California Initiative to Advance Precision Medicine

Equitable Consent Working Group
Draft Meeting Summary, February 2022

Reviewed one-pager for outreach

Emphasize community engagement, community partnerships, involvement of community-based organizations

Review of Outreach Meetings

- Jazmine Garcia Delgadillo, DrPH, Health and Equity Program Manager, SGC, OHE-AC member
    - Emphasize why it matters, up front
    - Explain how it contributes to health equity
    - Address power imbalances and coercion
    - Identify where CHWs could be an asset
    - Latino Coalition for a Healthy California
    - Introduction to OHE-AC staff
- Stanford Cancer Disparities Community Advisory Board, including Mike Witte, CMO for CPCA
    - Present as a model FQHCs that have existing IRBs
    - Patients from FQHCs are higher risk, in higher density populations, older, Medi-Cal participants; including them in prevention trials is even more important
    - Include people with disabilities as a subpopulation
    - Have patient-centric endpoints
    - Merck initiative to increase diversity in cancer trials
- Sara Bernstein, Manager, Research Information, National MS Society
    - Include considerations about running trials during COVID (Online support groups)
    - Include links to lists of clinical trails
    - Engage medical writing programs for review
    - “Consent is a process, not a one-time event”
    - “Dentro De Mi”, Lilyana Amezcua, USC
    - Minority MS engagement toolkit
    - Acknowledgement that chronic diseases are unique; more about learning to live with it
    - Include call to action, steps to take; inspire them to do something; Rethink the title of the webpage to be more active
    - “A wonderful and comprehensive effort”.
- Maya Sabatello, PhD, Center for Precision Medicine and Genomics; Division of Ethics, Columbia University
    - Importance of continuous engagement
    - It’s not that potential participants are distrustful, it’s that researchers aren’t trustworthy
    - The line between care and research is being blurred with the mining of EHRs
    - Funding should be tied to ADA compliance

- Referring physicians often assume people with developmental disabilities lack the capacity to participate, even if they live independently; they also don't refer patients who have disabilities even when the disability has nothing to do with the study
- Documents should be available in braille, for example, as opposed to having someone read aloud to a participant with visual impairment
- Patient-centered endpoints: 65% of autism research funds are to look at genetic underpinnings, as opposed to finding ways to enhance life satisfaction

Review project presentation for outreach

- Include information about longitudinal studies, return of results
- Include historical case studies in which authentic participation by communities of color led to good outcomes, demonstrating best practices
- Look at work of Esteban González Burchard, UCSF

Phase Rollout

PHASE 1- expected summer 2022

- Introduction
- Existing laws and policies
- Content for existing and potential research participants, excluding stories

PHASE 2- expected fall 2022

- Content for researchers, excluding population-specific guidance
- Content for research staff

PHASE 3- expected winter 2022

- History and case studies
- Population-specific guidance

PHASE 4- expected spring 2023

- Content for sponsors
- Content for healthcare providers, CBOs, and clinics
- Stories of participants

Outline view

1) Introduction — PHASE 1
   a) Race, ethnicity, ancestry, and genetics
   b) Different types of consent
   c) Current state of URM in research
   d) EC Definition
   e) Equitable engagement process- timeline

2) History and Case studies — PHASE 3

3) Existing Laws and Policies — PHASE 1

4) **For existing and potential research participants**
   a) Why it matters — PHASE 1

b) Questions to ask — PHASE 1
c) Rights and responsibilities — PHASE 1
d) Consent process — PHASE 1
e) Immigration status and public charge — PHASE 1
f) Stories, quotes, videos — PHASE 4

5) **For researchers**
a) COVID considerations — PHASE 2
b) General considerations — PHASE 2
c) Proportional representation — PHASE 2
d) Recruitment — PHASE 2
e) public charge — PHASE 2
f) Return of results — PHASE 2
g) UCLA consent templates — PHASE 2
h) MRCT report — PHASE 2
i) Consent Process and Language — PHASE 2
j) Consenting for genetics and genomics — PHASE 2
k) Partnering with industry — PHASE 2
l) Compensation — PHASE 2
m) Data Sharing — PHASE 2
n) Population-specific guidance — PHASE 3

6) For research and clinic staff — PHASE 2
a) Why it matters
b) Data/sample collection
c) Printable one-pagers
d) Checklists

7) For research sponsors — PHASE 4
a) RFP Development
b) Evaluation

8) For healthcare providers, CBOs and clinics — PHASE 4
a) Process
b) Bias
c) Regulations
d) Insurance
e) Communicating with the research team

Public Comment

- James Stewart, NMSS District Activist Leader

  Consider more complete posting of available clinical trials, populated by trail sponsors and patient advocacy groups

- Cathy Hickinbotham, Council on Criminal Justice and Behavioral Health, based out of CA Corrections and Rehabilitation

  Looking forward to connecting in the future, particularly around the $10M depression research budget item

- Ben Rubin, Precision Medicine at UCSF

  Questions about the dissemination

  What does success look like, and how will the program be evaluated?

  Can we capture the changes in rates of participation by URM in research, that makes use of the tools and resources that are presented?

Next Steps

- Continue 1:1 meeting with thought leaders
- Continue to present at meetings with relevant groups and organizations
- Create a more granular timeline of the rollout
- Create a dissemination plan
- Move ahead with added consultant and staff
- Continue content development and organization