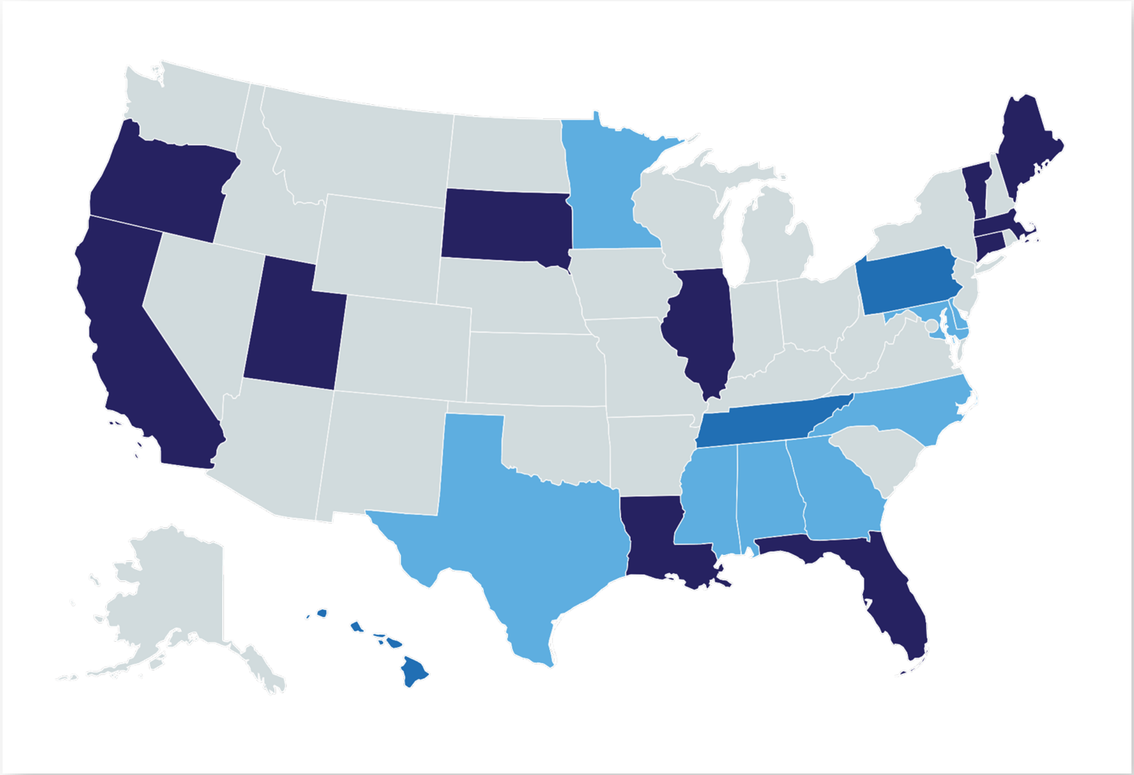
(2) The use or disclosure by a covered entity that is a group health plan, health insurance issuer that issues health insurance coverage, or issuer of a medicare supplemental policy of protected health information that is genetic information about an individual **for underwriting purposes under the group health plan, health insurance coverage, or medicare supplemental policy** shall not be a permitted use or disclosure.

States Limiting Insurance Use of Genetic Information



Generalities Regarding State-Level Protections

- Limit to **certain types of test providers** (e.g. DTC)
- Limit to **certain types of insurance** (e.g. life insurance, disability, long-term care)
- Limit **certain uses** (e.g. insurance underwriting, coverage decisions)
- Limit **certain insurer behaviors** (e.g. requiring genetic testing, asking for test results)
- Confer **certain responsibilities** (e.g. mandatory withholding)



Takeaways

1) Relevant laws exist at both the federal and state levels (the latter often building on the former)
2) There's a lot of dynamism in relevant laws, requiring potentially frequent updates to process implementation
3) The good news is that lots of states copy each other
4) Informed consent for genetic testing has state-specific requirements (but none that are mutually exclusive)
5) Privacy and confidentiality protections depend on a variety of factors, including data ownership and participant locality
6) The patchwork of state laws makes it really difficult to explain potential risks of testing related to insurability

All of Us
RESEARCH PROGRAM

Questions?

