California Initiative to Advance Precision Medicine

Equitable Consent Working Group Meeting Summary, June 2022

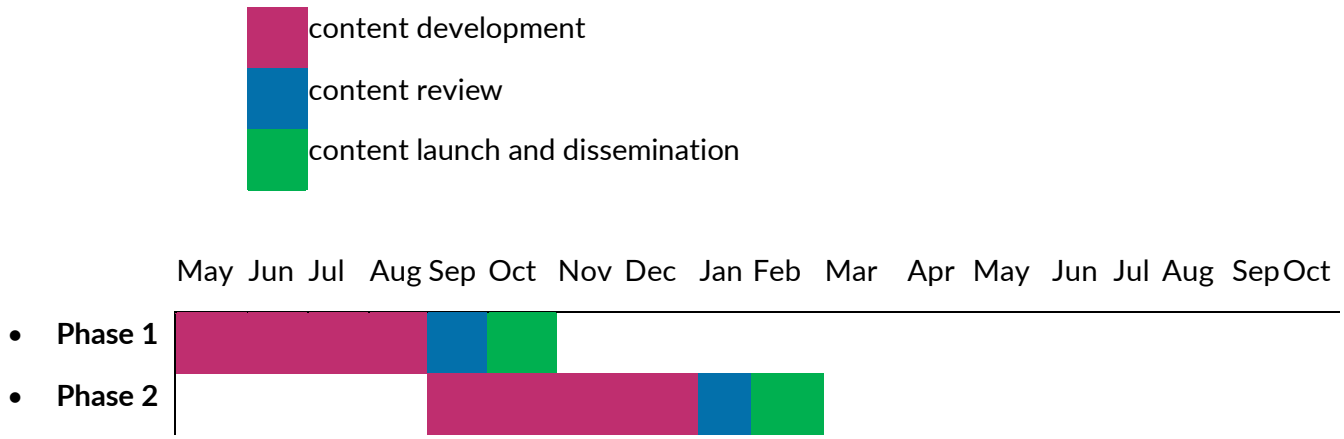
Introduction: Bridgette Smith

Bridgette Smith will soon come on board as a graduate student intern focused specifically on the Equitable Consent Working Group project. She is a doctoral candidate in the Epidemiology Graduate Program at University of California, Davis. Her research aims to increase health equity through exploring the distribution of health outcomes in relation to the social and built environment to inform institutional policy. Additionally, Bridgette works with Dr. Alice Popejoy on race, ethnicity, and ancestry, and their relationship to health outcomes. She received her master's degree in public health from UC Davis and her bachelor's degree in microbiology from UC Merced. Ultimately, Bridgette is dedicated to community-engagement efforts, and hopes that through her work she amplifies the voices of historically vulnerable communities and ensures that research is equitable and representative of the public health challenges and its population.

Review of April meeting

- Outreach meetings:
    - David Higgins, PhD, CIRM Board of Directors, UCSD Parkinson's Patient Advocacy Group Leader
    - Robb Layne, Senior Advocate, Policy and Legislative Affairs, CA Council of Community Behavioral Health Agencies
    - Debra Cooper, PhD, California Black Health Network Board of Directors Member
- Preview of content- existing laws and policies
- Plan for phased rollout of content, including detail

New rollout timeline



- **Phase 3**
- **Phase 4**

Phase 1 Rollout Detail

	June	July	August	September	October
Phase 1			*Miro board	*In web test pages	
	content generation		legal review	Comms prep	Twitter Post
			comms review	External content review:	Email announcement
			Internal content review:	California Black Health Network	Outreach to specific stakeholder groups
			Council members	Behavioral Health Clinics	CIAPM and OPR newsletters
			Governor's Office	Parkinson's Patient Advocates	LinkedIn
				Professor of Disability rights	Notion page
				MS Society Communications	
				CIRM	
				Health Equity Program	
				Takeda Executives	
				ADA compliance	

Discussion: Administrative Barriers to Research Participation

Fatima- it can be a burden for participants. We (at San Ysidro Health) focus on the critical pieces, based on the consent form, and make it very simple. Everything else, (legal matters, principles, etc.) should be available in a way that it's easy to find. Offer contact information for questions. Some participants will review all the materials, and will research all the aspects of the project, which is great, because they are more likely to engage going forward

Ysabel- Tiered information, perhaps delineated by color. Participant navigation at all levels will help. The disparate policies between US, states, institutions, public health agencies, legislative bodies, etc., make it especially difficult, for researchers *and* participants, etc.

Fatima- from the patient perspective, the differing laws don't really matter, and we should focus on the researchers. Aligning the goals of the participants, researchers, and sponsors will help.

Ysabel- point at groups that have done it successfully

Fatima- Offsetting the burden with incentives; grouping visits together (one seven-hour visit, instead of seven one-hour visits, etc.) Being transparent and explicit during the consent process can help, because they understand why different aspects of the project are important.

Ysabel- the navigation piece is becoming more popular, and will eventually be the norm, but the question remains about who that will do that, and the explicit scope of that work. Offering transportation and dependent care, a digital navigator can make the difference.

Ken- Studies using electronic diaries can be tough, because people have to be trained. The problems are being addressed by clinical research firms (transportation, compensation, etc.) Suggest $25-$50 per hour. A research coordinator could do it at a small site, but there are different roles at larger sites. But every study is going to be different.

Fatima- Covering transportation helps, but even if they have their own car, the distance, or convenience is also a factor.

Ken- a research participant liaison can communicate between the research center, the FQHC, and the participant.

Fatima- That also reduces a lot of the questions, problems, etc.

Ken- it's important to have high touch at the beginning, to develop trust.

Public Comment

Bridgette Smith: Would it be possible to conduct key informant interviews or focus groups of sponsors or researchers to gather these administrative burdens/bottlenecks?

Shannon: The planning and execution of focus groups takes time and resources that we don't have, but with the new $9.25 million budget item about increasing participation by underrepresented minorities in research, we may be able to fold that work into this project.

Fatima: The focus groups are a good idea, because it's a better way to learn how to reflect the needs of our community. The integration with the representation project would be great.

Bridgette Smith: Perhaps on the website, we can include some sort of feedback mechanism, asking people directly what they perceive as barriers.

Shannon: That's an interesting idea, maybe including a link to an online form will be enough.

James Stewart: With the goal being to increase participation of underrepresented subpopulations in clinical research, it seems to me a metric as simple as how many patients find a clinical trial through the Precision Medicine website would help. This could be broken down by underrepresented communities. Ask patients via survey if and which barriers are a hindrance.

Shannon: We will check into analytic possibilities once phase 1 launches.

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