The Precision Medicine IRB: Who are we, and what are our commitments?

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Outline for today

• What is the All of Us Research Program?
• How is the AoURP IRB constituted?
• Issues IRB has raised with investigators
• Future questions likely to be faced
• Ethical promise/caution of PMI-
  – IRB always aware of both
All of Us Research Program

• “Cornerstone” of NIH Precision Medicine Initiative
• >1 million Americans to enroll
• **Data**: questionnaires, EMR, health tracker data, physical exam, biological samples, location data
• **Uses**:  
  – Cohort’s data available for observational study  
  – Huge research-friendly cohort self-identified for other studies’ recruitment
“Diverse” sample defined four ways

- People
- Health Status
- Geography
- Data Types
Two Methods of Outreach/Recruitment

DIRECT VOLUNTEERS

HEALTH CARE PROVIDER ORGANIZATIONS
Participation in the *All of Us* Research Program will be **open** to interested individuals.

The program will reflect the rich **diversity** of America.

Participants will be **partners** in the program.

Trust will be earned through robust **engagement** and full **transparency**.

Participants will have **access** to information and data about themselves.

Data from the program will be broadly **accessible** to **empower research**.

The program will adhere to the PMI **Privacy** and **Trust** Principles and the PMI **Data Security** Policy Principles and Framework.

The program will be a catalyst for **innovative research** programs and policies.
PMI Institutional Review Board (IRB) roster

- **Nancy Kass**, Professor of Bioethics and Public Health, Johns Hopkins (Chair)
- **Anita Allen**, Vice Provost for Faculty, Professor of Law and Philosophy, University of Pennsylvania
- **Arlene Chung**, Assistant Professor of Medicine, Pediatrics, Bioinformatics Core, University of North Carolina
- **Ysabel Duron**, Founder, Latinas Contra Cancer
- **James Jackson**, Distinguished Professor, Psychology Director, Institute for Social Research, University of Michigan
- **Loretta Jones**, Founder and CEO, Healthy African American Families
- **David Magnus**, Professor of Medicine and Biomedical Ethics, Stanford University
- **David Murray**, Associate Director for Prevention, NIH
- **Gail Jarvik**, Head, Division of Medical Genetics, University of Washington Medical Center
- **Duke Morrow**, Reverend and Prisoner Advocate
Precision Medicine IRB

• Central IRB
  – For master protocol
  – For sites
  – Future studies using PMI data- a bit unclear

• Mostly work remotely (email, phone)
  – 2-3 in-person meetings/year
Approvals and “pipeline”

- 3 pilot protocols approved
- Master protocol approved
  - 500 participants enrolled!
- Site applications (focus: recruitment strategy, targets, engagement, diversity training)
  - 6 approved; 5 pending approval; 4 just submitted
- NIH has funded…
  - 50 organizations
  - 137 locations
Issues IRB has focused on?

• Privacy/Data security
• Pilot testing/Comprehension of survey questions
  – Especially for low literacy populations
• Piloting/comprehension of (mobile) consent
• Truly diverse enrollment
  – How to achieve?
  – Engagement of target populations?
  – Cultural sensitivity?
  – Diversity in photos/images without stereotypes
Issues IRB has focused on

• Not exaggerating “promise of precision medicine”
• Emphasizing that program is research
• Voluntariness of patients/employees
• Developing translation policy (especially given careful wording of questionnaires, etc.)
Future ethics questions to be faced...

- Access to data in future by other researchers
  - What data can be accessed by whom?
  - How identifiable?
  - What types of access require specific consent?
  - Open data = value; can anonymity can be promised?

- Which results should be returned?

- BIG PICTURE: Are the research interests of diverse populations being equitably addressed?

- BIG PICTURE: How to help realize promise of improved care from this knowledge? Including for all groups who volunteered.
The potential of PMI...

• Research has the power to do good
• PMI provides resource efficiency (not recreating cohorts with every question) to allows more questions to be addressed more quickly
• >1 million people enrolled allows certain questions to be answered that take huge cohorts or hard to find small subgroups
...and Ethics stakes are high and critically important

• Largest government study on its own people
• When government does science, participant welfare and trust are essential
  – May be no second chances
• Promises made must be upheld
  – About data security
  – About enrolling diverse sample
  – About respectful engagement
  – About partnership “every step of the way”
  – About Americans’ health care improving as a result
Thank you!

- Thoughts?
- Ideas?
- Questions?