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@AllofUsResearch
#JoinAllofUs

AllofUs.nih.gov

NIH
National Institutes of Health

All of Us Solutions

The *All of Us* Research Program | Diversity at Scale

Diversity of Resources: Deliver a national resource of deep **clinical, environmental, lifestyle, & biological data** from one million or more participants who are consented & engaged to provide data on an ongoing, longitudinal basis

Diversity of Participants: Reflect the broad diversity of the U.S.—**all ages, races, ethnicities, sexes, genders, SESs, geographies, & health and disability statuses**—and over-recruit those historically underrepresented in biomedical research

Diversity of Researchers: Build the tools & capabilities that make it accessible to the public and easy for researchers—**from citizen and community scientists to scientists from premier university labs**—to make discoveries using *All of Us*

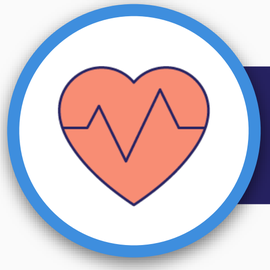
The *All of Us* Research Program | Comprehensive Research Resources

Participant Surveys

- The Basics
- Lifestyle
- Overall Health
- Personal & Family Medical Hx
- Health Care Access & Utilization
- COVID-19 Participant Experience
- Mental Health
- Social Determinants of Health

Electronic Health Records

- Medical Records
- *Claims Data*
- *Pharmacy Data*
- *Vision and Dental Records*



Physical Measurements

- Blood Pressure
- BMI
- Heart Rate
- Height
- Hip Circumference
- Waist Circumference
- Weight

