SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-01S1.

What Is SMART Talk?

An approximately monthly forum with:

- Presentations on topics relevant for single IRB review
- Q&A on topic presented as well as questions submitted when participants register

Open and free to anyone with interest

Upcoming sessions

Coming in 2021:

- Single IRB and planned emergency research
- Harmonization Working Group Recommendations on Ancillary Reviews

Recent Harmonization Steering Committee Documents

Comment period ended → working on finalization

- Post-Approval Auditing for Studies Subject to Single IRB Review
- Single IRB Continuing Review Process

New working groups coming!

FYIs

A recording of this talk will be posted on the SMART IRB website

A link to the talk will be sent to those who registered for the talk when it is posted

If you have any questions for the panelists, please use the chat function to submit them

Save the date for the next
SMART Talk
February 17, 2021
2:00-3:30 pm ET

Single IRB and planned emergency research

Questions?
Contact help@smartirb.org

Register at smartirb.org

Sign up for our mailing list to be notified of future offerings

SMART Talk

All of Us RESEARCH PROGRAM

Kituria Gaines
Allison Lea
John Horigan

National Institutes of Health

January 20, 2021

Our Plan

- Tell you about *All of Us*
- Fill you in on how our IRB might be different from yours
- Highlight some lessons learned
- LOTS of time for Q&A

All of Us

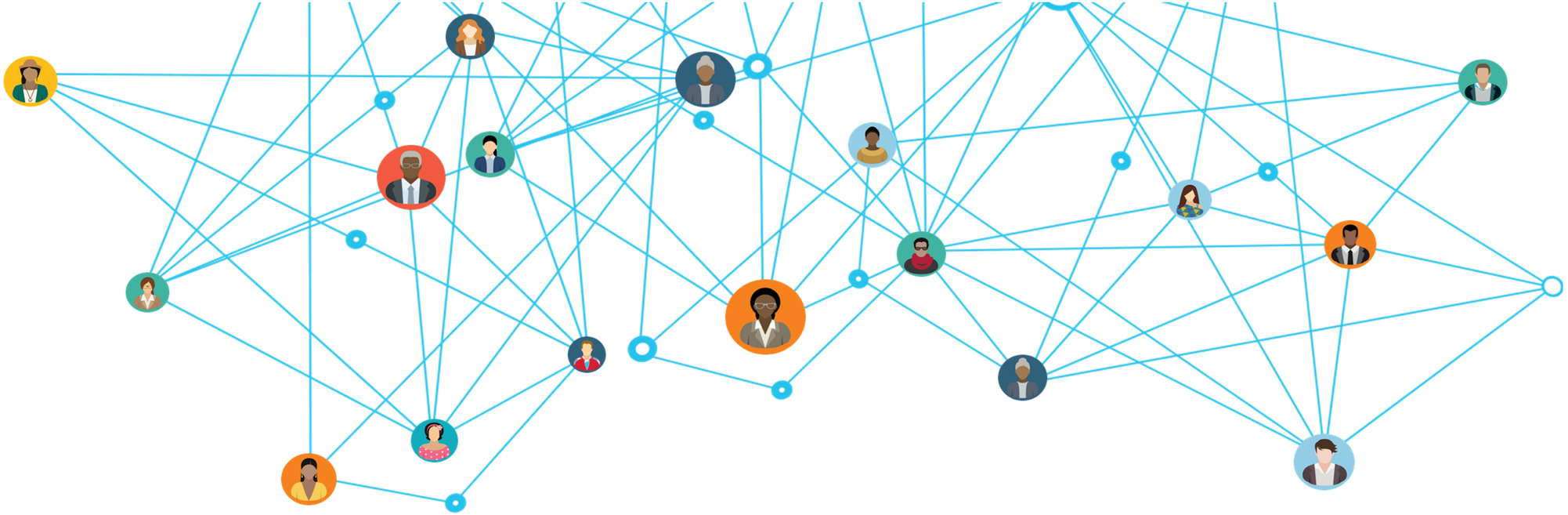
What is *All of Us*?

- Started with the Precision Medicine Initiative (PMI) kicked off by the White House in 2015

- ***A Rich, Longitudinal Resource***: A national resource to support a broad range of research using information from a million participants (or more!) who provide of deep **clinical, environmental, lifestyle, & genetic data** on an ongoing, longitudinal basis (60+ years!)

(Adapted from Ericka Thomas's segment of PRIM&R AER 2020 session "A Conversation with All of Us: Considerations for a Diverse Cohort at a National Scale")

What is *All of Us*?



- The most ambitious registry/repository in the U.S.

- Enough Americans sharing enough data allows researchers (from anywhere!) use modern “big data” approaches to answer key questions about health.

How do you build a 1M participant Registry/Repository?

- Health Provider Organizations
  - *Engage with their local patient population and local/regional communities*
  - *Includes 268 regional medical centers, 19 FQHCs, and 7 VAMCs.*
- Direct Volunteer
  - *Anyone anywhere in the US can sign up to participate in the program*
  - *Use Walgreens and Quest to collect physical measurements and biospecimens (at ~85 sites across the US)*
- Engagement Partners
  - *Working with trusted organizations across the country to talk about the program and build awareness*
  - *National network of ~140 partners*

A LOT of Partners!

