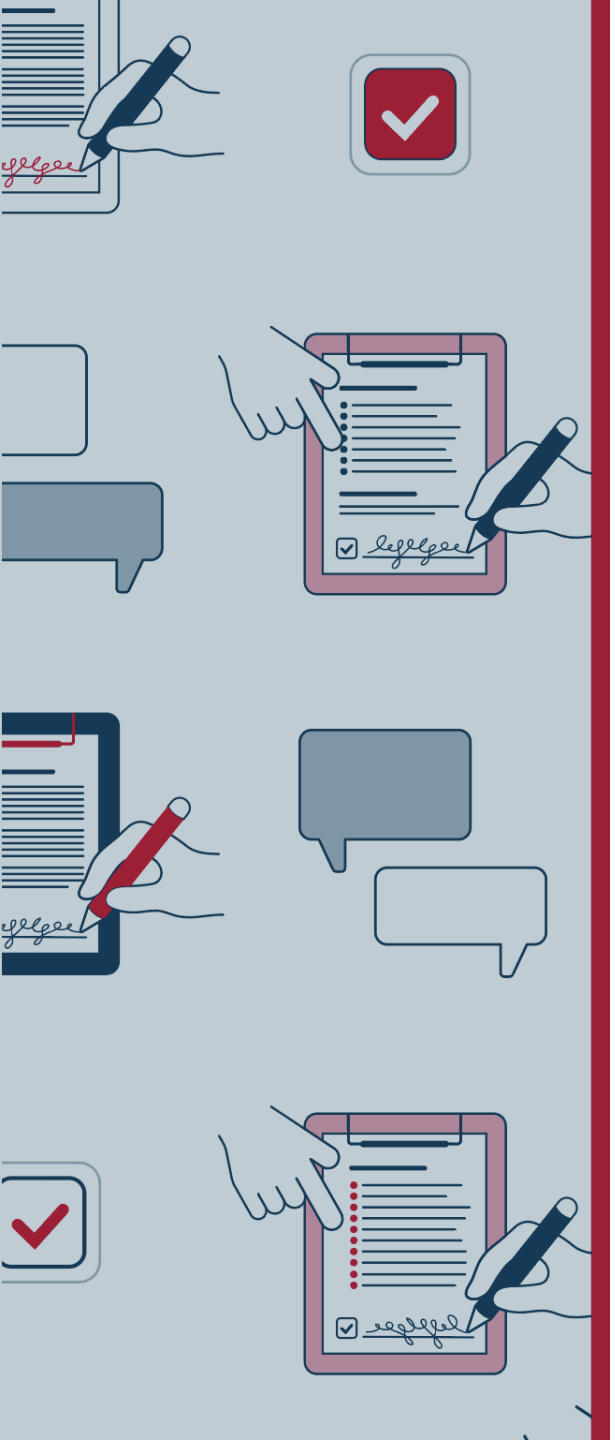


MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Designing Impactful Informed Consent Processes

That Empower Participants

10/10/2024

Welcome!

Thank you for joining this webinar today!

Tips for today's session

- Use the Q&A – we will do our best to answer live.
- Feel free to use the Closed Captioning

Disclaimers

The opinions contained are those of the speakers and are not intended to represent the position of Brigham and Women's Hospital, Harvard University, or any other entity.

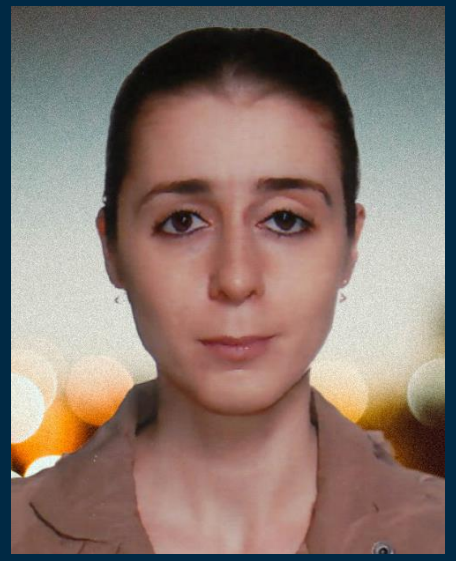
The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions and government entities (see www.MRCTCenter.org), as well as by grants.

We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results, and deliverables.

Session Overview

- Welcome and Introductions
- Presentations:
  - MRCT Center's patient-centric Clinical Research Glossary
  - The Office of Human Research Protection's training to support communication of consent information
  - All of Us Research Program's innovative approaches to informing participants and obtaining empowered consent
- Moderated discussion and Q&A
- Wrap up and thank you.

Meet the Speakers

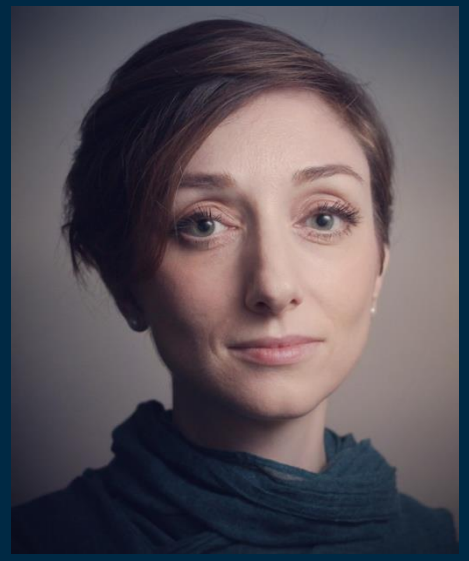


Marianna Azar, MA
Program Specialist

Division of Education and Development,

Office for Human Research Protections (OHRP),

U.S. Department of Health and Human Services



Katherine Blizinsky, PhD
Director of Policy

All of Us Research Program

Moderated by:

Sylvia Baedorf Kassis, MPH
Program Director

MRCT Center

The MRCT Center

The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics, and regulatory environment of clinical trials.

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

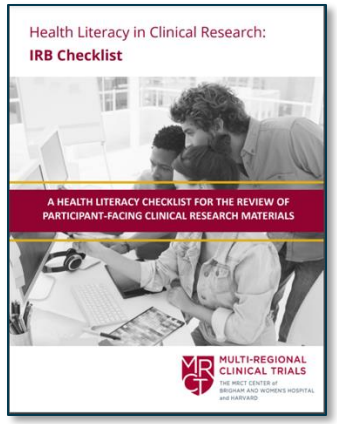
Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

www.mrctcenter.org

The MRCT Center and Health Literacy

2017

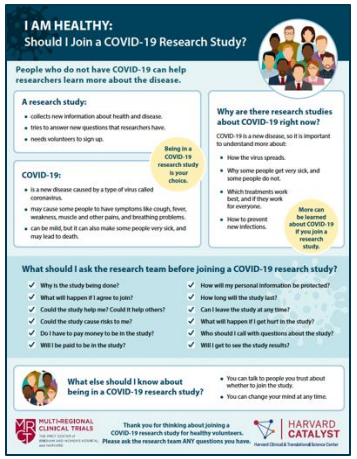


2019

Glossary Pilot Project

2018 - 2019

2020



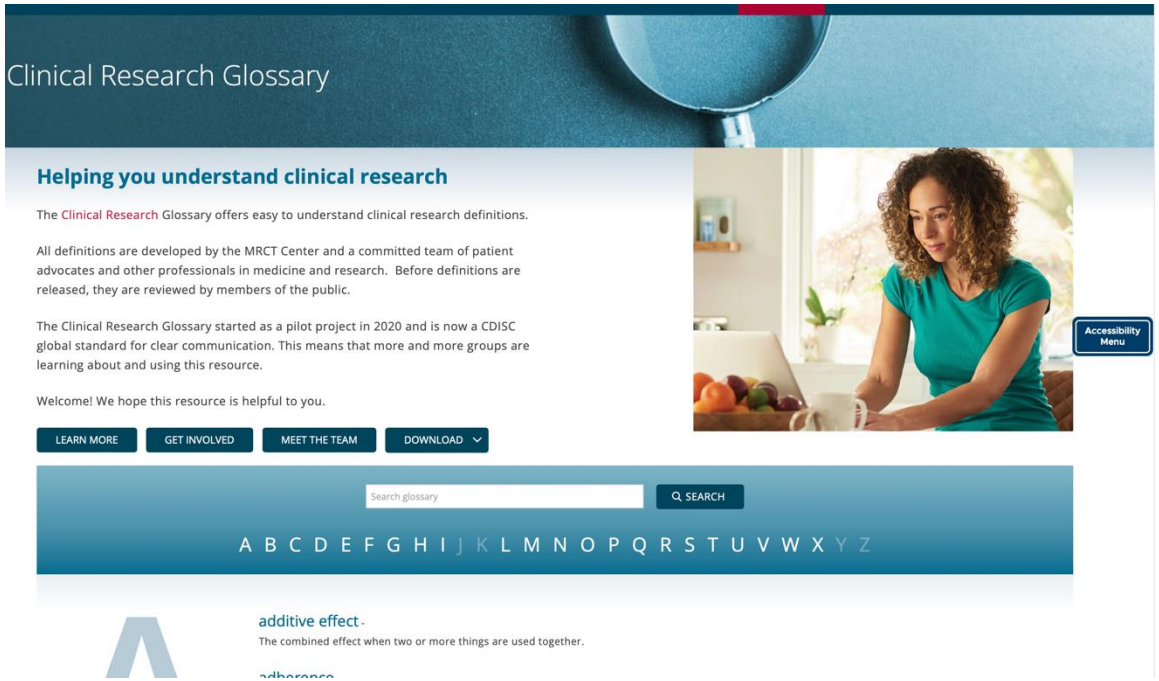
The Clinical Research Glossary Timeline

2021 **2022** **2023** **2024** **V 2.0**

Clinical Research Glossary Expansion Efforts

Baedorf Kassis S, White S, & Bierer B. (2022). Developing a consensus-driven, plain-language clinical research glossary for study participants and the clinical research community. *Journal of Clinical and Translational Science,* 1-20. doi:10.1017/cts.2022.12

Clinical Research Glossary Highlights



- Living, governed resource
- Includes 187 words – new words continually developed
- Especially developed images
- Special section especially for people thinking about joining a study
- Downloadable as Excel and PDF
- All content useable and shareable under the MRCT Center Creative Commons License
- Referenced in the CDISC/NCI Thesaurus

…. and **participant-centered**!

Home | Glossary | phase

phase

cdisc

A step in the overall clinical research process to test a new drug, device, or treatment.

Example of *phase* in a sentence

Research is done in *phase*s to make sure a study treatment is safe and then whether it works before it is approved.

More Info

A phase is a step in the research process. Phases of research studies build on each other and each phase has a separate goal.

Phase 1 studies are usually the first to enroll humans and test for safety.

Phase 2 studies test if the drug, device or treatment works.

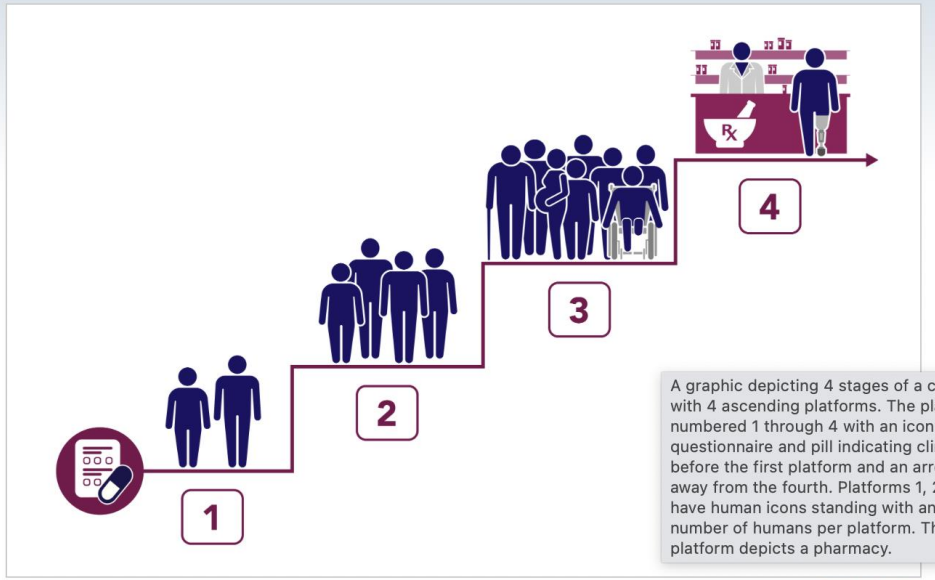
Phase 3 studies compare the study treatment to the usual, standard treatment.

Phase 4 studies continue to collect data after a study treatment is approved. These are sometimes called post-marketing studies.

Other info to think about when joining a study

You may see the term "phase" when you are reading about clinical trials.

Before you enroll in a clinical trial you may want to ask about what phase the study is in. You may also want to know more about the information the study team already has about the risks and benefits of the study treatment that is being tested.