Biospecimens

- Blood
- Urine
- DNA (from blood or *saliva*)
- *Saliva*
- *RNA*

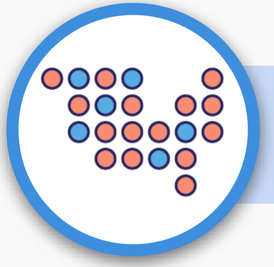
Mobile/Wearable Tech

Assays

- COVID Serology
- *HbA1c*
- *Heavy Metals*

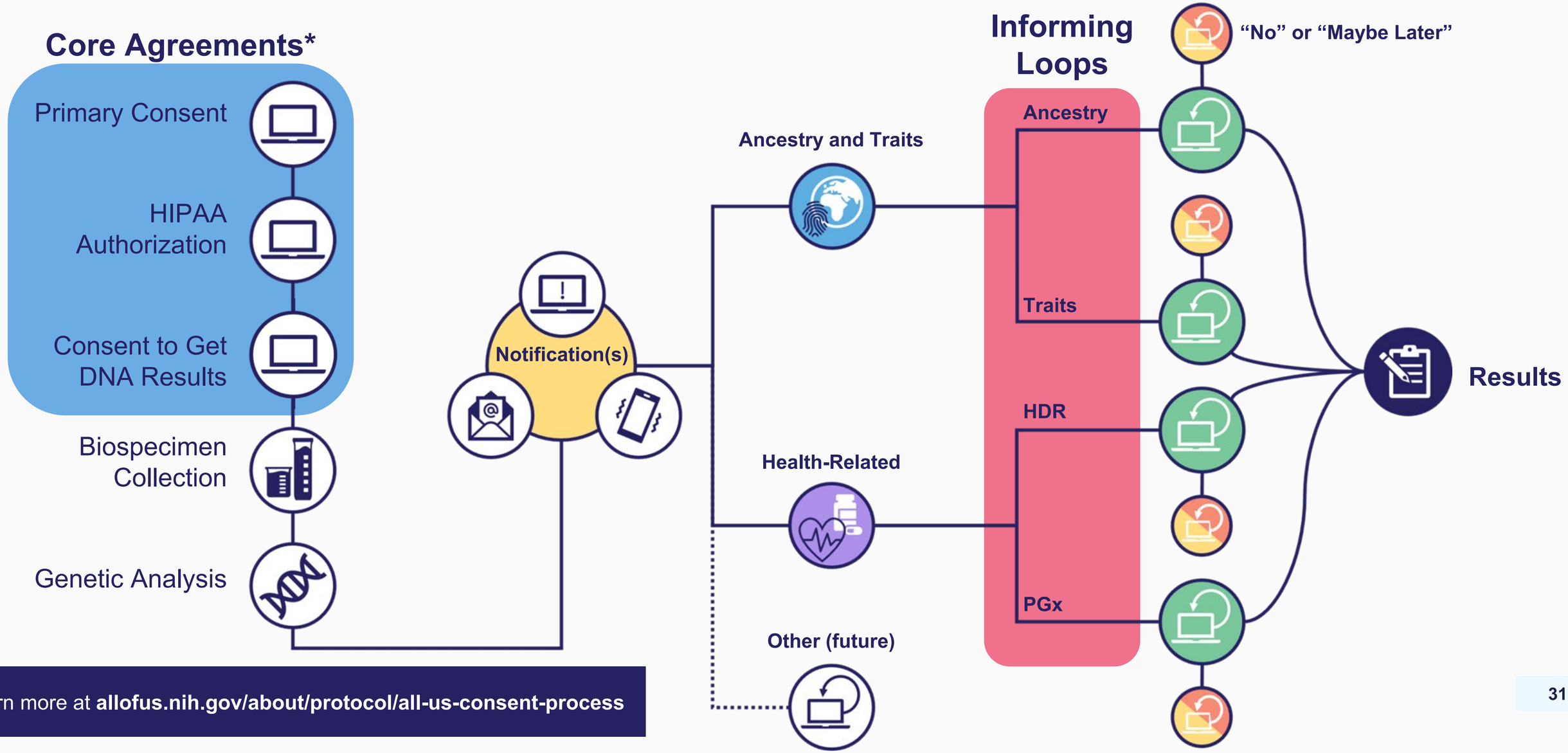
Omics

- WGS
- Arrays
- *Other Omics*



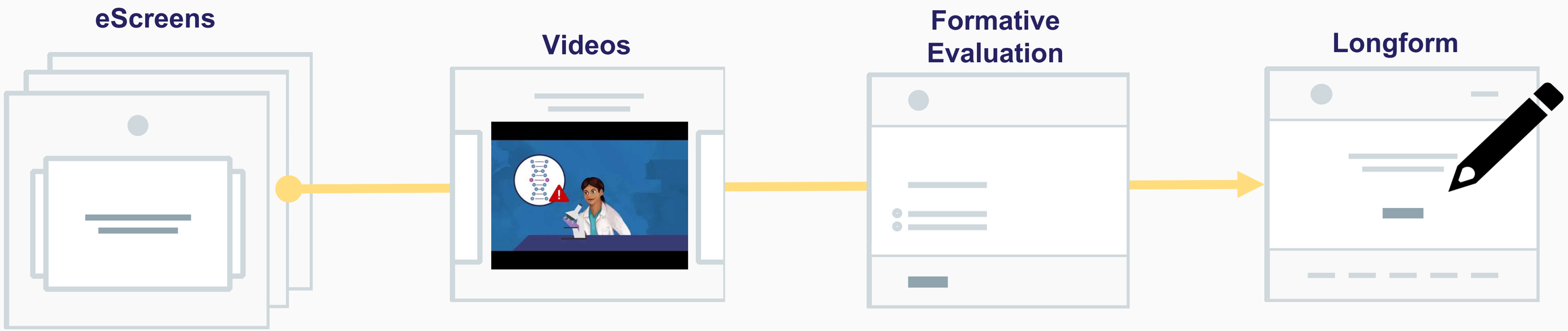
Geospatial/Environmental Data

The *All of Us* Consent Process | Overview



learn more at **allofus.nih.gov/about/protocol/all-us-consent-process**

The *All of Us* Consent Process | Consent Modules



learn more at **allofus.nih.gov/about/protocol/all-us-consent-process**

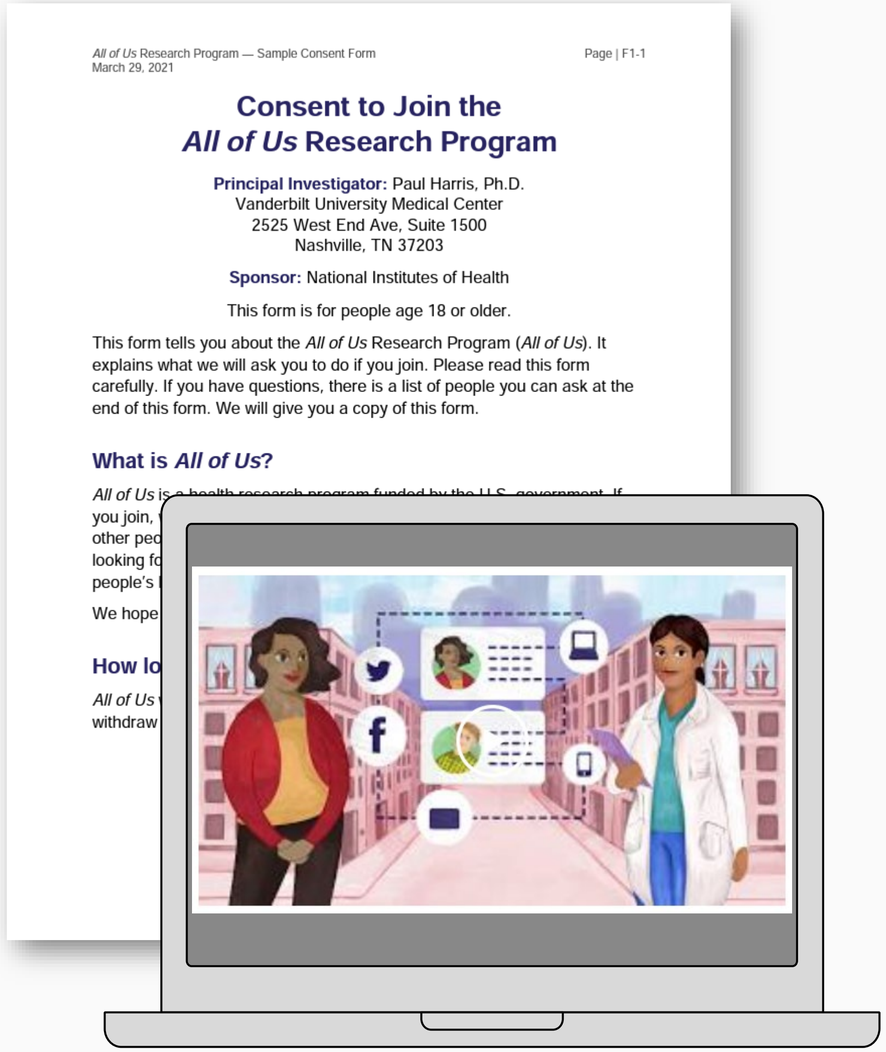
Primary Consent | Setting the Stage

PURPOSE

Orient participants to the *All of Us* Research Program overall and give them information salient to projected risks and benefits of participation; set expectations about participation into the future.