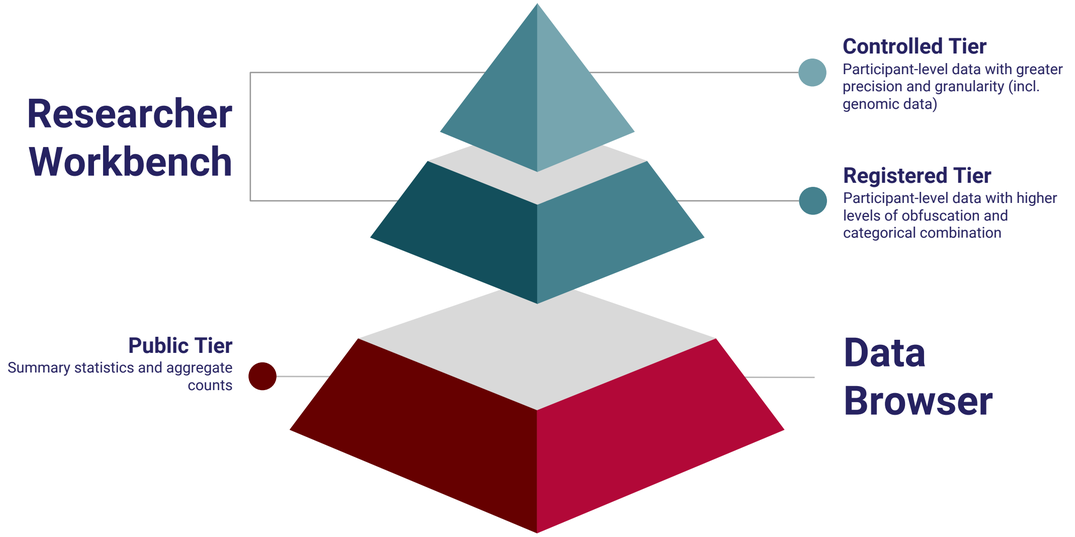
Unique Features

1. Participation is open to all.
2. Participants reflect the rich diversity of the United States.
3. Participants are partners.
4. Transparency earns trust.
5. Participants have access to their information.
6. Data are broadly accessible for research purposes.
7. Security and Privacy are of highest importance.
8. The program will be a catalyst for positive change in research.