A graphic depicting 4 stages of a clinical trial with 4 ascending platforms. The platforms are numbered 1 through 4 with an icon of a questionnaire and pill indicating clinical trial just before the first platform and an arrow pointing away from the fourth. Platforms 1, 2 and 3 all have human icons standing with an increased number of humans per platform. The fourth platform depicts a pharmacy.

Download image

Related Words

clinical research

clinical trial

preclinical study

Other Resources

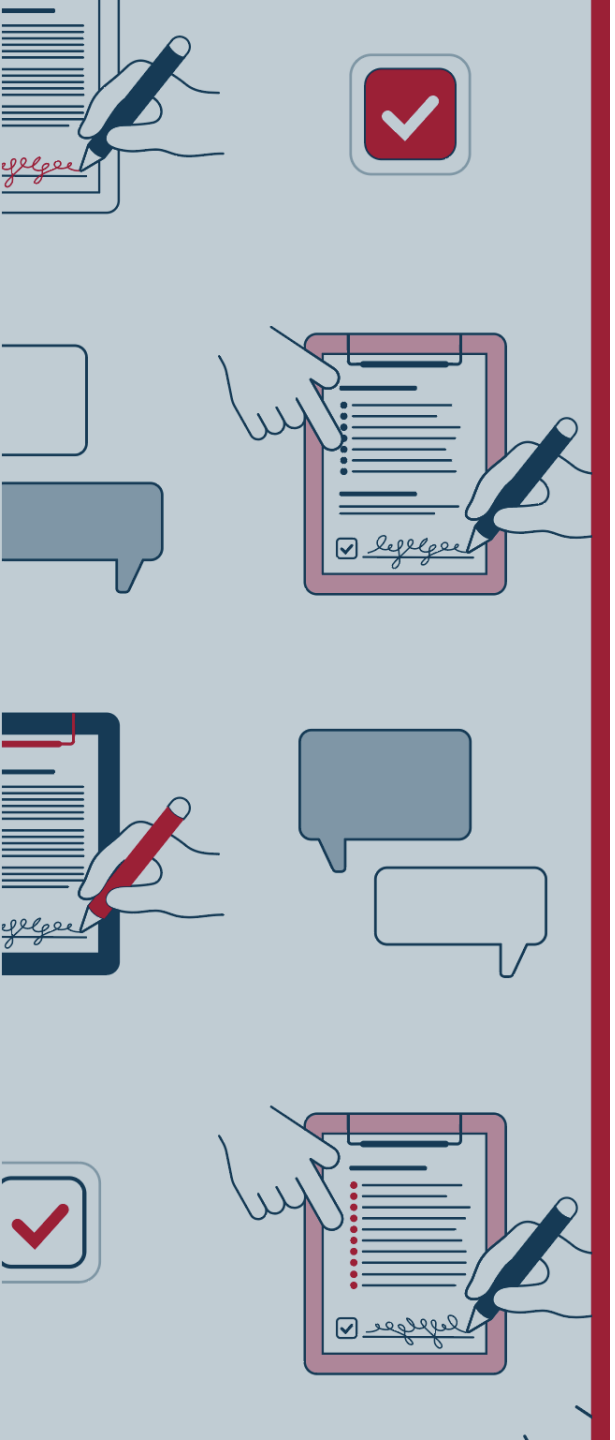
NCI Thesaurus

FDA - The Drug Development Process, Step 3: Clinical Research

If you know of other resources we should link to to help explain this word, please contact us.

Version 2.0 September 2024

Was this information easy to understand? Yes No



Marianna Azar, MA

OHRP's Interactive Participant-Centered Informed Consent Training

Marianna Azar, Program Specialist, DED
HHS Office for Human Research Protections (OHRP)
Division of Education and Development (DED)

October 10, 2024

OASH | Office for Human Research Protections

Disclaimer

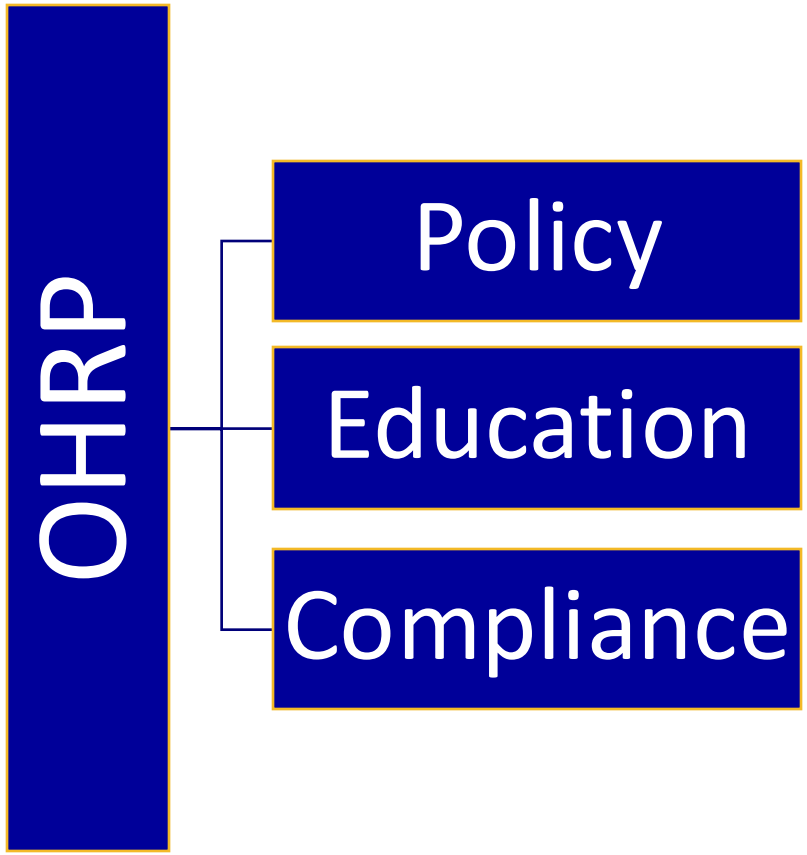
The opinions expressed are those of the presenter and do not necessarily reflect the policy of the U.S. Department of Health and Human Services or the Office for Human Research Protections (OHRP).

For a complete and accurate description of the regulatory requirements, please refer to the text of the Common Rule available on OHRP's website.

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html

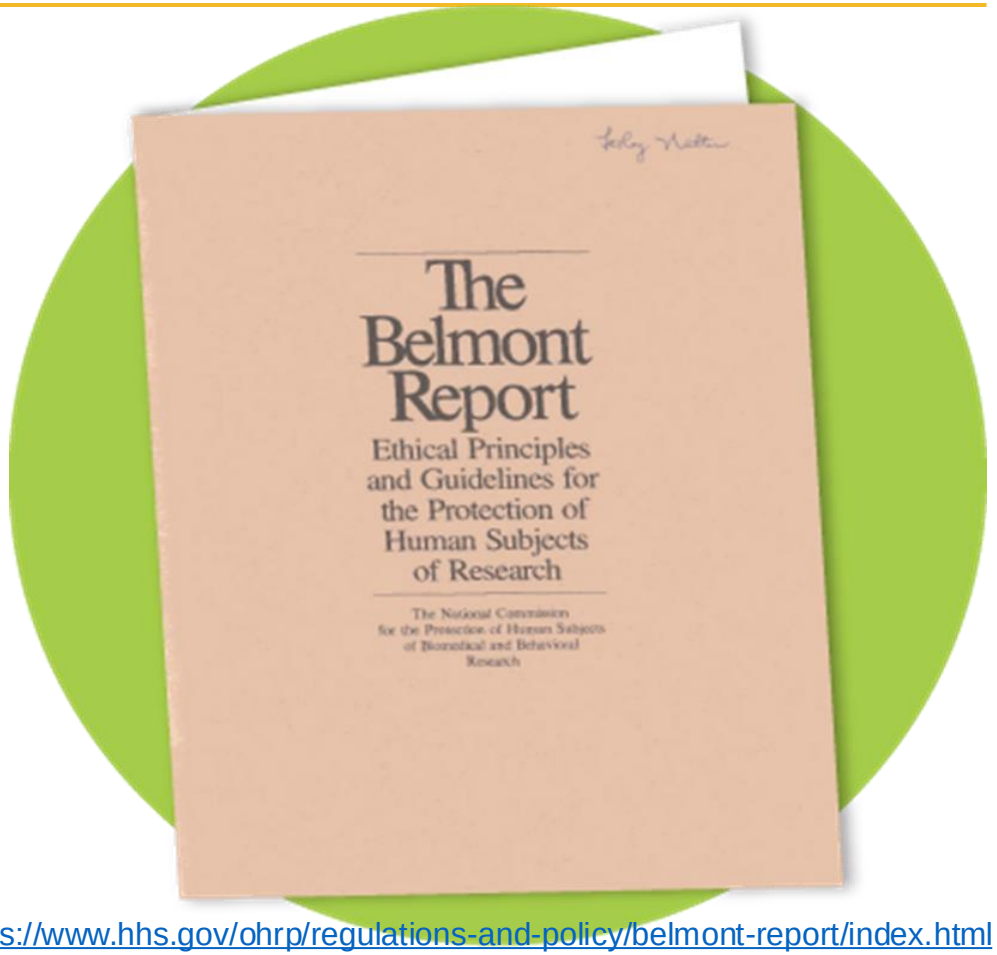
The Office for Human Research Protections (OHRP)

- Housed in the US federal Department of Health and Human Services (HHS) under the Office of the Assistant Secretary for Health (OASH).
- OHRP holds the regulatory authority for 45 CFR 46 and oversees all **HHS-conducted or supported *nonexempt human subjects research*** (regardless if also regulated by FDA)**.**
- OHRP leads and coordinates the effort for human research protections across federal agencies and departments.



The Underlying Ethics – Belmont Report's Principle of Respect for Persons

- Individuals decide for themselves according to their own values and opinions (autonomy)
  - ✓ Voluntariness
  - ✓ Informed decision making
- Those whose autonomy is compromised should be protected
  - ✓ Attention to undue influence and coercion
  - ✓ Additional protections



https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Applying ‘Respect for Persons’ Through ‘Informed Consent’

To respect someone is to give appropriate weight to the person’s opinions and choices.

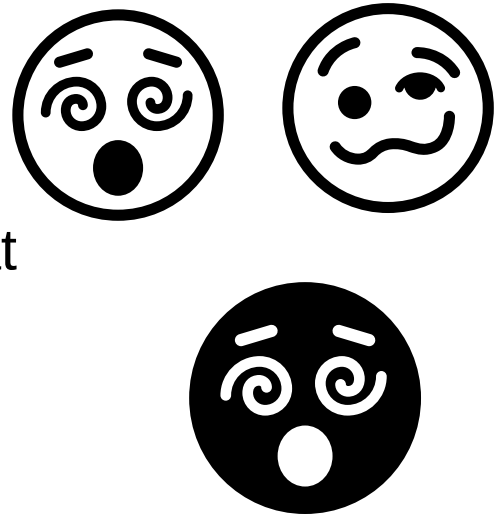
Seeking informed consent shows respect by ensuring potential participants have the information they need to make an informed decision about research participation.

Some of the Regulatory Requirements for Informed Consent - §46.116

- Provide information in understandable language.
- Provide information that a **reasonable person** would want to have in order to make an informed decision about whether to participate.
- Begin with the **key information** that is most likely to assist a prospective subject in understanding why one might or might not want to participate.
- Present information in sufficient detail and organized & presented in a way that does not merely provide lists of isolated facts, but rather facilitates understanding of the reasons why one might or might not want to participate.

Fulfilling the Purpose of Informed Consent

Consent forms should **empower potential participants** to make informed decisions.



HOW?

Create **participant-centered consent forms —** that is, forms that are **understandable** and **meaningful** to your potential participants.

WHY?

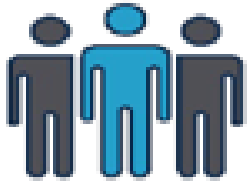
Unclear consent forms risk **undermining our relationships** with participants and **hampering study recruitment and retention**.

Common Problems with Consent Forms

- Too much information and unnecessary details.
- Overly complex language.
- Dense formatting with minimal white space.
- Written for scientific reviewers.
- Disjointed content copied directly from research protocols or grant applications.
- Complicated legal-sounding language in passive voice.

How Can We Do Better?

Know Your Audience

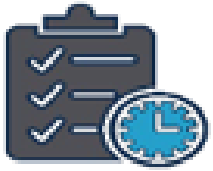


Understand how potential participants may receive information about the research. Our understanding of the audience shapes the content and the tone we use to present information.

Communicate Clearly

Use common, everyday language and format consent forms in ways that make them easier to read and understand.

Organize Information



Organize your consent forms in a way that helps potential participants understand what information is most important to them, i.e., the information most likely to affect their decision to participate. Begin by summarizing the key information and provide more details later in the consent form.

Using a Participant-Centered Approach

Keep the participants' perspectives in mind –

- Frame, explain, and present information to help potential participants make informed decisions.
- Explain research concepts meaningfully.
- Fulfill ethical responsibility of informed consent.