CHALLENGES

- State laws and regulations
- Changes (program operations, technological developments, social context) → Threshold for re-consent



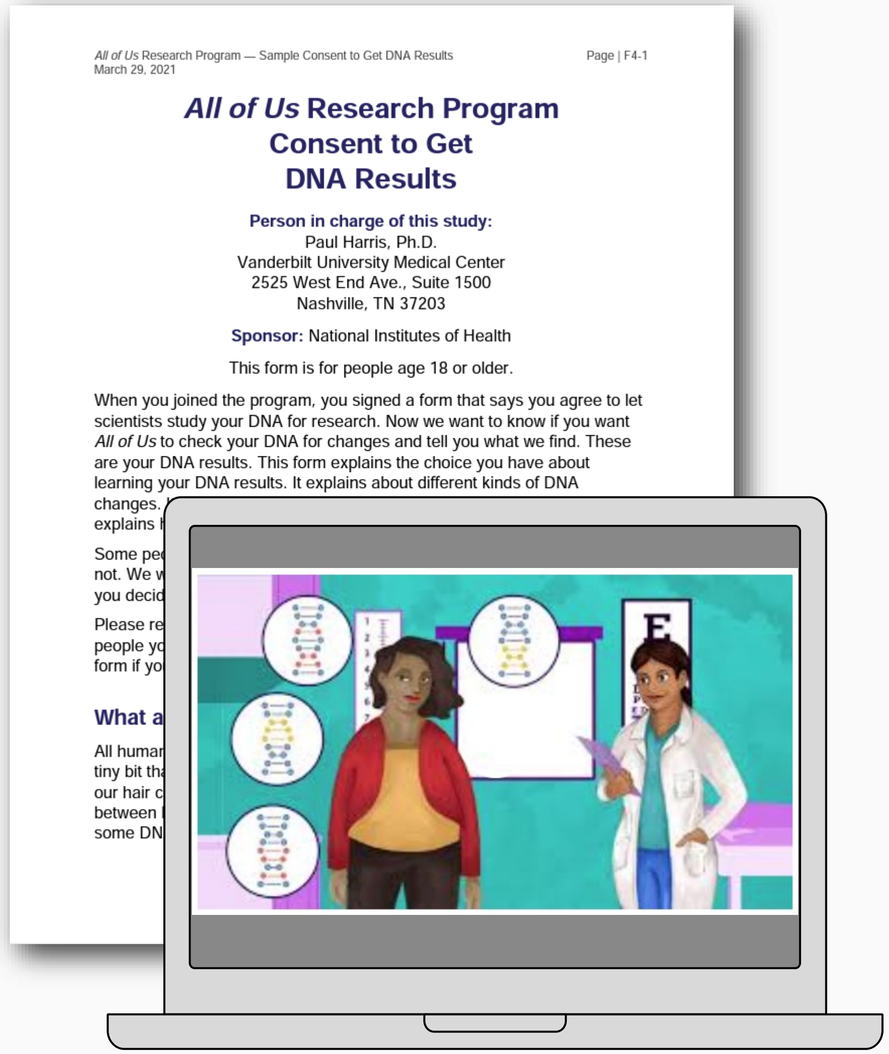
Consent to Receive DNA Results | Consenting to Return of Information

PURPOSE

Describe the process and limitations of return of genetic and genomic results; set realistic expectations for participants about what they can expect to receive; explain potential risks and benefits to learning such results

CHALLENGES

- Different reason for obtaining consent
- Rapidly changing, complicated science
- Social and cultural implications
- Inconsistent legal protections



yes means yes.

everything else means no.

