# 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
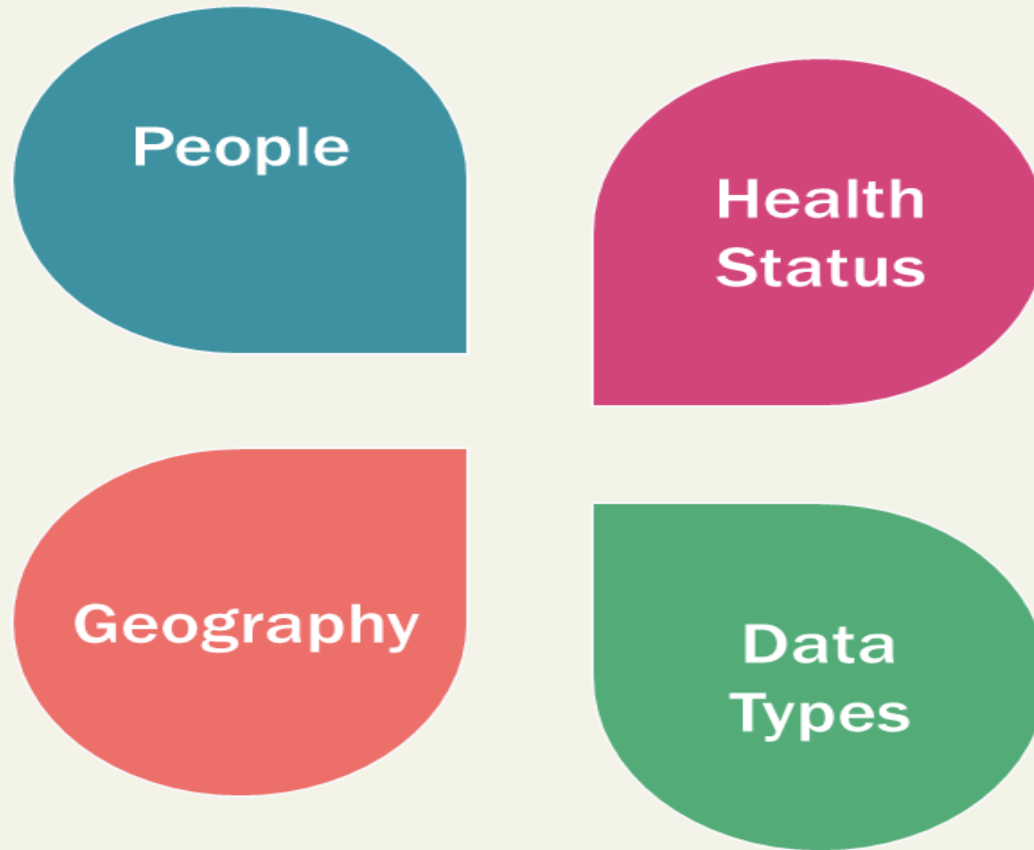
# Two Methods of Outreach/Recruitment

**DIRECT VOLUNTEERS**

**HEALTH CARE PROVIDER ORGANIZATIONS**

# *All of Us* Values

- 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?