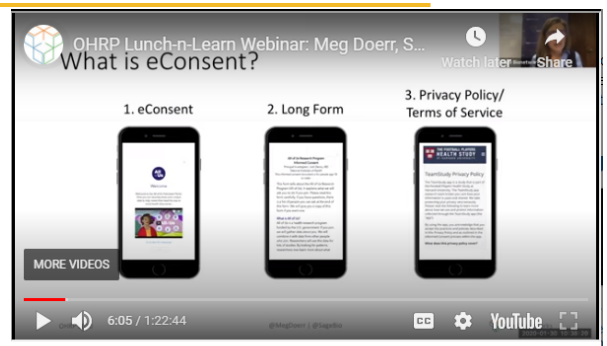
https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-training/participant-centered-informed-consent-training/index.html

A Preview!

Informed Consent Educational Videos – Online Education and Luminaries Lecture Series

https://www.hhs.gov/ohrp/education-and-outreach/online-education/videos/index.html

https://www.hhs.gov/ohrp/education-and-outreach/luminaries-lecture-series/index.html

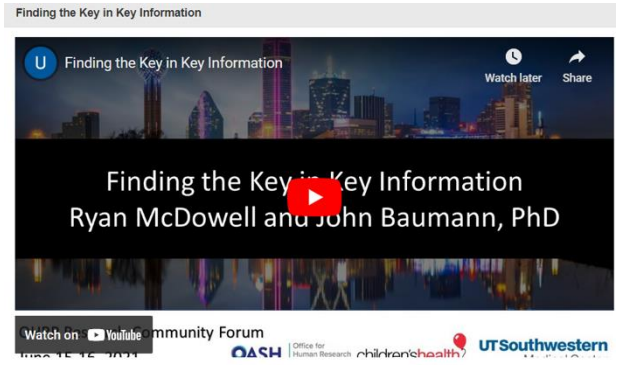


February 4, 2020

Use of eConsent in Human Subjects Research

Megan Doerr, MS, LGC, principal scientist at Sage Bionetworks delivered a lunch-and-learn webcast for OHRP in January 2020. Ms Doerr described various forms of e-consent, the importance of accessibility and readability, the use of apps for research purposes, and shared case studies to explore ways of approaching e-consent to satisfy regulatory requirements and ethical standards. Sage Bionetworks posted this video for public distribution.

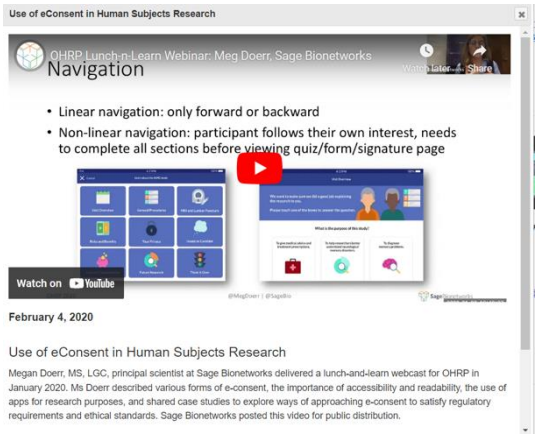
- Review the FDA/OHRP 2016 Guidance on Use of Electronic Informed Consent: Questions and Answers at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/
- Review OHRP featured video ***"Simplifying Informed Consent"*** at https://www.hhs.gov/ohrp/education-and-outreach/online-education/videos/index.html



June 15, 2021

Finding the Key in Key Information

Speakers John R. Baumann, PhD, Associate Vice President for Research Compliance at Indiana University and Ryan McDowell, Director of the Office of Research Integrity at Children's Mercy Research Institute, discussed approaches for how to develop and communicate "key information" to prospective research participants. Their presentation was delivered at the OHRP Research Community Forum co-sponsored with the University of Texas Southwestern in June 2021.



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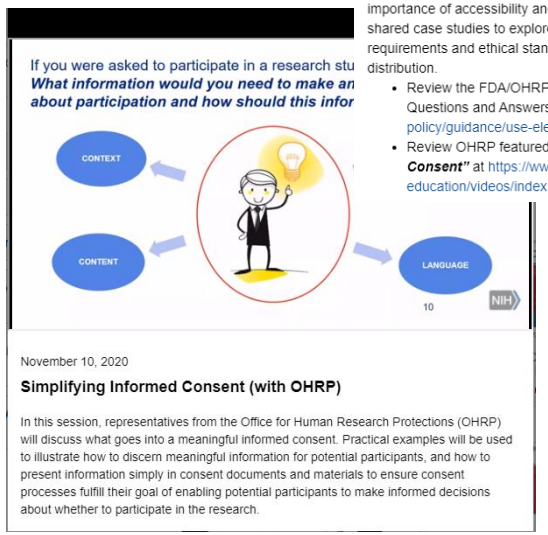


November 10, 2020

Simplifying Informed Consent (with OHRP)

In this session, representatives from the Office for Human Research Protections (OHRP) will discuss what goes into a meaningful informed consent. Practical examples will be used to illustrate how to discern meaningful information for potential participants, and how to present information simply in consent documents and materials to ensure consent processes fulfill their goal of enabling potential participants to make informed decisions about whether to participate in the research.

Guidance Documents on Informed Consent

Informed Consent

Exculpatory Language in Informed Consent Documents: Examples of Acceptable and Unacceptable Language (OPRR Letter, 1996)

Informed Consent Checklist (1998)

Informed Consent of Subjects Who Do Not Speak English (1995)

Informed Consent Requirements for In Vitro Medical Device Clinical Investigations Conducted Under FDA's Interim Final Rule at 21 CFR 50.23(e) (OHRP Guidance, 2006)

Informed Consent Requirements in Emergency Research (OPRR Letter, 1996)

Informed Consent Tips (1993)

Informed Consent, Legally Effective and Prospectively Obtained (OPRR Letter, 1993)

IRB Review of Protocol and Informed Consent Changes for NCI/CTEP-Sponsored Clinical Trials

IRB Review of Protocol and Informed Consent Changes in Cooperative Group Protocols (OHRP Memo to the National Cancer Institute, 2008)

Student Subject Pools and Use of Penalties for Students Who Fail to Show up for Scheduled Research Appointments (January 8, 2010)

Use of Electronic Informed Consent: Questions and Answers

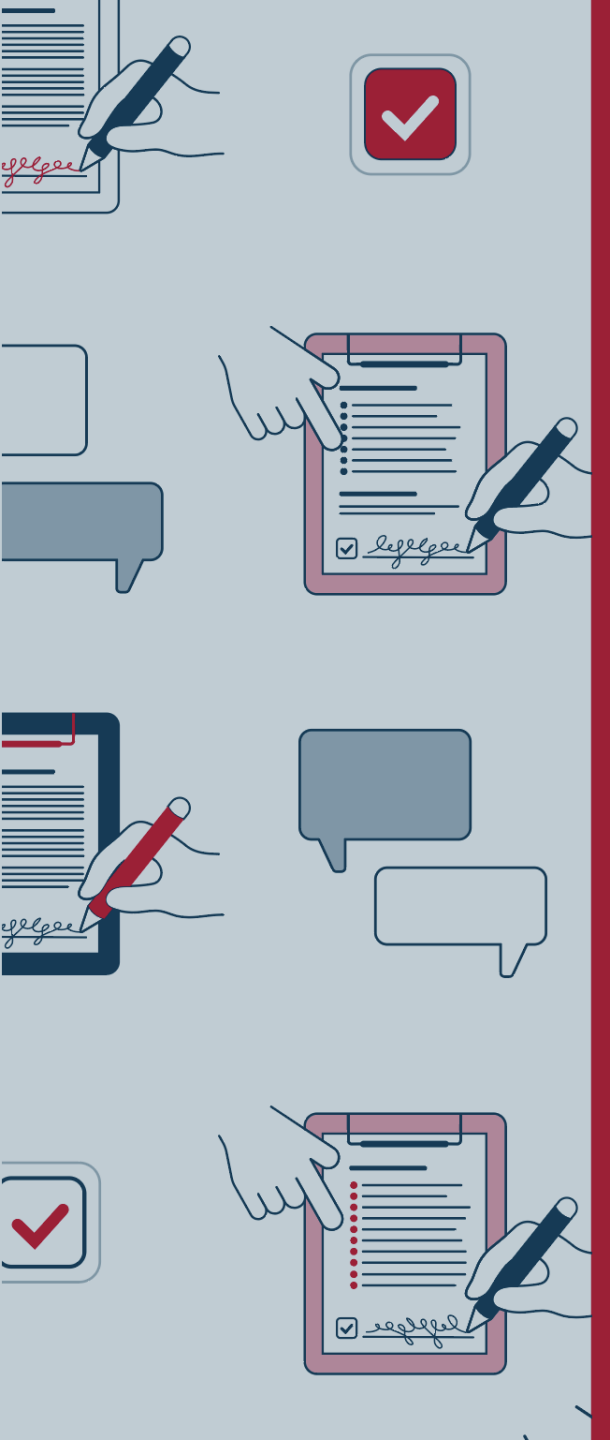
Use of Penalties for Students Who Fail to Show up for Scheduled Research Appointments (January 8, 2010)

Informed Consent Guidance Docs:
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent/index.html

Informed Consent FAQs:
https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

Questions? Send us an e-mail!

OHRP@hhs.gov
OHRP-EDU@hhs.gov



Katherine Blizinsky, PhD

Reaching a Million

The *All of Us* Research Program Approach to Consent

10 October 2024

Katherine D. Blizinsky, Ph.D.
Policy Director
All of Us Research Program
National Institutes of Health

The *All of Us* Research Program

Diversity at Scale

***Diversity of Participants* |** Recruit and retain at least one million participants that reflect the broad diversity of the U.S.—**all ages, races, ethnicities, sexes assigned at birth, genders, SESs, geographies, and health and disability statuses**—and over-recruit populations historically underrepresented in biomedical research

***Diversity of Resources* |** Deliver a national resource of deep **clinical, environmental, social, and biological data** collected on an ongoing, longitudinal basis

***Diversity of Researchers* |** Build the tools & capabilities that make the resources accessible to the public and easy for researchers—**from citizen and community scientists to scientists from premier university labs**—to use to make discoveries

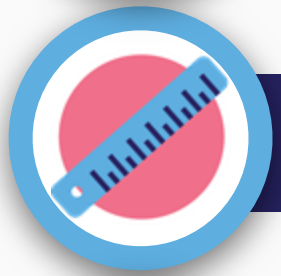
The *All of Us* Research Program | Research Resources

Participant Surveys

- The Basics
- Overall Health
- Lifestyle
- Health Care Access & Utilization
- Personal & Family Health Hx
- Social Determinants of Health
- COVID-19
- Mental Health and Wellbeing

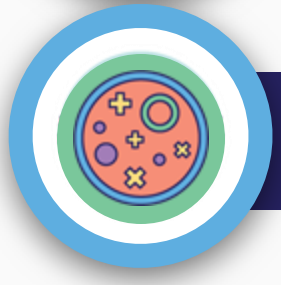
Electronic Records

- Medical Records
- *Claims Data*
- *Pharmacy Data*
- *Vision & Dental Records*
- *Environmental Data*



Measurements/Imaging

- Physical Measurements
- Cognitive Indicators
- *Retinal Imaging*



Biospecimens

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

Mobile/Wearable Tech

- **Fitbit**
  - Heart Rate
  - Daily Activity & Steps
  - Sleep Data
  - Vitals
  - Device & HealthKit Data
- *Other Devices*