Informing Loops | Just-in-Time Information

Overall potential risks and benefits of learning DNA results

General overview of DNA, variants, limitations of current knowledge

Legal information, disclaimers, and resources

Choice to be offered for each DNA result type in the future (as available)

Consent

Shared Emphasis on…

Participant Choice

Research Results

Informing Loops

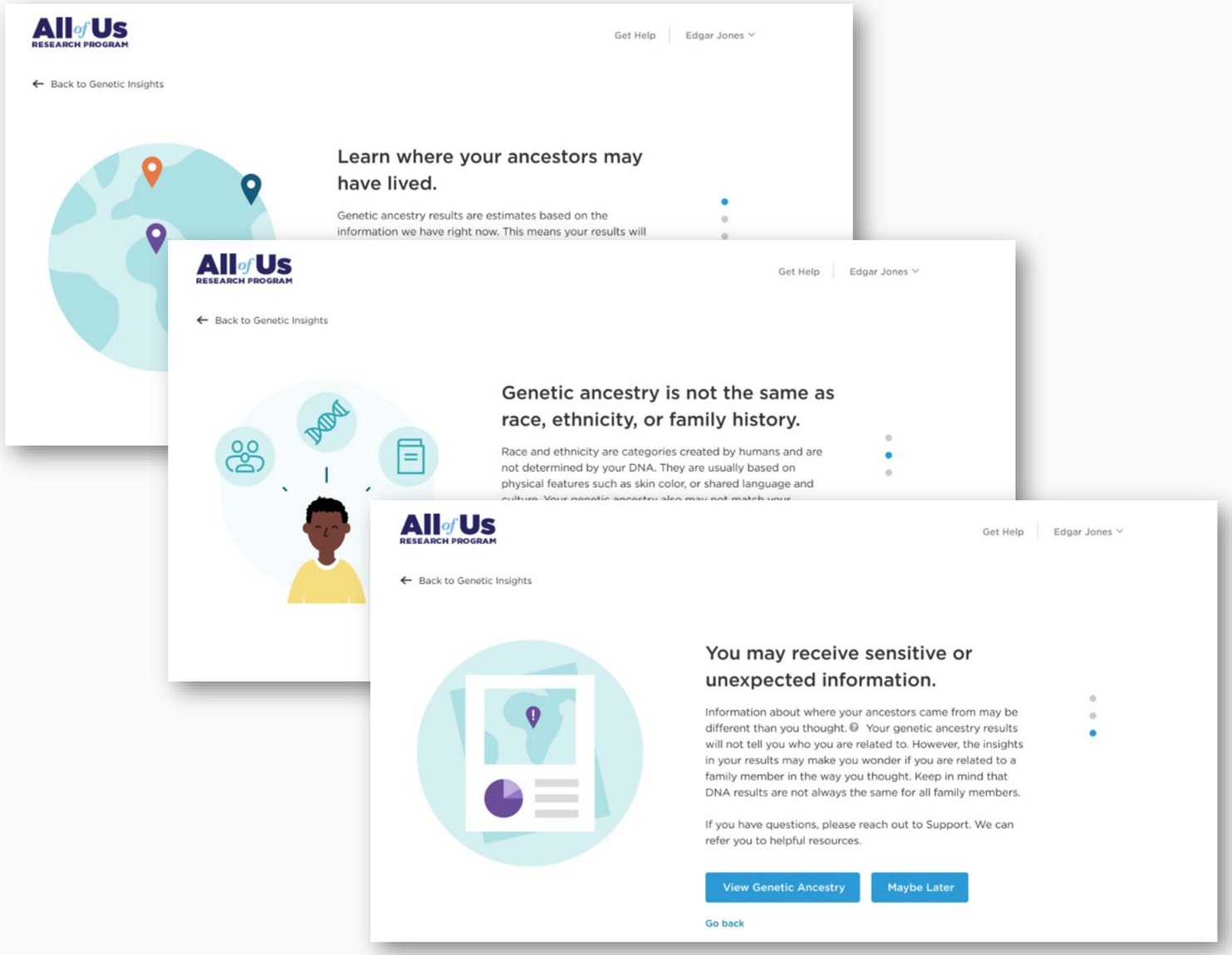
Potential risks and benefits of that specific type of DNA result

Examples of the type of information one could learn from that type of DNA result and limitations of those results

Link to Learning Center to help participants find more information

Choice to receive that specific type of result

Informing Loops | Just-in-Time Information



- Set participant expectations
- Explain limitations of the science
- Provide additional information (?)
- Integrate paths to assistance

Consent | Integrated Assistance

Are you ready?

If you have questions along the way

We're in this together. We're always here to answer any questions you may have about *All of Us*.

Contact our Support Center

Talk directly to a person on our team.

