June 24, 2019

Policy Implementation

Ericka Thomas, NIH
John Wilbanks, Sage Bionetworks
Purpose

- Explain the core protocol design and implementation
- Walkthrough of informed consent process + available data
- Policy overview
Sage Bionetworks governance team

Tori Allen
Vanessa Barone
Megan Doerr
Sarah Moore
Ann Novakowski
Allie Seroussi
Christine Suver
Amy Truong
Protocol Integration Process

Mental model of the protocol

- 80-20 principle
  - National core protocol
  - Site-specific amendments
- Separation of concerns
  - Standalone protocol elements for key functional areas (DRC etc)
  - Isolate "bugs" so they don’t spread
- Leverage national core protocol as best practices emerge
  - Communications
  - Engagement
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<th>Name</th>
<th>Submitted by</th>
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13 records
Protocol

Protocol and IRB submissions

News:
The IRB has approved Protocol 1.10 as of March 5th, 2019.
Please check our new page, which links to statuses of IRB submissions.
There is a new version of the ISIA annual update template posted here.
Please check the Annual Update Calendar and Strategy Guide 2019/2020 to find your institution’s annual update deadline.

Shortcuts to:
- Status of IRB Submissions
- Consent documents
- Core Protocol
- IRB-Approved Core Materials
- Scripts for partner organizations

Space Content
- All Things IRB
  - IRB Submission Status
  - IRB Best Practices & Lessons Learned
  - IRB Templates/Forms
  - IRB SOPs
  - Local Site Incident Reports
- IRB-Approved Core Materials
  - Core Protocol Corner
  - Getting to Protocol V1.5
  - Consent
  - HPO Scripts
  - IRB-Approved ISIAs - Page Maintained by:...
what do people want to know about?

How to?
- Where is the research taking place?
- Will transportation be provided?
- Who can participate in All of Us?
- Is there a cost involved?

How does it work?
- What is research? (generally/specifically)
- How will All of Us interact with participants?

Why is this part of the research?
- Why do you want my blood and what are you going to do with it?
- Why is DNA included?
- Why do you need my medical records?
- What are you looking for?

What are you not telling me?
- What are they trying to do with people?
- Who else will have access to my medical records?

Privacy concerns
- Who will see this?
- What protections are there?
- Why are you putting my privacy at risk?

Results
- Will I have access to my test results?
- What will the results tell me?
- Who will have access to the results?
what words make sense to people?

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<th>Kind of know/maybe familiar</th>
<th>Know/comfortable</th>
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The biggest lie on the internet: “I have read and understood the terms of service”

On July 7, two US academics published a paper entitled “The Biggest Lie on the Internet: Ignoring the privacy policies and terms of service policies of social networking services” which details an experiment they carried out on 543 students, asking them to open
• Mobile or web-app highlight reel of the informed consent form (“long form”)
• Series of participant self-navigated, self-paced screens
• May include animation, video, other interactive elements
• May include summative or formative assessment
• One of three major user agreements for app-mediated research
  • eConsent
  • Long form
  • Privacy Policy/Terms of Use
All of Us informed consent requirements

• Single national consent that is also compliant with all state/territory-specific regulations*

• Accommodate both at home and in person completion

• Scalable

• Comprehensible

• Transparent

*see PMID: 30963079
All of Us eConsent structure
All of Us eConsents

- Consent is modular
  - Primary consent
  - HIPAA Authorization
  - Others as needed
- Written at the 5th grade reading level
- Primary eConsent includes nine 15-45 second videos
- Linear navigation
- “Get help” buttons link to national support center
All of Us primary long form & HIPAA Auth

- Primary long form and HIPAA Auth each written at the 5th grade reading level
  - Primary consent reading ease 77
  - HIPAA Auth reading ease 74
- Lots of white space
- 14 point type
- No sections in all caps
does it work?
What is the purpose of *All of Us*?

- To help scientists make discoveries about health.
- To give medical advice and treatment.
Do I have to take part in *All of Us*?

- Taking part is voluntary. I get to choose if I want to do it.
- Taking part is required. I have to do it.
If I join, can I withdraw ("quit")?

- I can withdraw at any time.
- I can’t withdraw ever.
Using smartphones, apps, and sensors are always a potential risk to privacy. Can All of Us guarantee your privacy?

- Risks to my privacy are minimized, but are not zero.
- My privacy is guaranteed.
Using smartphones, apps, and sensors are always a potential risk to privacy. Can *All of Us* guarantee your privacy?

- Risks to my privacy are minimized, but are not zero.
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Policy Implementation
Policy Development

- Federal/State laws and regulations that apply
- Federal laws and regulations that do not strictly apply but are adopted as policy choices
- Policies that were written to shape the program
- Policies drafted by All of Us Governance bodies
- Policies derived from need
**Policy Development**

- Federal/State laws and regulations that apply
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**Federal/State Laws and Regulations that Apply**
e.g., State Laws and Informed Consent

*All “flavors” available in both English and Spanish*

**Primary Consent**

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**HIPAA Authorization**

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**Return of Genomic Results**

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Federal Laws and Regulations that Do Not Strictly Apply but are Adopted as Policy Choices

e.g., FISMA and Security Practices

Identify
Protect
Respond
Detect
Recover
Policy Development

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Policies Written to Shape the Program
e.g., PMI Privacy and Trust Principles and Data Resource Structure
Policy Development

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Policies Drafted by *All of Us* Governance Bodies

*E.g.*, CAPS and the Data Use Agreement

Director

Executive Committee

Steering Committee

Participant Provided Information

Special Populations

Digital Health Technologies

Access, Privacy & Security (CAPS)

Omics

Science

Participant Eval & Assessment

Resource Access

Publications

Incident Notifications

Assay IRB Submission

Modules

Survey Completion

Pediatric Operations

Biospecimen Access

Data Privacy & Security

Compliance & Adjudication

User Application
Policy Development

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Questions?

joinallofus.org

@AllofUsResearch | #JoinAllofUs

*Precision Medicine Initiative, PMI, All of Us, the All of Us logo, and The Future of Health Begins With You are service marks of the U.S. Department of Health and Human Services.*