Assays

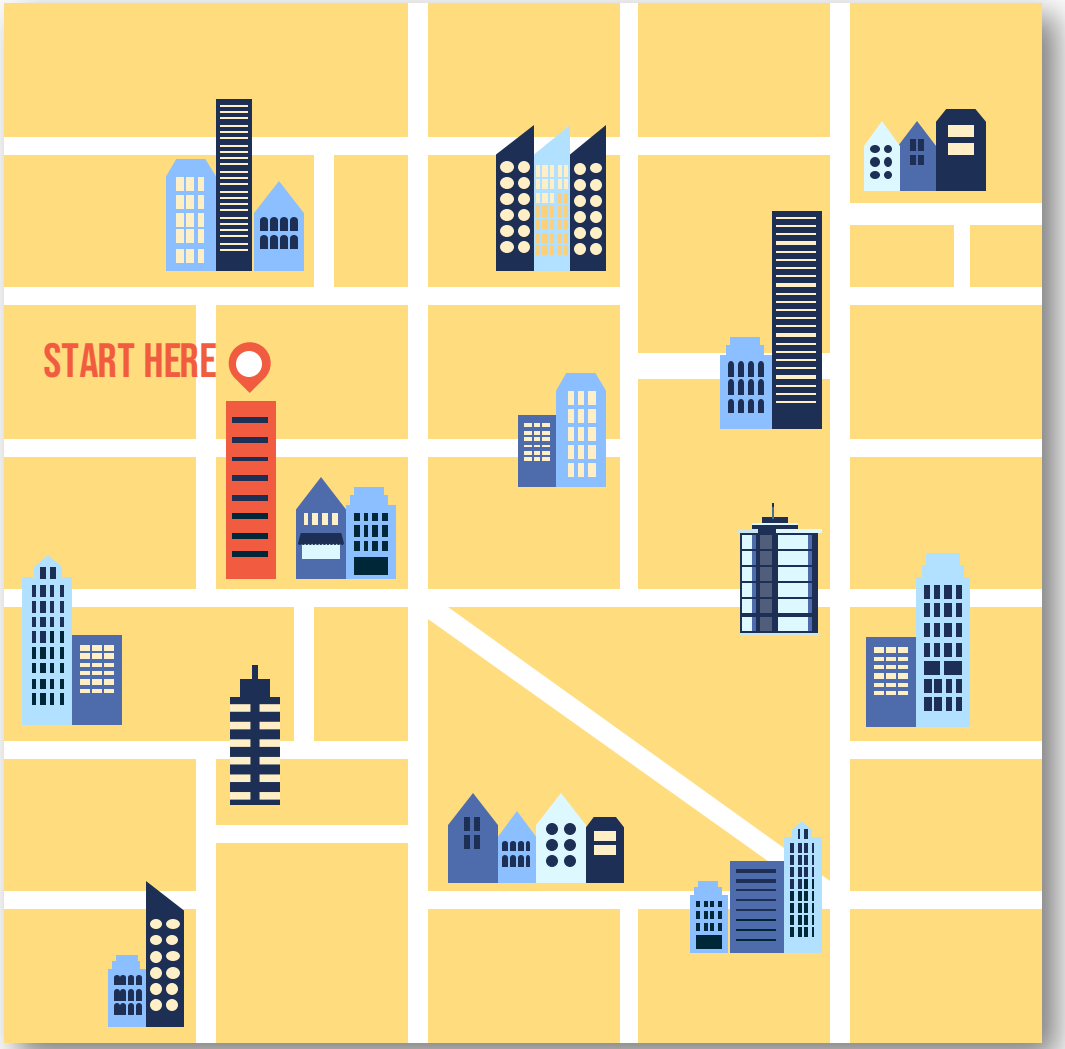
- COVID Serology
- *HbA1c*
- *Metabolic Function*
- *Heavy Metals*

Omics

- **DNA**
  - Arrays
  - WGS
  - Long Reads
  - Structural Variants
- *Other Omics*

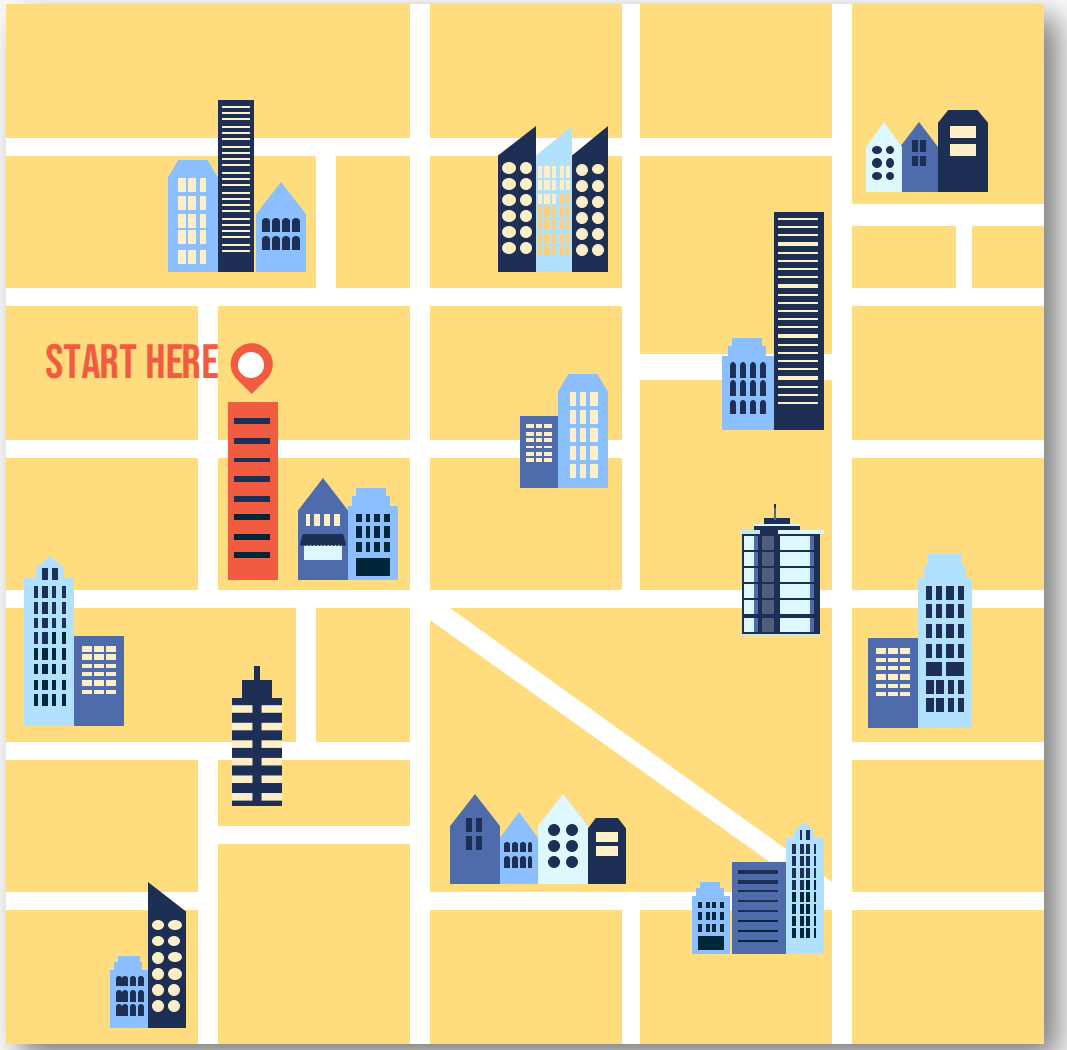
For more on upcoming additions, please visit the Data Road Map at **allof-us.org/Roadmap**

All of Us Participant Agreements | Considerations and Principles



- Multi-part, longitudinal study
- Legal, regulatory, and ethical obligations
- Diverse participant needs
- Distributed program catchment

All of Us Participant Agreements | Considerations and Principles

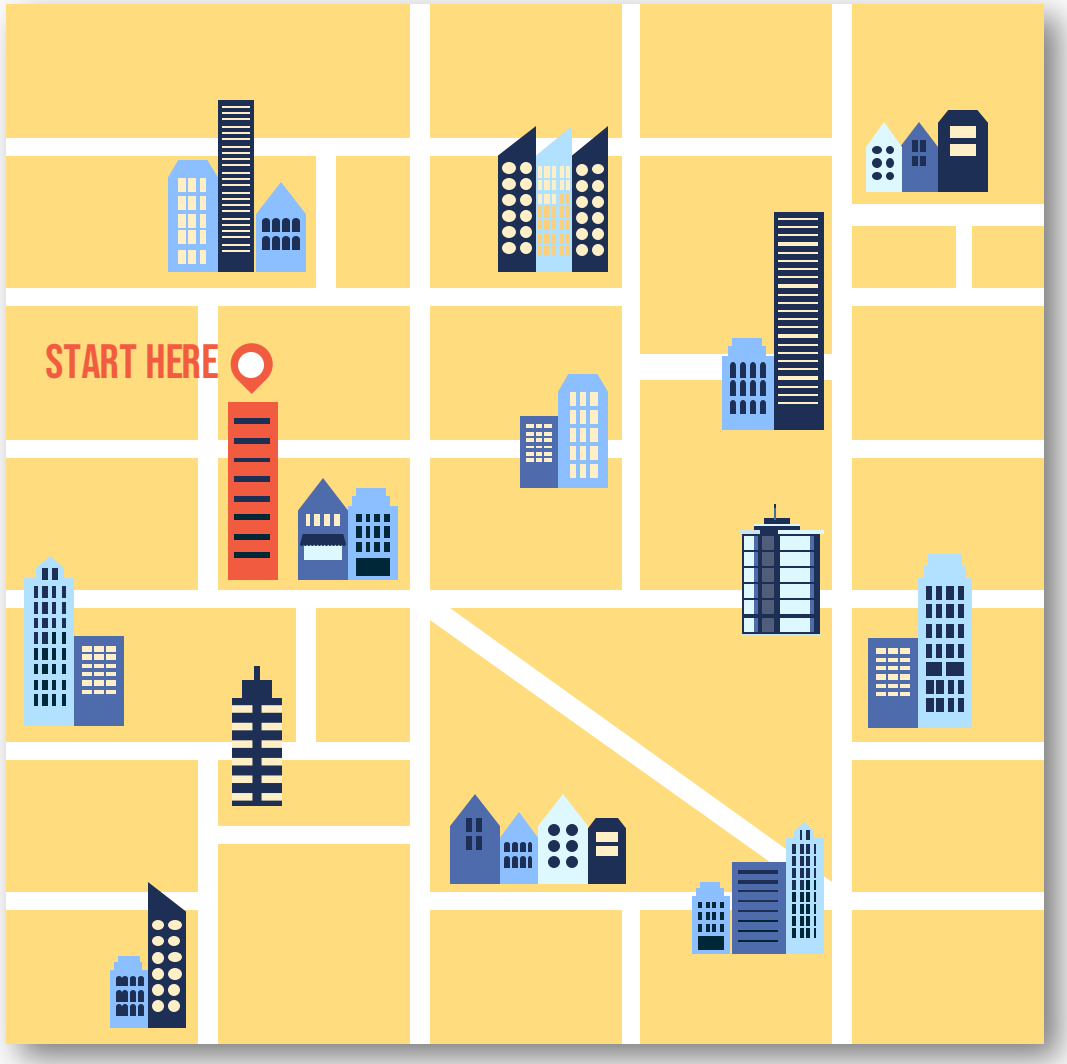


- Multi-part, longitudinal study
- Legal, regulatory, and ethical obligations
- Diverse participant needs
- Distributed program catchment

Design Principles

- Accuracy
- Clarity
- Cultural humility
- Support
- Choice

All of Us Participant Agreements | Considerations and Principles



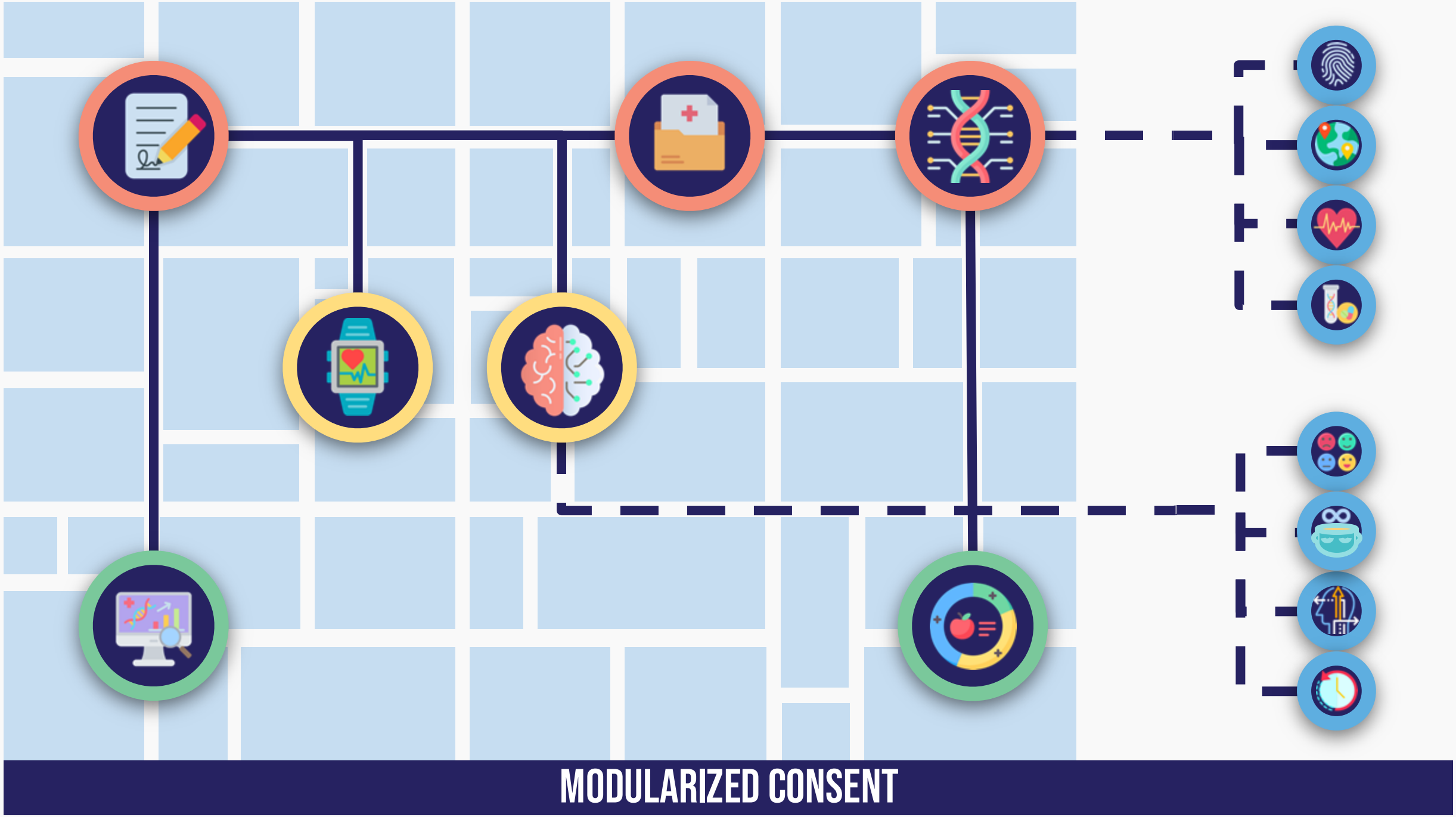
- Multi-part, longitudinal study
- Legal, regulatory, and ethical obligations
- Diverse participant needs
- Distributed program catchment