1-844-842-2855

Chat now

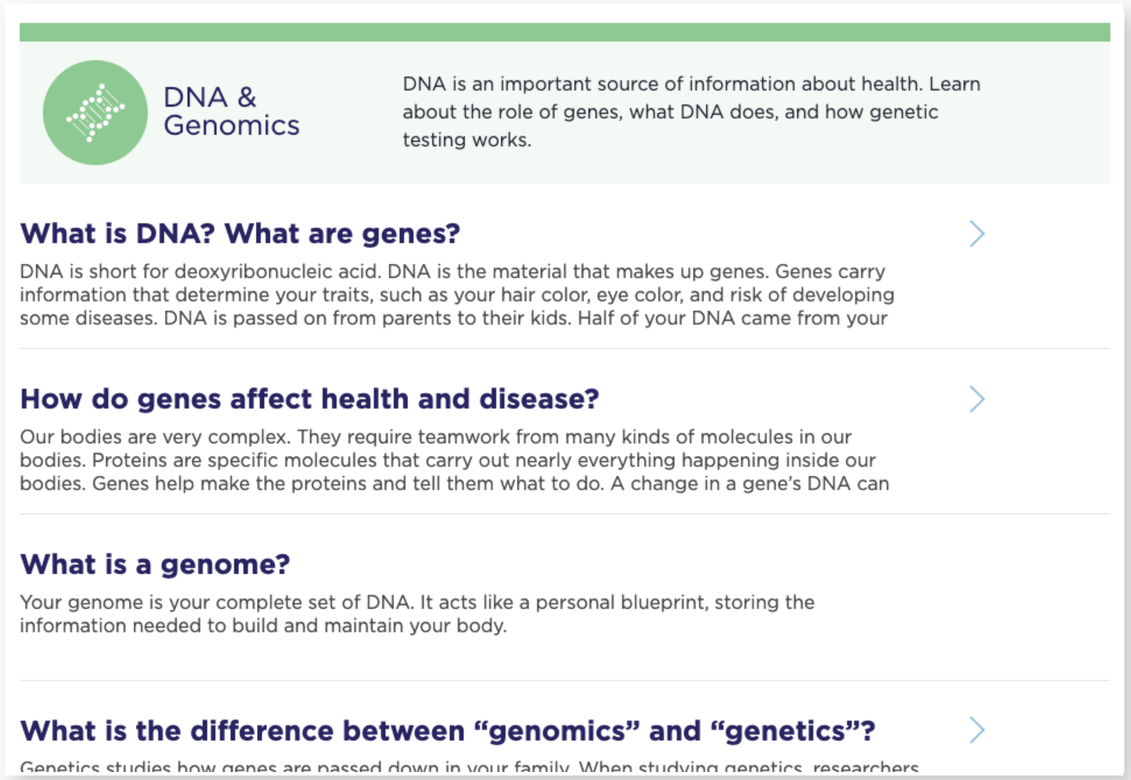
Send us a message. We'll respond within 48 hours

help@joinallofus.org

Toll-free TTY-based Telecommunications Relay Service is available by dialing 711.

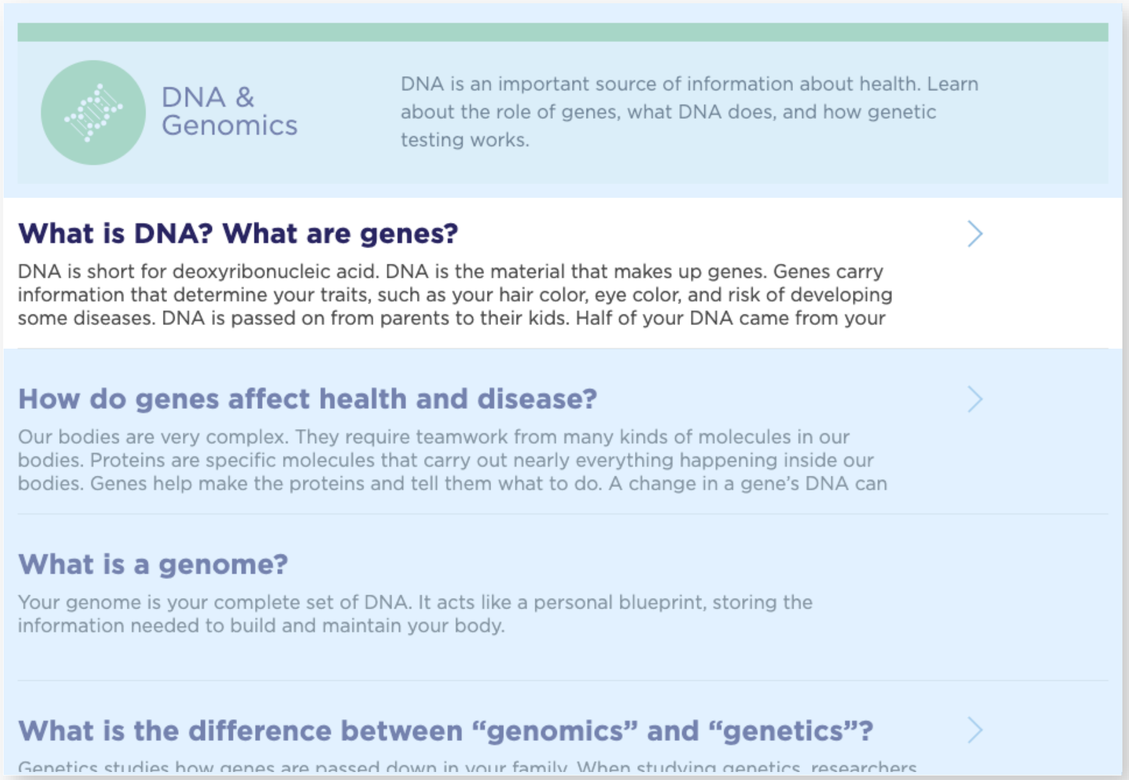
Supported Decision Making | *All of Us* Education and Decision Tools

