



Project Overview: Equitable Engagement and Consent in Research

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California Initiative to Advance
Precision Medicine

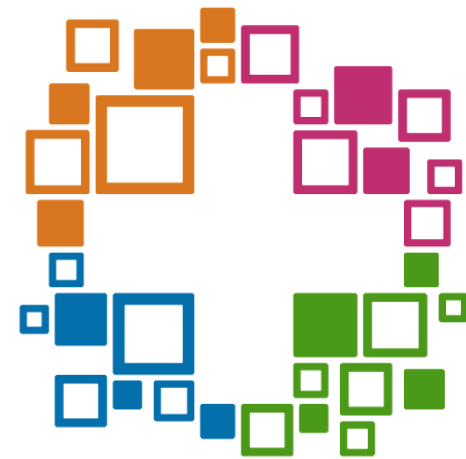
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California Initiative to Advance Precision Medicine (CIAPM)

- Established in 2015
- \$47 million investment
- Grantmaking to support demonstration research projects
- Focus on **cross-sector partnerships** between researchers, communities, health care providers, industry, and others
- Mission includes **reducing health disparities**
- Strong emphasis on **community-researcher collaborations** to ensure research results are aligned with California communities' priorities



California Initiative to Advance
Precision Medicine

Project: Equitable Engagement and Consent in Research

Overarching Goal

Advance health equity by increasing participation of underrepresented subpopulations in clinical research



Project: Equitable Engagement and Consent in Research

Justification

Marginalized racial, ethnic, gender, age, and geographical subpopulations are underrepresented in clinical research. Consequently, medical diagnostics, treatments, and devices may not be equally safe or effective for all potential patients.



Project: Equitable Engagement and Consent in Research

Website

Create and curate an online collection of resources that conveys the importance of authentically engaging diverse communities as partners in clinical research and provides best practices for stakeholders to increase participation by underrepresented subpopulations.



Project:

Equitable Engagement and Consent in Research

Website Features

- Provide resources and best practices for clinical research stakeholders
 - Sponsors
 - Researchers
 - Research staff
 - Potential and current research participants
 - Health care providers who may refer patients, and clinics
- Content is culturally and linguistically appropriate and accessible
- Stay current by adding new resources



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Website Scope

- Ongoing engagement
- Recruitment
- Consent
- Retention
- Recontacting



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— Website Content —



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Introduction

- Definition: *equitable consent* for research
 - Cultural competency
 - Proportional representation
- Different types of consent
 - Consent for medical treatment
 - Consent for sample use
 - Consent to be a participant
- Equitable engagement in research timeline
- Current state of URM in research
- Primer: Race, ethnicity, and ancestry



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Importance of Precision Medicine

- Case studies of race, ethnicity, and/or ancestry
 - Viagra
 - Crestor
 - Bildil
- Case studies of gender differences
 - Ambien
 - etc.
- etc.



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History

- Introduction
- Interactive graphic/timeline
- Case Studies
 - Vesicovaginal fistula surgery
 - Pellagra
 - Tuskegee Syphilis Study
 - Nazi Prison Camps
 - Radiation experimentation in the US
 - Willowbrook State School hepatitis studies
 - Henrietta Lacks
 - Prisoners as research subjects
 - Guatemalan study
 - Forced sterilizations
 - Conversion Therapy



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Laws and Policies

- Hippocratic Oath
- Nuremberg Code
- Declaration of Helsinki
- Belmont report
- State Law- CalGINA
- Federal Law: National Research Act, GINA
- UC
- NIH/All of Us
- FDA
- Americans with Disabilities Act



Project:

Equitable Engagement and Consent in Research

Best practices, guidance, and toolkits: Sponsors

Family foundations, state research programs

- RFP development
 - CABs
 - Proportional representation
 - Selection criteria
 - Selection committees
 - Accessibility
- Evaluation



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Best practices, guidance, and toolkits: Researchers

- General considerations
 - Transportation
 - Dependent care
 - Care givers
 - Notes for Participation
- Proportional representation
- Recruitment
- Consent that facilitates data sharing
- Payment for participation
- Partnering with industry
- Consenting for genetics and genomics
- Consent process and language
 - How to adapt existing materials
 - Syntax
 - Health Literacy
 - Comprehension and Retention
 - Digital divide
 - Accessibility
- Return of results
- Bias
- Accessibility
- COVID considerations
- Population-specific guidance
 - African Americans
 - Hispanic/Latino
 - AAPI
 - Native Americans
 - Women
 - Recent Immigrants/ undocumented
 - GSM- Gender and sexual minorities
 - Individuals with disabilities
 - Minors
 - Older Americans
 - Religious considerations
 - Intersectionality



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Best practices, guidance, and toolkits:

Research/Clinic/Hospital staff

- Why it matters
- Checklists
- Data/sample collection
- Printable one-pagers to provide to community members



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Best practices, guidance, and toolkits:

For Physicians who may refer, and clinics

- Process
- Bias
- Regulations
- Insurance
- Communication with researchers



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Best practices, guidance, and toolkits:

For Existing and Potential Research Participants

- Why it matters
 - To the individual
 - To the community
- Questions to ask
- Rights and responsibilities
 - Involvement of primary care provider
 - Coverage for care after the trial
 - Provision of notes from doctors
 - Transportation, dependent care
 - Care givers
- What the consenting process entails
- Immigration status or information/public charge
- Stories/quotes/videos from community members



Project:

Equitable Engagement and Consent in Research

Style

- Appropriate language for different stakeholders
- Translations
- Inclusive imagery
- Accessibility and ADA compliance
- Digestible content
- Link out to resources



Project: Equitable Engagement and Consent in Research

Ways to contribute

- Provide comments on scope and style
- Review draft content
- Invite project staff to present at meetings
- Dissemination on website, in newsletters, etc.

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Precision Medicine

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