Design Principles

- Accuracy
- Clarity
- Cultural humility
- Support
- Choice

YES MEANS YES, AND EVERYTHING ELSE MEANS NO

learn more at **allofus.nih.gov/about/who-we-are/all-of-us-participant-partners**


MODULARIZED CONSENT

All of Us Participant Agreements | Consents and Loops

Informed Consent

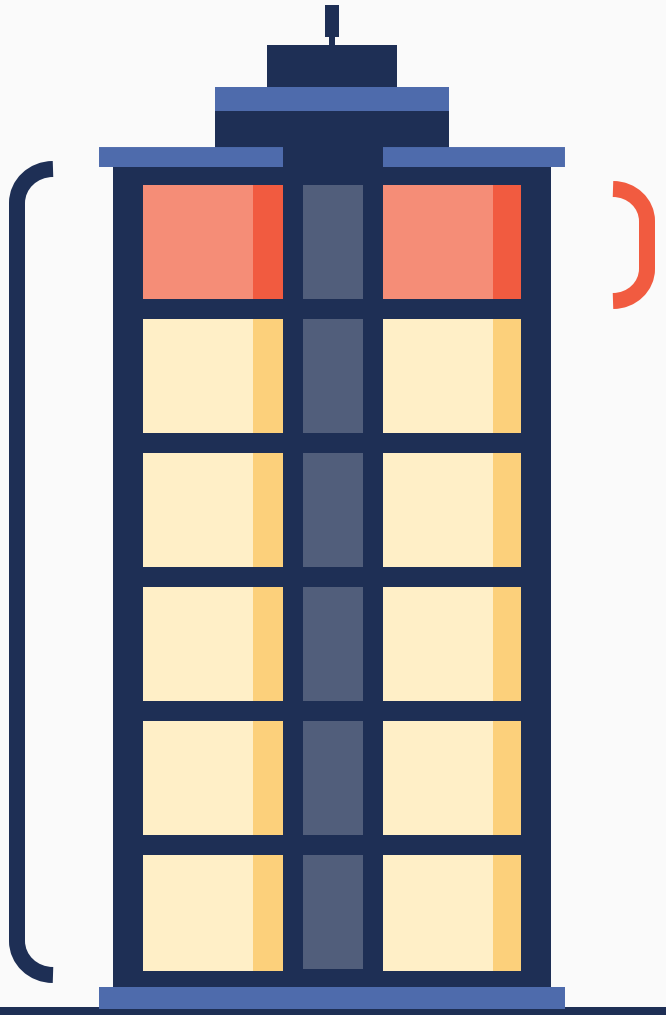
Broad Choices

Present overview of the research and topical information

Set general expectations for/of participants*

Discuss overarching risks and benefits

Establish individuals' choices about collection of participation options



Informing Loops

Granularized Choice

Presentation of detailed topical information proximate to choice point

Relevant expectations for/of participants with examples

Discuss specific risks and benefits associated with the research

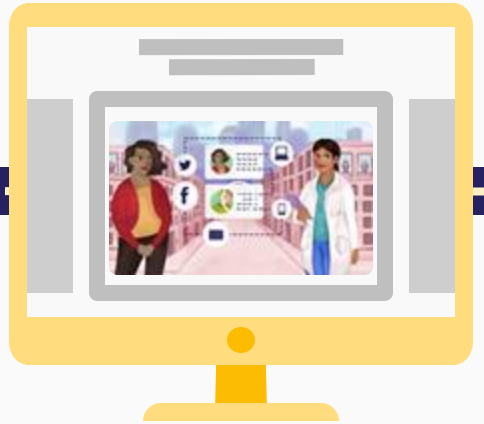
Establish individuals' choices about specific participation option

All of Us Participant Agreements | Interactive, Multimodal Process

CONSENT

eScreens

Videos



Formative Evaluation

Longform & Signature

LOOP

eScreens

Decision Point

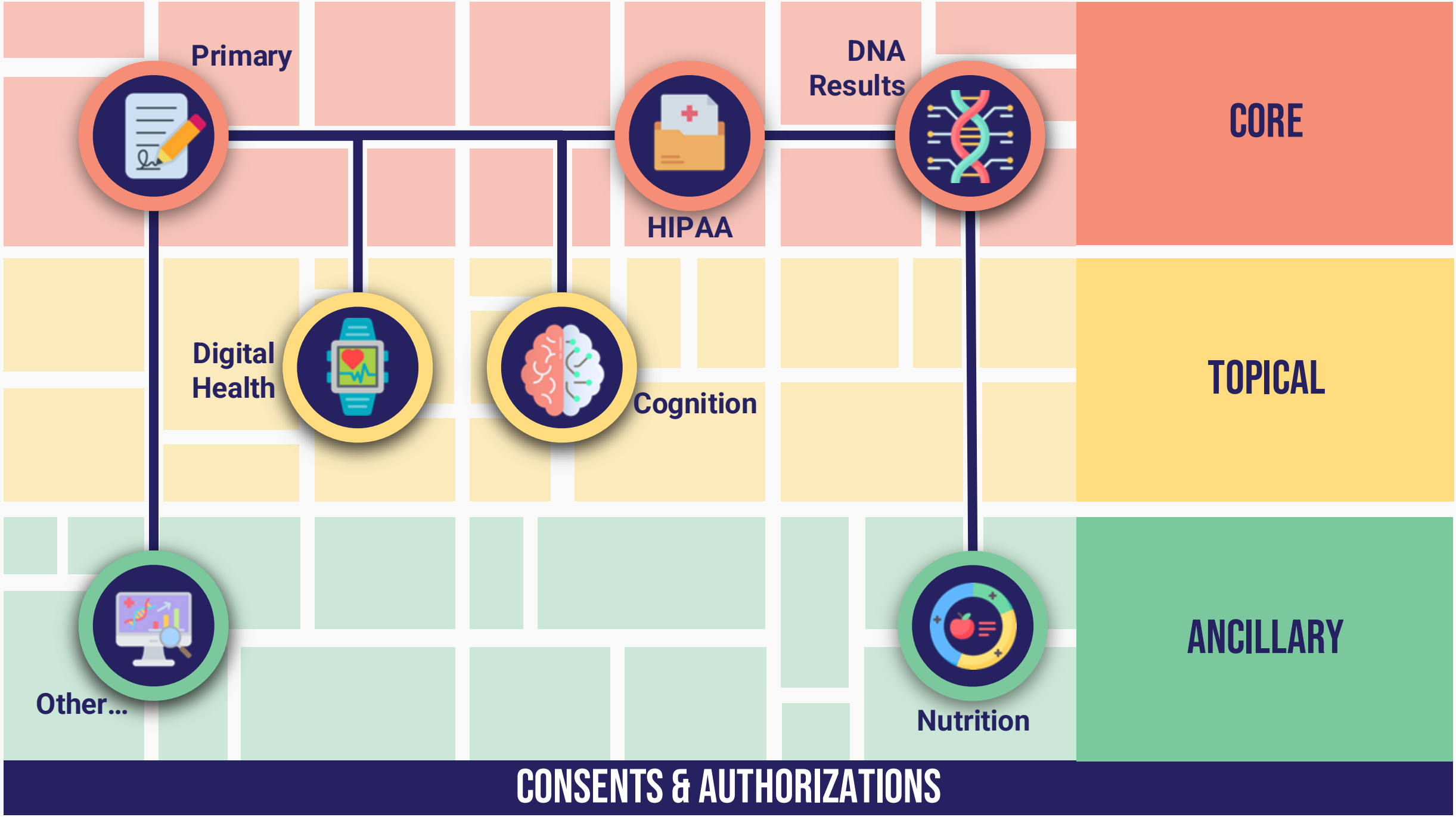
learn more about the *All of Us* agreements process at
allofus.nih.gov/about/protocol/all-us-consent-process

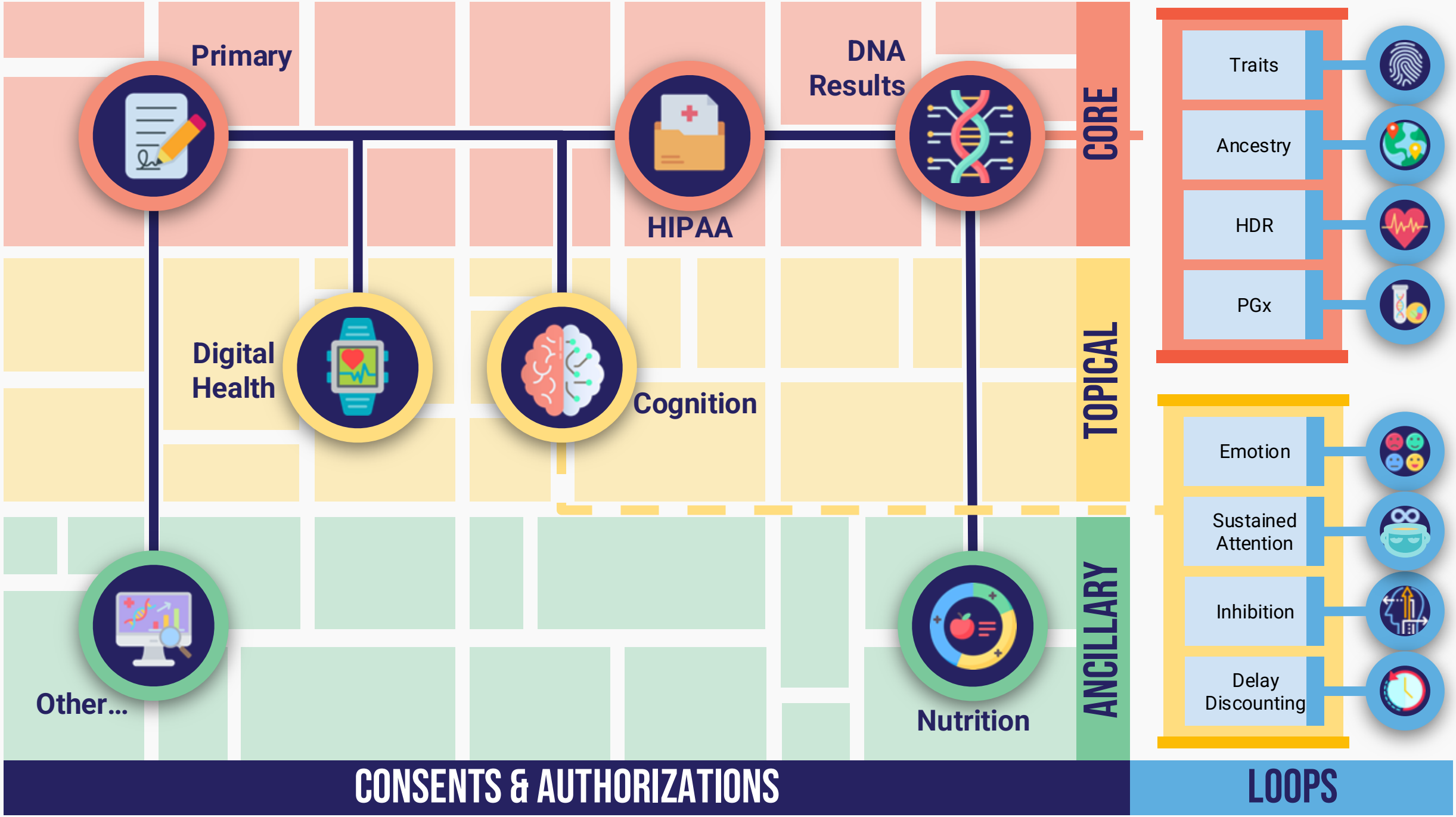
All of Us Participant Agreements | Integrated Assistance

