



## Equitable Consent Working Group Meeting Summary, April 2022

### Review of Outreach Meetings

- David Higgins, PhD, CIRM Board of Directors, UCSD Parkinson’s Patient Advocacy Group Leader
  - Several Parkinson’s clinical trials have ended prematurely because of lack of enrollment
  - There is a serious lack of diversity in Parkinson’s support groups despite extensive outreach efforts in multiple languages
  - Will connect with UCSD neurology faculty who has headed the support groups
  - Will connect with a USC Parkinson’s researcher
  - Will help with content review and dissemination
- Robb Layne, Senior Advocate, Policy and Legislative Affairs, CA Council of Community Behavioral Health Agencies
  - Lots of communities are “inappropriately served”- Native tribes example
  - There must be trust that information won’t be shared with law enforcement, for example. No matter the safeguards, risk will always exist.
  - Will help connect with representatives from the social justice space
  - Will help with content review and dissemination
- Debra Cooper, PhD, California Black Health Network Board of Directors Member
  - Connect to Executive Director, Rhonda Smith
  - Trust-building is vital, and the onus is on the researchers
  - Might invite to present to entire board, and connect with community events
  - Remember that subpopulations are not a monolith
  - Will help with review and dissemination

### Content Development

Highlight of timeline for existing laws and policies (summaries and links not included)

Law Name	Year Enacted
Hippocratic Oath	5th Century BCE
AMA Code of Medical Ethics	1847 (updated 1903, 1912, 1947, 1957, 1980, 2001)
Pure Food and Drug Act	1906 (amended 1912)
Food Drug and Cosmetic Act	1938
Public Health Service Act	1944
Nuremburg Code	1947
Universal Declaration of Human Rights	1948

Kefauver-Harris Amendments	1962
Declaration of Helsinki	1964 (amended in 1975, 1983, 1989, 1996, 2000, 2002, 2004, 2008, & 2013)
Beecher Article	1966
AHA Patient Bill of Rights	1973 (revised 1992)
National Research Act	1974
Medical Device Regulation Act	1976
CA Penal Code Behavioral and Biomedical Research; Prisoners' Rights as Research Subjects (Sections 3500-3523)	1977 (amended 1985, 1995, 2003, and 2016)
California Information Practices Act	1977 (amended 2021)
CA Protection of Human Subjects in Medical Experimentation Act	1978 (amended 1979, 1996, 1999, 2003, and 2013)
FDA Protection of Human Subjects	1978 (updated regularly)
Belmont Report	1979
Protecting Human Subjects	1981
UC Protection of Human Subjects in Research	1981 (updated 2020)
Human Genome Project ELSI	1990
Omnibus Budget Reconciliation Act of 1990	1990 (amended 1991)
Federal Policy for the Protection of Human Subjects ('Common Rule')	1991 (Revised 2018)
Patient Self-Determination Act	1991
Prescription Drug User Fee Act	1992
NIH Revitalization Act	1993
UC Gender and Ethnicity Representation in Health Research	1993
WHO GCP	1994
CA Education Code 51513	1995
Health Insurance Portability and Accountability Act	1996
ICH E6(R2) Good Clinical Practice	1996 (amended in 2016) – EWG draft updated released in 2021
Health Center Consolidation Act	1996
Universal Declaration on the Human Genome and Human Rights	1997
FDA Demographic Rule	1998
NIH Required Education in the Protection of Human Research Participants	2000
FDA Guidance on Collection of Race and Ethnicity Data in Clinical Trials	2005
The Genetic Information Act Nondiscrimination Act	2008
Patient Protection and Affordable Care Act	2010
CalGINA	2011
Food and Drug Administration Safety and Innovation Act	2012
Drug Quality and Security Act	2013
21 <sup>st</sup> Century Cures Act	2016
All of Us Research Program – ELSI White Paper	2020

## Detailed rollout of phases

### Phase 1 (2022)

- March – May: Content development
- June: Content review
- July: Content launch and dissemination

### Phase 2 (2022)

- June – September: Content development
- October: Content review
- November: Content launch and dissemination

### Phase 3 (2022-2023)

- October – December 2022 : Content development
- January 2023 : Content review
- February 2023: Content launch and dissemination

### Phase 4 (2023)

- January – March: Content development
- April: Content review
- May: Content launch and dissemination

## Phase 1 Rollout Detail

### Content Development

*March – April 2022*

- Content Generation

*May 2022 – in word doc*

- Legal review
- Comms review
- Internal content review:
  - Council members
  - Governor's Office

### Content Review

*June 2022 - in web test pages*

- Comms prep
- External content review:
  - California Black Health Network Behavioral Health Clinics
  - Parkinson's Patient Advocates
  - Professor of Disability rights
  - MS Society Communications
  - CIRM
  - Health Equity Program

- Takeda Executives
- ADA compliance

## Content Launch and Dissemination

*July 2022*

- Twitter Post
- Email announcement
- Outreach to specific stakeholder groups
- CIAPM and OPR newsletters
- LinkedIn
- Notion page

## Public Comment

- James Stewart, NMSS District Activist Leader
  - Focus on making connections between patients and clinical researchers

## Next steps

- Continue 1:1 and organization meetings
- Finalize staff hiring
- Continue content development and organization
- Develop content review process
- Begin content review
- Continue development rollout plan