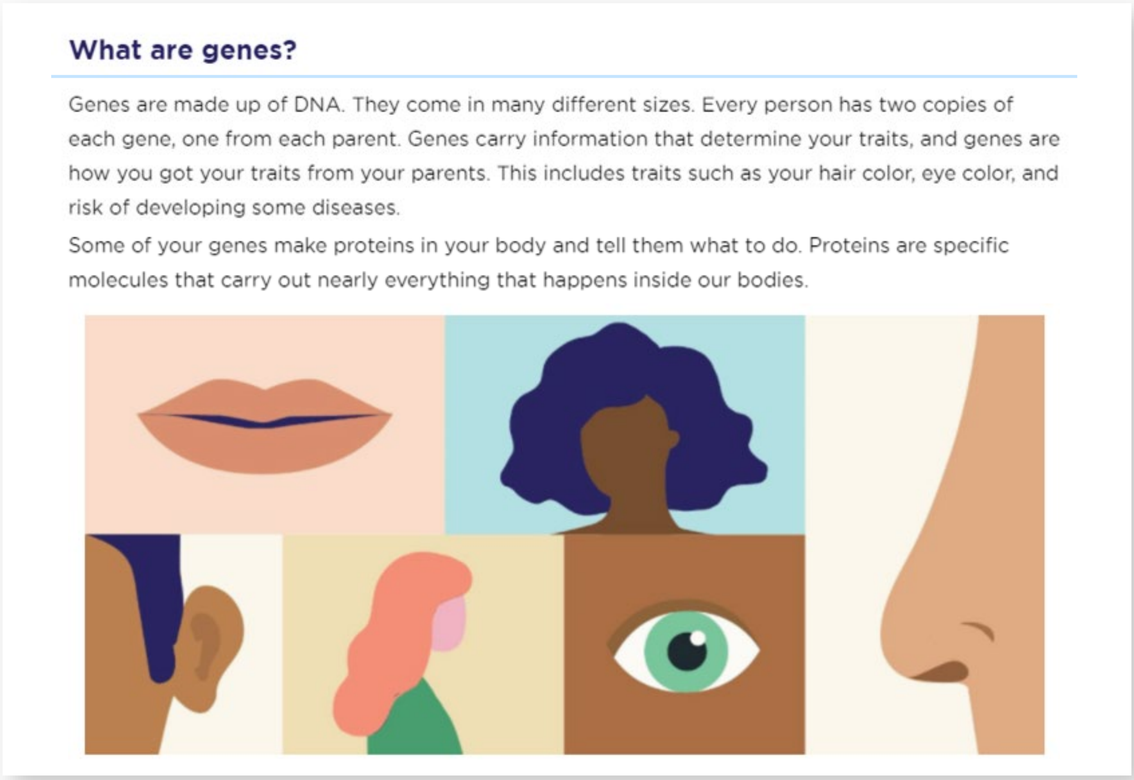
Participant Learning Center



Supported Decision Making | *All of Us* Education and Decision Tools

Participant Learning Center

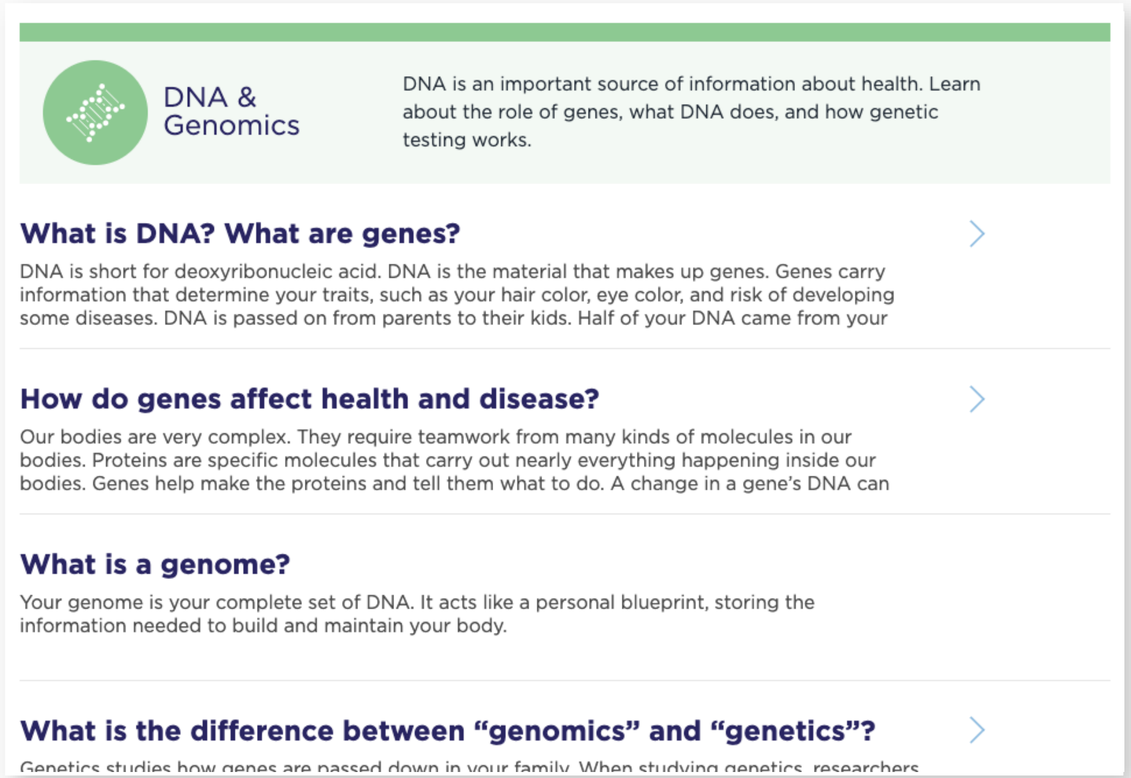




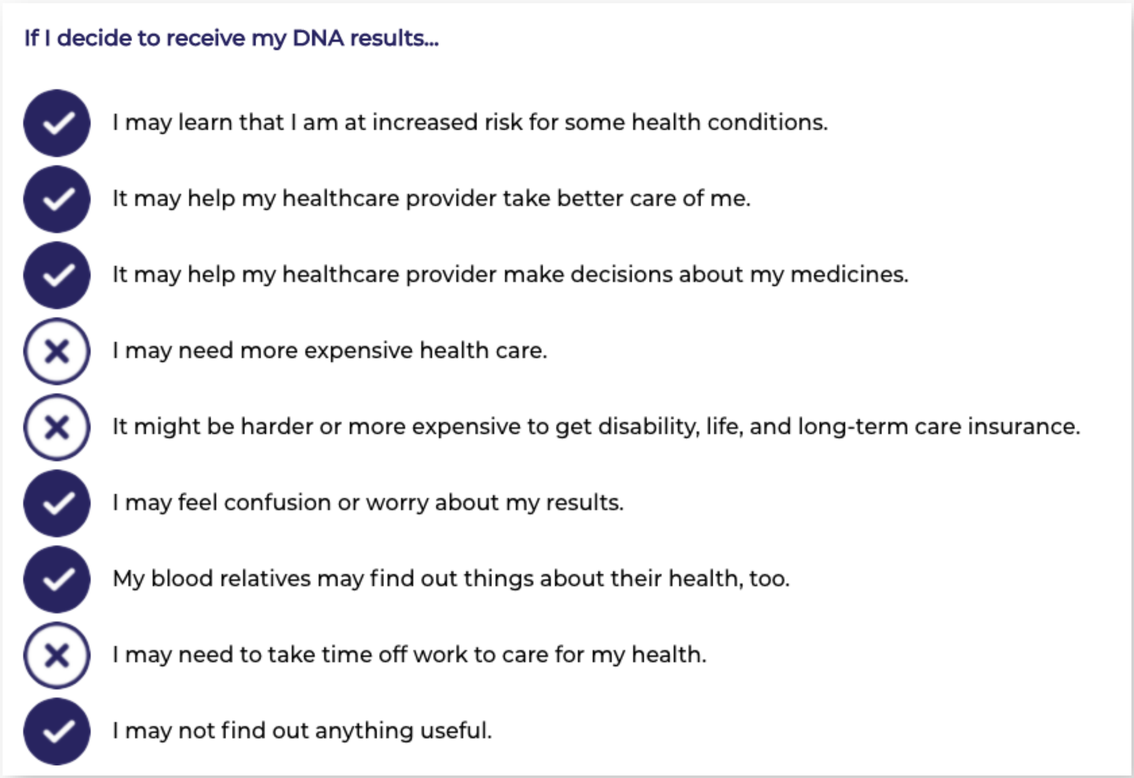
Video from University of Utah: http://learn.genetics.utah.edu/content/basics/proteins

Supported Decision Making | *All of Us* Education and Decision Tools

Participant Learning Center



Decision Support Tool



All of Us
RESEARCH PROGRAM

Questions?

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