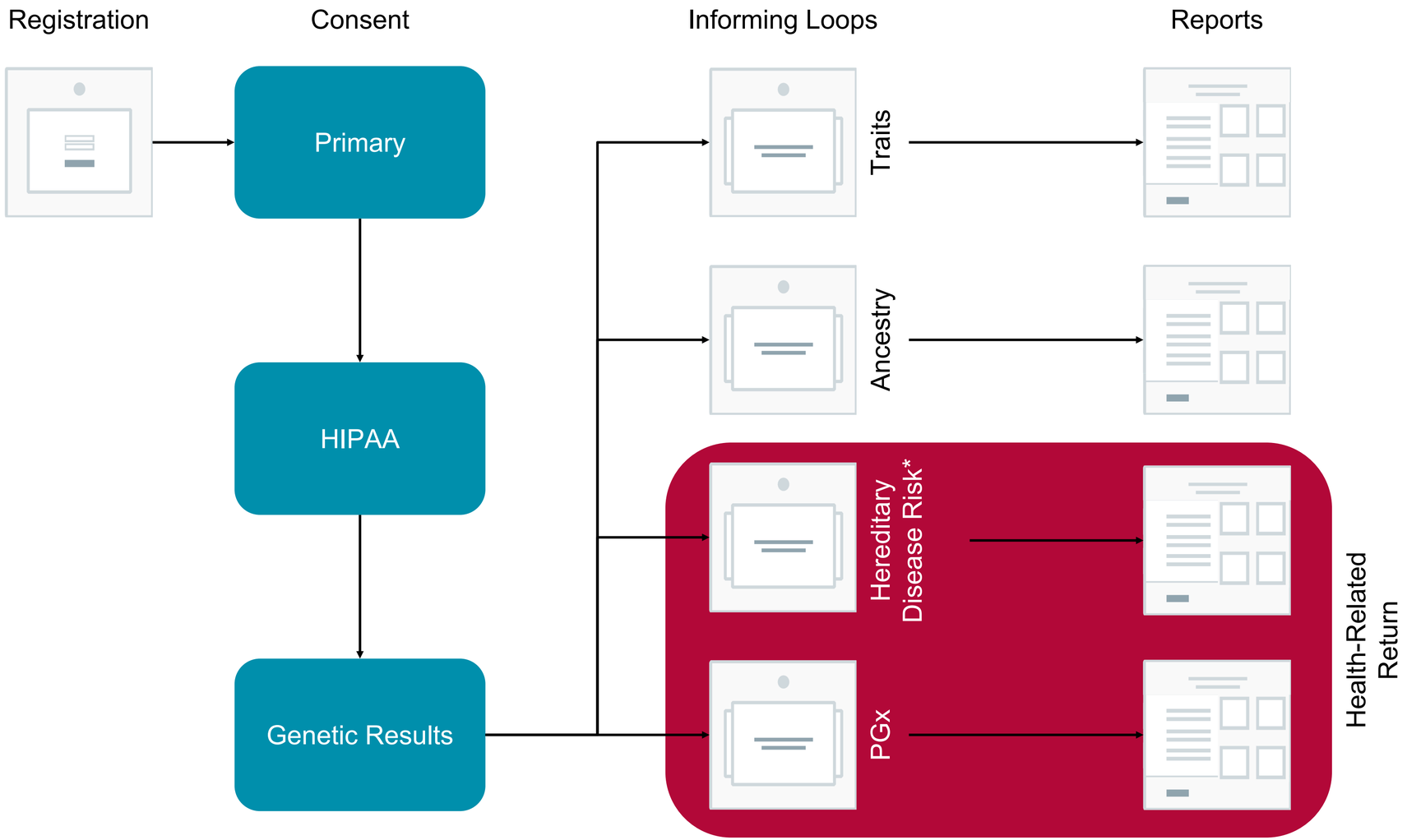
Unique Features

1. Data will be available on a cloud-based resource
2. Data will be available to all types of users
3. Data doesn’t leave our platform

5. Access is tiered
6. Projects will be made public and auditable



Unique Features



(Borrowed from Kate Blizinsky's segment of PRIM&R AER 2020 session "A Conversation with All of Us: Considerations for a Diverse Cohort at a National Scale")

The *All of Us* IRB* & How it's not like other IRBs.

*the IRB Formerly Known as The PMI IRB

Things to know about the *AoU* IRB

- Created specifically for the *AoU* Research Program
  - But for the program the IRB would not exist
- Single IRB by design
  - Everything about it was custom-created for or tailored to this program (Policies and Procedures, reviewer platforms and worksheets, the selection of members, etc.)
- IRB created and supported by contract mechanism through NIH OSP
  - Keeps IRB and its operations at an arm's length from research operations
- 1:1 Ratio of Studies to IRB
  - Reviews one really big research protocol and all sorts of embedded sub-studies.
- Members are unaffiliated with the *AoU*RP
  - All but one unaffiliated with the NIH.
  - Come from across the country

Things to know about how the *AoU* IRB Works

- All reviews are expedited reviews
  - Entire program is minimal risk research
  - Still holds regular meetings (called “Expedited Review Sessions”) to facilitate consistent reviews and keep all members informed
- Not just an IRB, but also an ethics resource for the program
  - Enforces the Program’s Core Values
  - Regularly consulted by program on various challenges

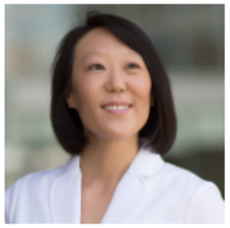
Our IRB Members

Chester Antone

O'odham Elder, Tohono O'odham Nation

Wilma R. Batiste, CRC, NCPT

Chair, Faith Communities Committee, Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco



Arlene Chung, M.D., M.H.A., M.M.Ci.

Associate Director of Health and Clinical Informatics, Assistant Professor of Medicine and Pediatrics, University of North Carolina School of Medicine

David Magnus, Ph.D.

Vice-Chair of IRB, Thomas A. Raffin Professor of Medicine and Biomedical Ethics and Professor of Pediatrics, Stanford University

Deven McGraw, JD, MPH

General Counsel and Chief Regulatory Officer, Ciitizen Corporation

Duke Morrow, M.Div., D.Min.

University of Michigan Health System IRB

Ysabel Duron

Founder and Director, Latino Cancer Institute

Kadija Ferryman, Ph.D.

Postdoctoral Scholar, Data & Society Research Institute

Aaron Goldenberg, Ph.D., M.P.H.

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David Murray, Ph.D.

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Professor of Pediatrics, Harvard Medical School

Nancy E. Kass, Sc.D.

IRB Chair, Vice Provost for Graduate and Professional Education, Professor of Bioethics and Public Health, Johns Hopkins University

Stephen B. Thomas, Ph.D.

Director, University of Maryland Center for Health Equity

Lessons we’ve learned

Lessons Learned (in no particular order)

- Reliance Agreements (Ugh…)
  - No matter how many times you've used it, how many institutions have signed it, how many lawyers have reviewed it, nearly everyone will have a comment on it.
- Investigators have love/hate relationships with IRBs
  - Whether they love or hate your particular IRB seems to have a whole lot to do with context at hand.
- Blind spots are real
  - You can't know everything about a PI or a site, no matter how extensive your forms.
- Communication, Communication, Communication
  - Across stakeholders – all of them – is crucial.
- Plurality
  - In other words: leaving room for local variation
  - It's tough, but oh so beneficial!