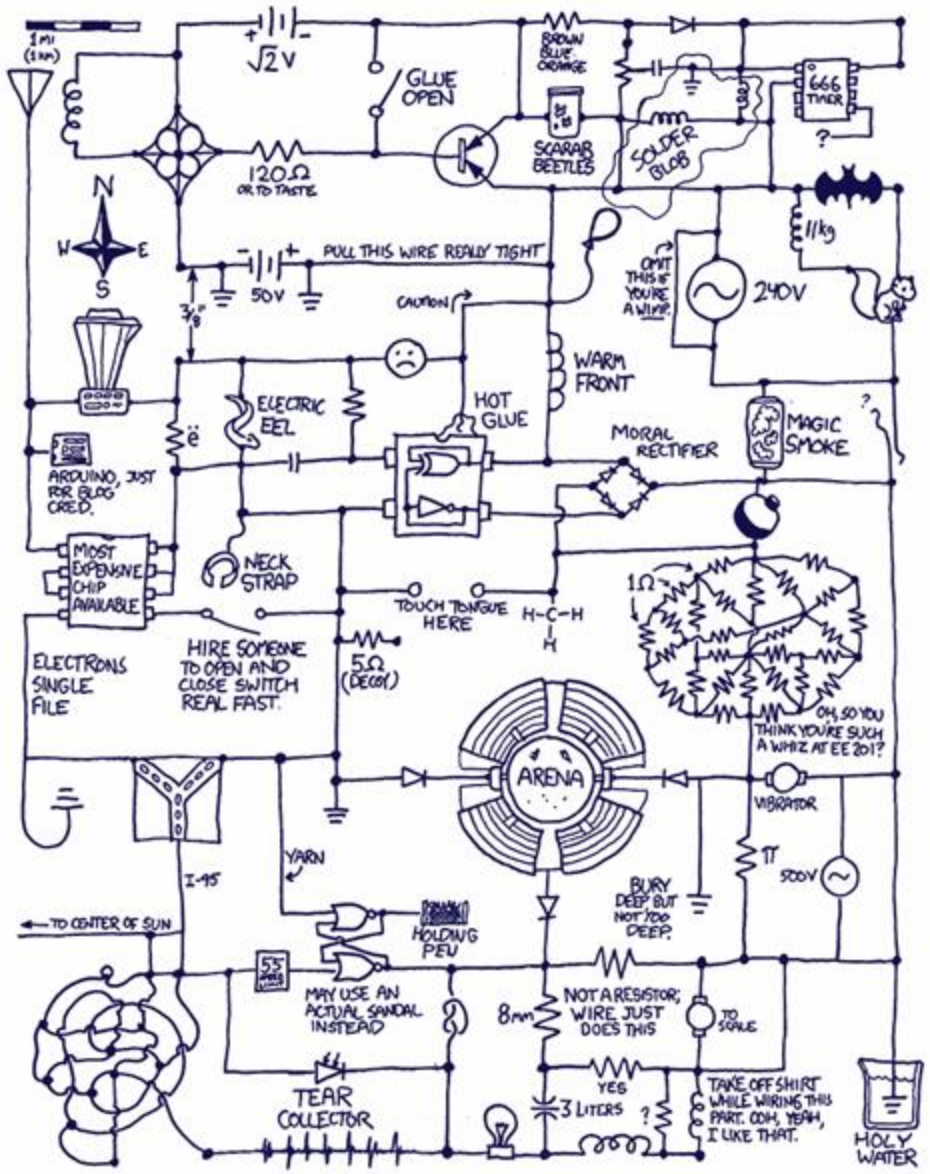
SUPPORT SERVICES

EDUCATIONAL RESOURCES

DECISION TOOLS


Primary
HIPAA
DNA Results
CORE
Digital Health
Cognition
TOPICAL
Other...
Nutrition
ANCILLARY
CONSENTS & AUTHORIZATIONS


Primary
HIPAA
DNA Results
CORE
Traits
Ancestry
HDR
PGx
Digital Health
Cognition
TOPICAL
Emotion
Sustained Attention
Inhibition
Delay Discounting
Other...
Nutrition
ANCILLARY
CONSENTS & AUTHORIZATIONS
LOOPS

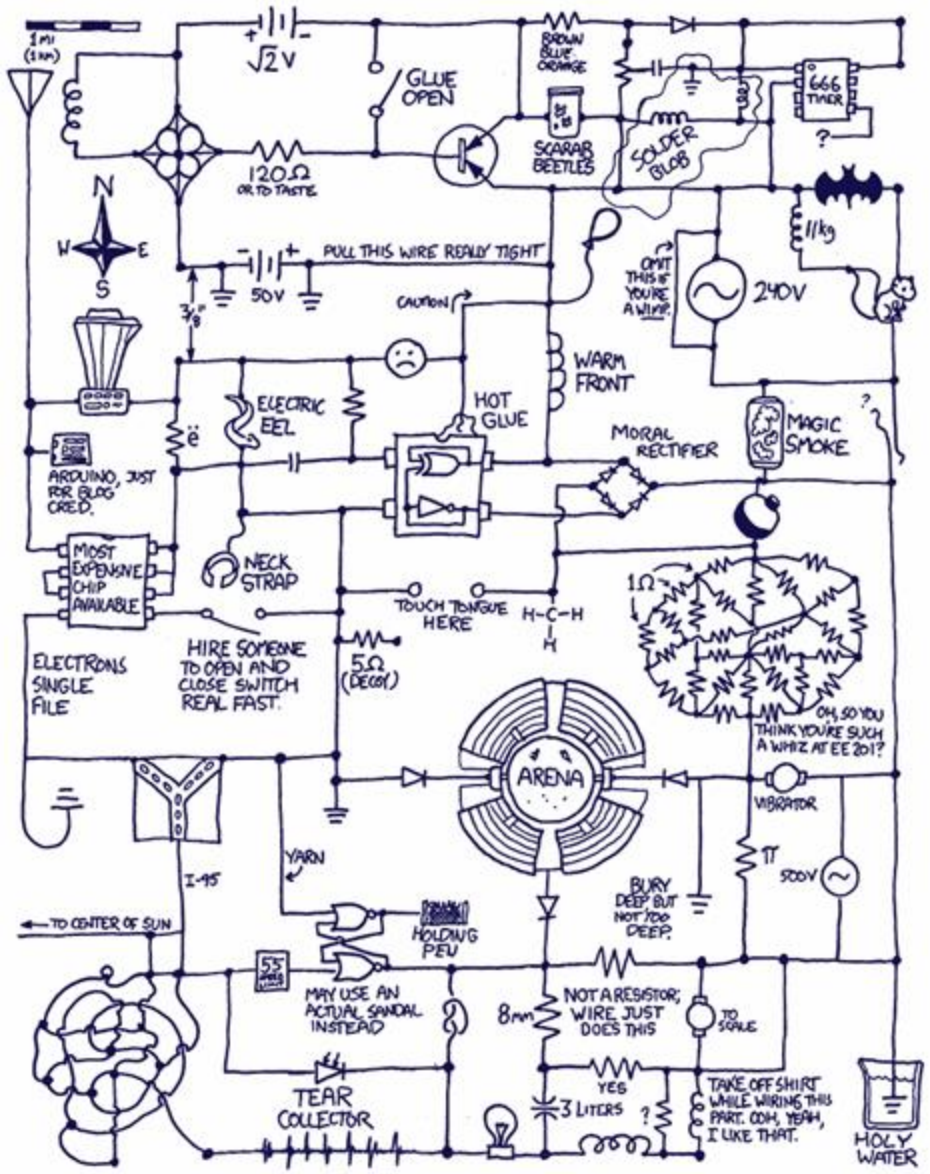


Many thanks to XKCD for this great cartoon!

The *All of Us* Agreements Strategy

Lessons Learned

- This is really hard to do well…
- … but that doesn't mean it's not worth trying to do well



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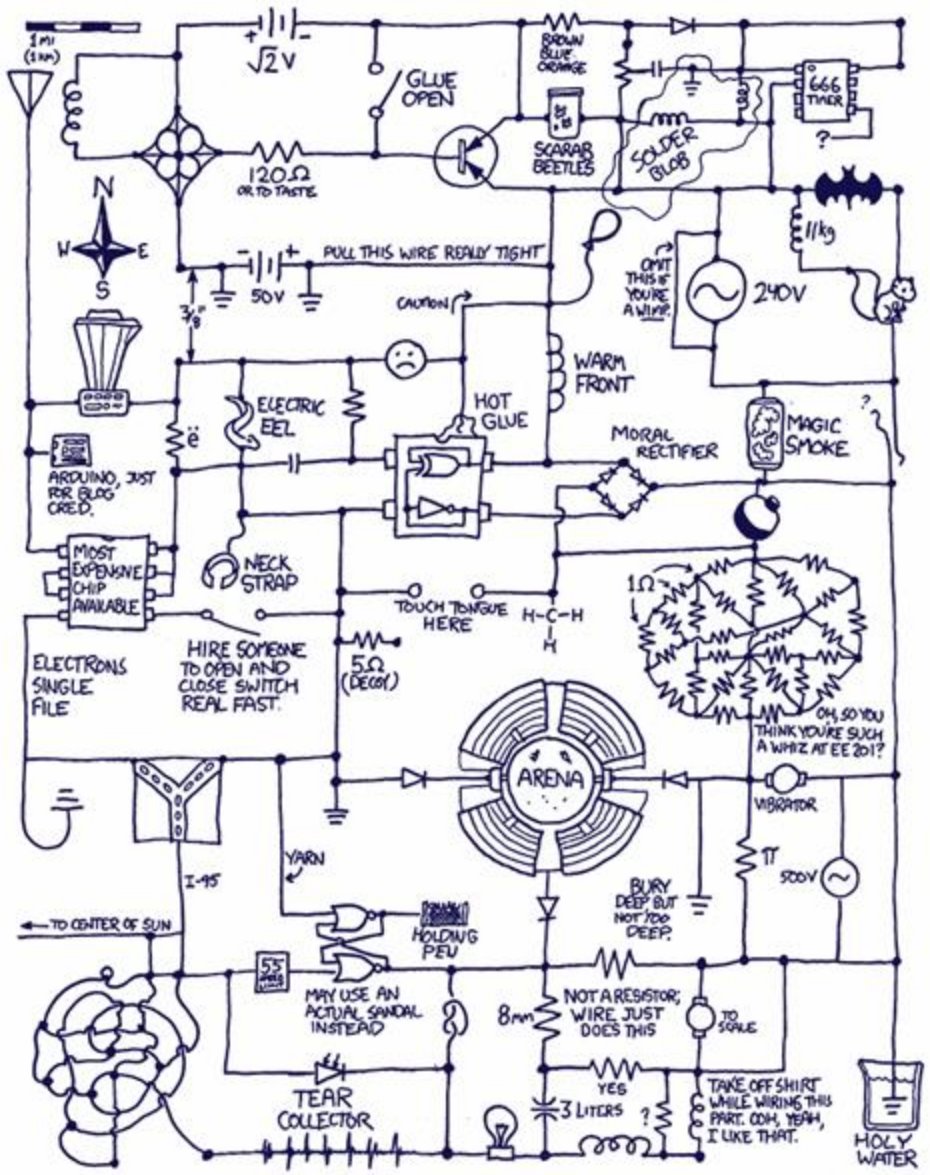

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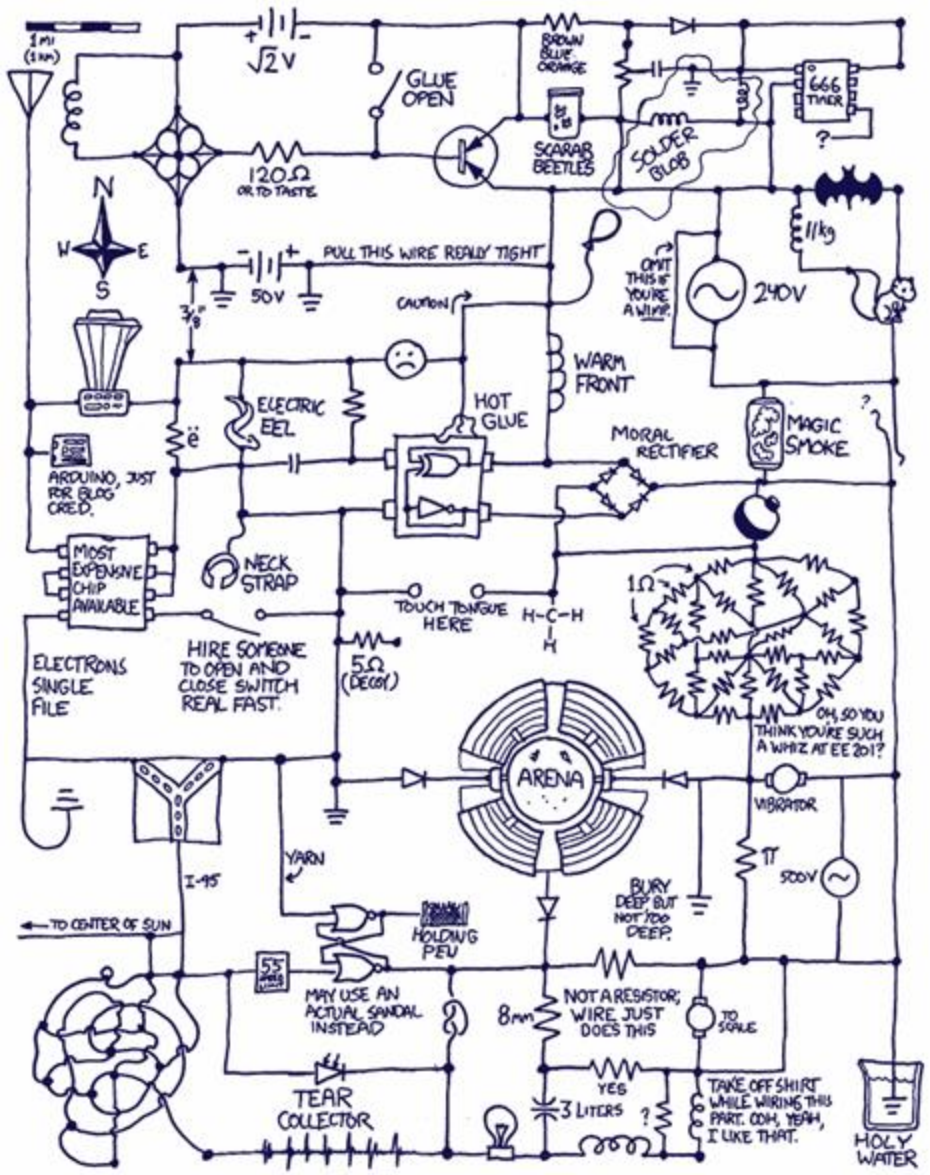

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- … up to a point

- Modularity increases participant autonomy…
- … and participant burden

nothing is as valuable as

TRUST

Thank you!

All of Us RESEARCH PROGRAM

National Institutes of Health

ResearchAllofUs.org

AllofUs.nih.gov

@AllofUsResearch
#JoinAllofUs

katherine.blizinsky@nih.gov
AoUPolicy@nih.gov

Extra Slides

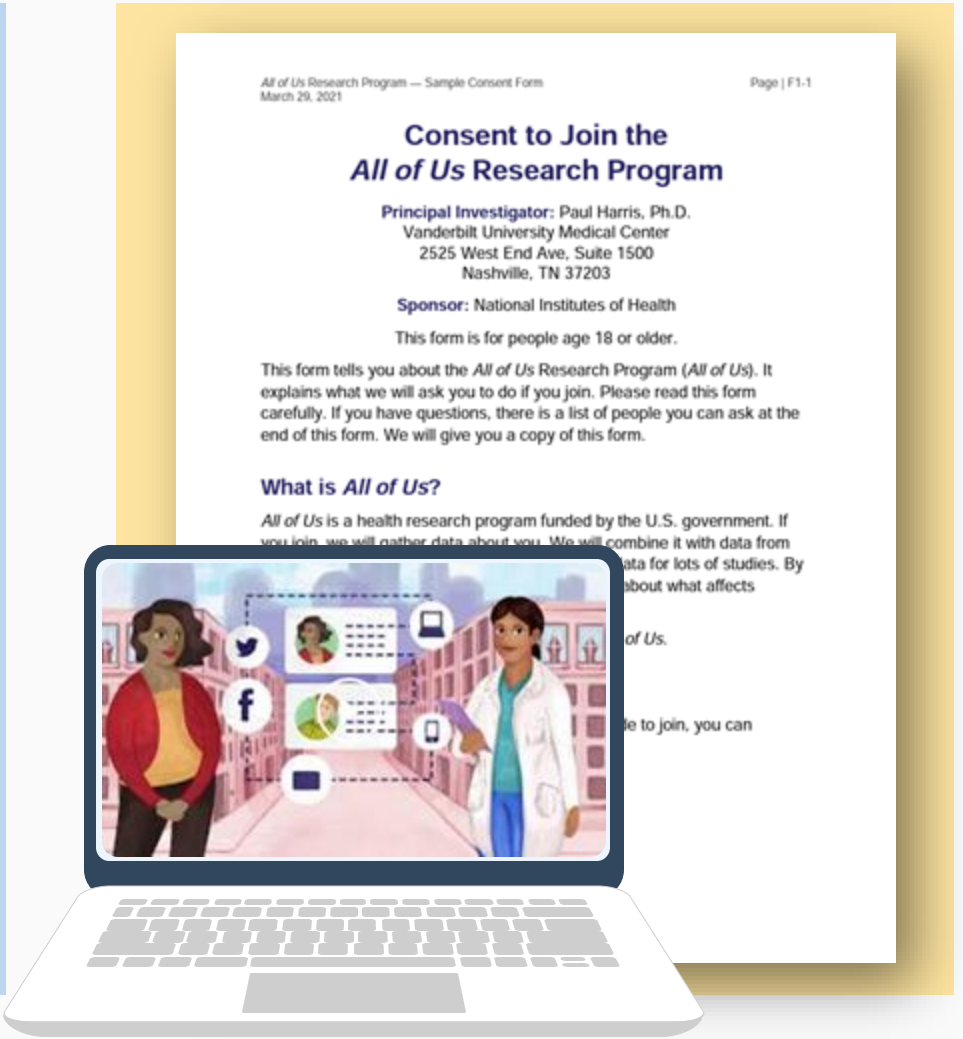
Primary Consent | Setting the Stage

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



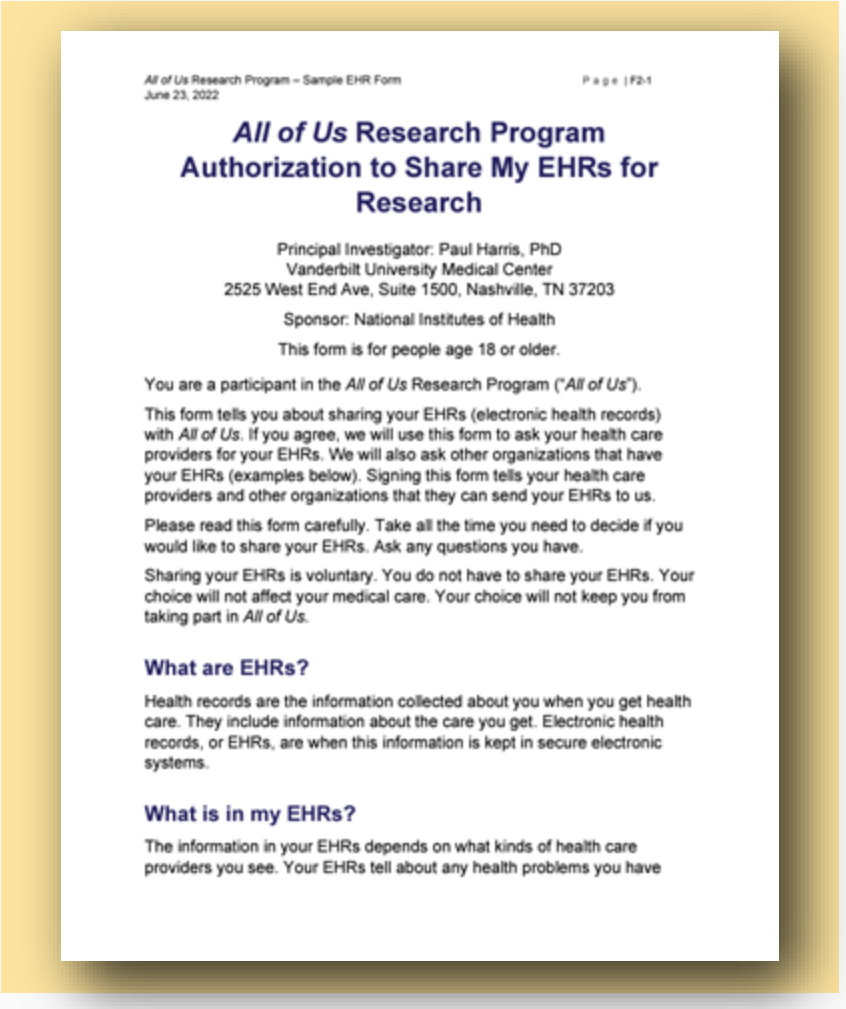
HIPAA Authorization | Legal and Regulatory Patchwork

PURPOSE

Present risks and benefits of sharing EHRs with the program; Explain individuals' rights

CHALLENGES

- State laws and regulations
- Explaining limitations with respect to coverage and protections of the law, insurability



All of Us Research Program – Sample EHR Form
June 23, 2022

Page | F2-1

All of Us Research Program Authorization to Share My EHRs for Research

Principal Investigator: Paul Harris, PhD
Vanderbilt University Medical Center
2525 West End Ave, Suite 1500, Nashville, TN 37203

Sponsor: National Institutes of Health

This form is for people age 18 or older.

You are a participant in the *All of Us* Research Program ("*All of Us*").

This form tells you about sharing your EHRs (electronic health records) with *All of Us*. If you agree, we will use this form to ask your health care providers for your EHRs. We will also ask other organizations that have your EHRs (examples below). Signing this form tells your health care providers and other organizations that they can send your EHRs to us.

Please read this form carefully. Take all the time you need to decide if you would like to share your EHRs. Ask any questions you have.

Sharing your EHRs is voluntary. You do not have to share your EHRs. Your choice will not affect your medical care. Your choice will not keep you from taking part in *All of Us*.

What are EHRs?

Health records are the information collected about you when you get health care. They include information about the care you get. Electronic health records, or EHRs, are when this information is kept in secure electronic systems.

What is in my EHRs?

The information in your EHRs depends on what kinds of health care providers you see. Your EHRs tell about any health problems you have

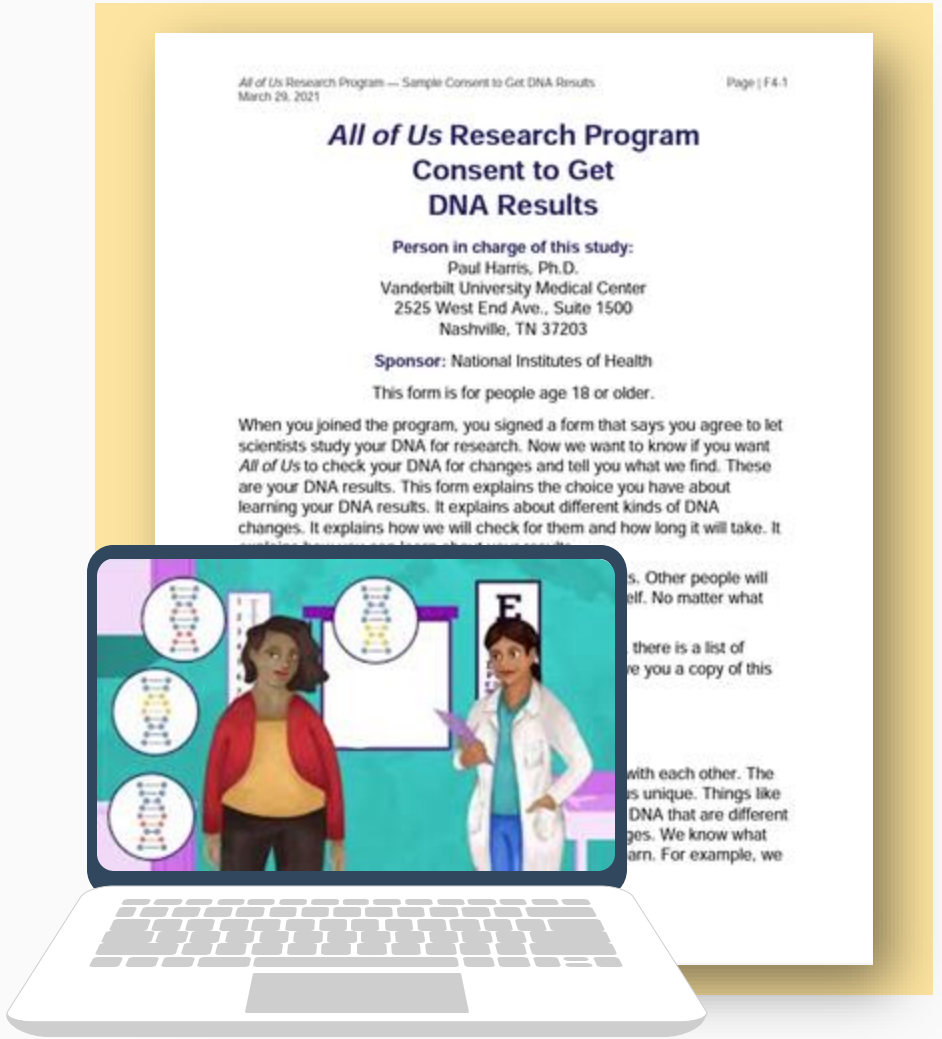
Consent to Receive DNA Results | Consenting to Return of Information

PURPOSE

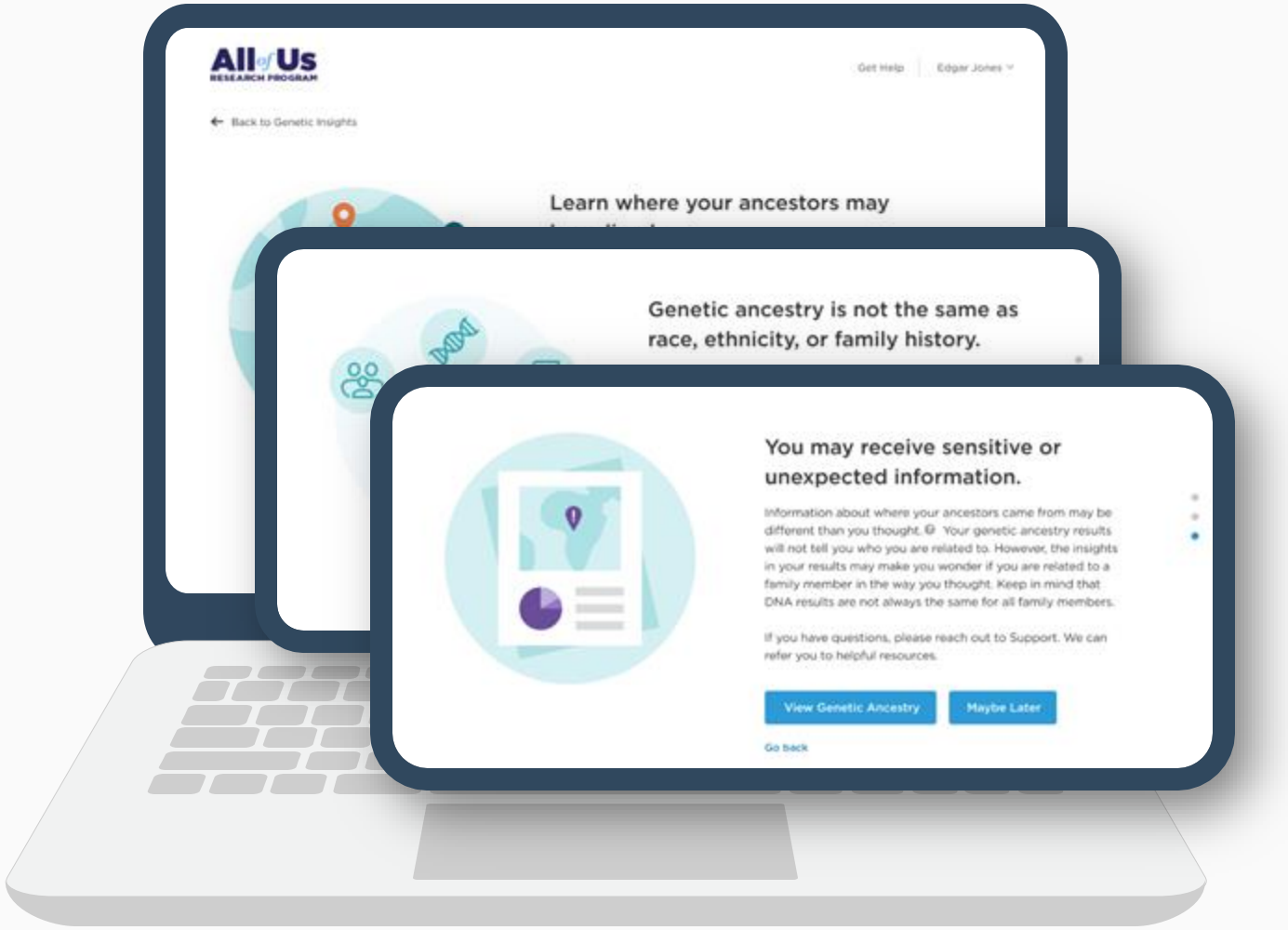
Describe the process and limitations of return of genetic and genomic results; Set realistic expectations for participants about what they can expect to receive; Explain potential risks and benefits to learning such results

CHALLENGES

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

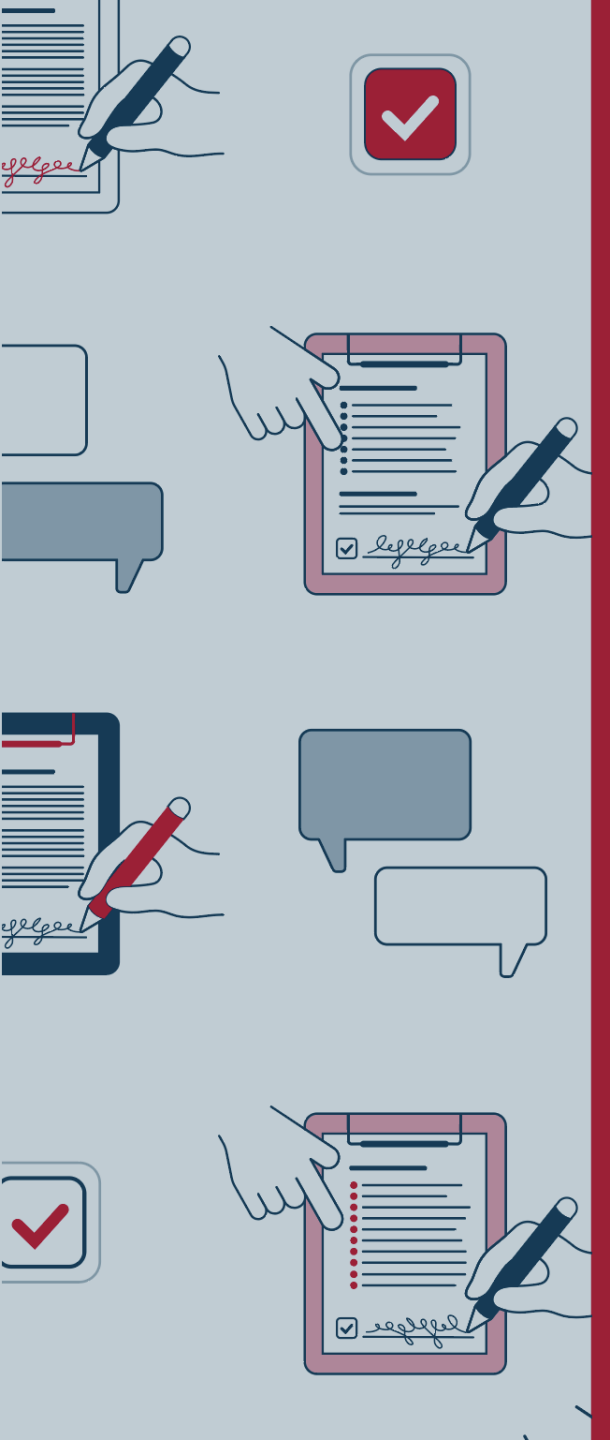


Informing Loops | Just-in-Time Information



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

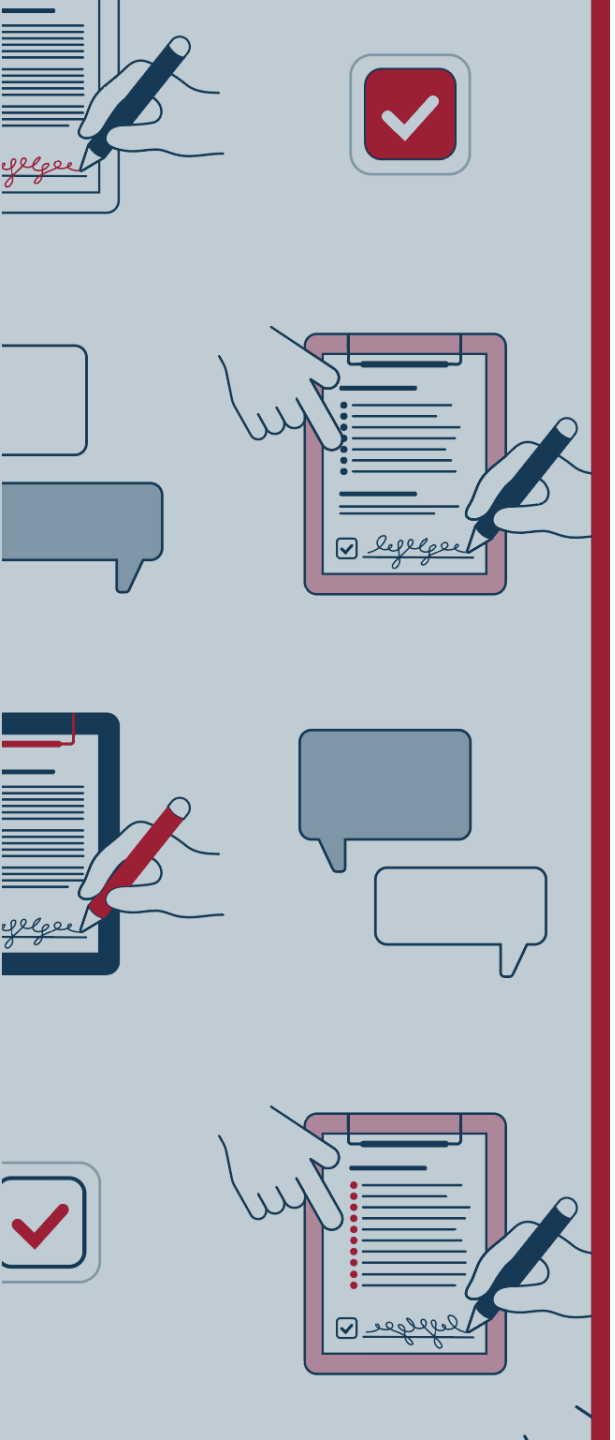
Katherine’s slides will be inserted here on the NIH Template



MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Q&A



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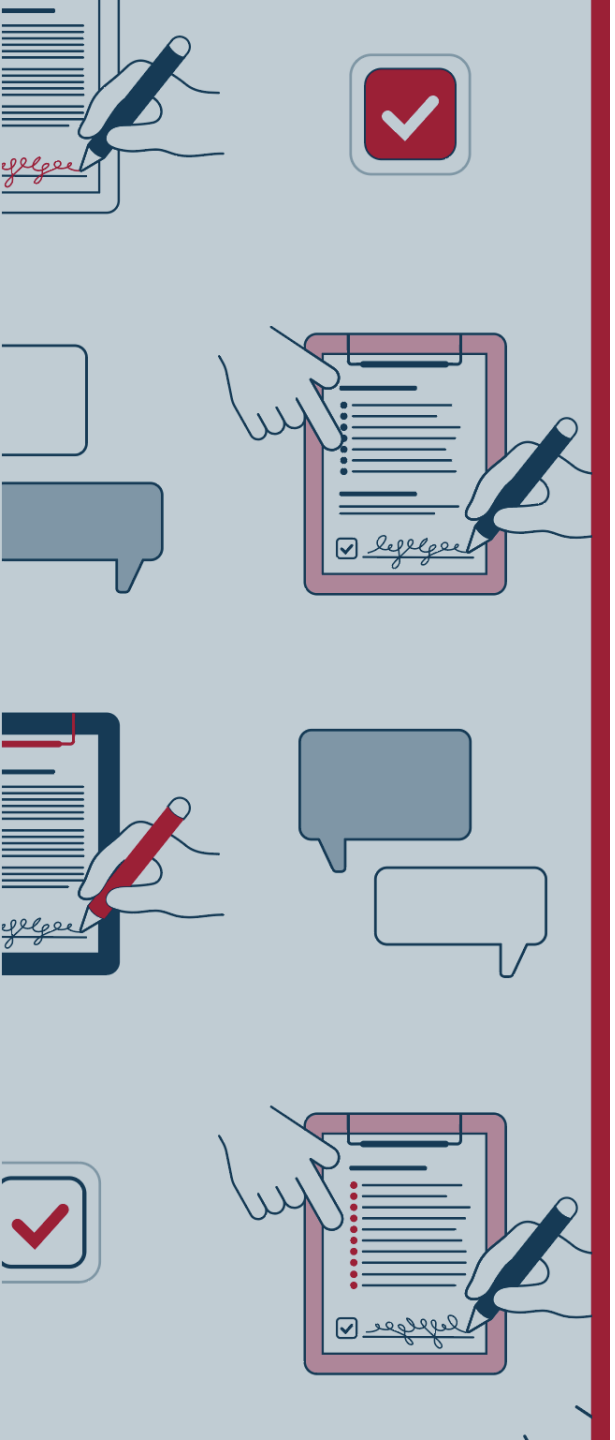
Happy Health Literacy Month!

There are two more webinars in the series. Register today!

October 17, 12 – 1 pm ET:
Session 2: Creating and Sharing Plain Language Summaries: One Team's Experience

October 22, 12 - 1 pm ET:
Session 3: Designing PowerPoint Presentations to Support Health Literacy and Accessibility



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Thank You!

Learn more at www.mrctcenter.org