California Initiative to Advance Precision Medicine

California Precision Medicine Advisory Council
Meeting Summary, November 2022

Introduction of New Advisory Council Member

Dr. Diana Ramos, Surgeon General

California Surgeon General Dr. Diana E. Ramos is dedicated to improving health care quality and equity. She recently served as the Assistant Deputy Director of Chronic Disease Prevention for the California Department of Public Health. Past roles include the Director for Reproductive Health in the Los Angeles County Department of Public Health and adjunct Associate Professor at the Keck University of Southern California School of Medicine.

Her areas of expertise include health disparities, social determinants of health, preconception/interconception health, preterm birth, contraception and quality improvement in health. Dr. Ramos has written and contributed numerous articles to the obstetrics and gynecology and public health literature and has lectured in Spanish and English, locally, nationally and internationally.

Dr. Ramos received her medical degree from the University of Southern California with honors and completed her residency training in obstetrics and gynecology at Los Angeles County-University of Southern California Medical Center. She received her MBA from the UCI Paul Merage School of business with an emphasis in entrepreneurship and innovation and her master's in public health from the University of California, Los Angeles. Dr. Ramos completed her undergraduate degree, a BA in Communications, Arts & Science from the University of Southern California.

Opening Remarks: Chair Lajonchere and Vice Chair Yam

- Welcome to Dr. Ramos to the Advisory Council and welcome to students and trainees. Excited to see the leadership that California has taken for reproductive health.
- Having Dr. Ramos the council bodes well for the California precision medicine effort. The precision medicine efforts ring strongly on how we want to move society. The precision medicine effort focused on being able to deliver the best

health advice, treatment, and care to the level of the individual; not to statistical groups that can lead to bias.

Updates from the Newsom Administration

Sam Assefa, Director of Governor's Office of Planning and Research

Welcome Yuki for joining the group and the state. Thank you all for what you do on behalf of California and what you do for advancing health.

As we embark on the second term of the Newsom Administration, OPR is looking forward to helping the Governor work toward his vision of a California for all. Details about the plan to achieve that vision will be made public at a later date. In the meantime, the precision medicine program is engaging partners in a new way, and at a scale that has never before been achieved. As you know, through the Representative Research Collaborative that Julianne is heading, OPR will be working formally with the Departments of Developmental Services, Rehabilitation, Aging, and others, as well as several non-state partners. The Collaborative represents a new chapter for OPR and the precision medicine initiative, and is an example of OPR living up to its mission to work across agencies and sectors, and align efforts to maximize the impact of state government's investments. Likewise, the Depression Research Program is just one of the many ways the Governor is addressing mental health issues in California. From the formation of the Governor's Behavioral Health Task Force and the Children and Youth Behavioral Health Initiative, the Governor is investing resources to improve behavioral health, and OPR is proud to be part of that effort.

Richard Figueroa, Deputy Cabinet Secretary

We are facing a tighter budget in terms of adding new things. We expect to receive ~$6-8 billion less than the past year. We have built a substantial economic resilience that will hopefully protect from reducing current activities.

Accepted May 2022 meeting summary

- CIAPM work is expanding
- Discussed the CIAPM impact assessment
- Discussed the Depression Research Program
- Discussed Representative Research Collaborative
- 2021 Annual Report
- Reports back from working groups

Depression Research Program

- $10 million: $9 million in grants, $1 million for admin
- Competitive grant program to support precision medicine-based approaches to preventing, diagnosing, and treating depression
- 3-5 projects
- Up to $3 million per project, 36-month project period

Senate Mental Health Caucus:

- Staff have started discussions with the Senate Mental Health Caucus as of day before the last meeting. If you are interested, please reach out and let Shannon know.
- Received feedback from the vice chair of the Senate Mental Health Caucus. A short meeting but was heavily focused on the mental health of women and girls
- Working with OPR legislative team to engage for the 2023 session. Looking into an informational briefing.
  Clara
  This is a great opportunity for us to move the needle.
- Working with OPR legislative team to engage for the 2023 session. Looking into an informational briefing.

  Process:
  ☐CPMAC: Discuss major points, suggest emphases, etc. (finished)
    - Individual meetings
    - Council meeting discussion
    - Invitation to submit comments
  ☐ RFP: Background research and drafting (ongoing)
  ☐ Procure an application management system (ongoing)
    - In the hands of our procurement team, once we secure a vendor we will have a more secure timeline.
  ☐ Set RFP Timeline
  ☐ RFP review with state entities (OSG, HHS, OHE, etc.)
  ☐ RFP released
  ☐ Recruit out-of-state selection committee
  ☐ Select finalists
  ☐ Select awardees

  Would like projects to start July 1, 2023, but outside of our control.

  Discussion:

  - Ysabel: Hope that the RFP application is precise its aims to serve DEI. As we are a majority minority state, we saw a lot of trauma with COVID in minority populations. We hope that the researchers will be precise in how they will serve

the population of choice, such as language, etc. This will make a huge difference for our children in these different communities.
- Clara: Strongly agree. Shannon, is there a diversity, JEDI statement required as a part of the RFP?
- Shannon: I have started adopted the language of some of the RFPs that you all shared in which acknowledged diversity needs well. Without sharing exact details of what is included in the RFP, the diversity aspect is something that will be strongly incorporated.
- Clara: Maybe an impact statement as well, would be great. It would be great for people to go above and beyond. We want to make sure folks are taking it seriously.
- Dr. Ramos: If there is a way that we can be deliberate that the RFP focus on a particular population and not just a translation. To really be culturally inclusive, we have the target audience as the outcome. Have seen so many missed opportunities when programs just translate.

Unfortunately, advisory council members will not be able to review the RFP before it is released due to the affiliation with institutes that may apply.

Due to Julianne's guidance for authentic collaboration, we will be using this guide again to share with the applicants. Along with the resource to asset inventory.

- Clara: If there is an opportunity for there to be a community advisory council group, as an external stakeholder. We can really work to make sure there is true impact.
- Shannon: Will look into how we can work with that, however, cannot promise with lack of staff.
- Keith: Support comments for external advisors. We may consider going back to previous external reviewers who have looked at applications in the past. This group have already shared their willingness to help out.
- Fatima: The RFP should reflect that the community partner should be involved in the planning and development process. The community advisory board should be included in the development phase of the project. We want to make sure it aligns with the DEI component.

Opportunities for engagement by council members:

- Notice of intent (NOI) dissemination
- RFP dissemination
- Recommendations for out-of-state reviewers
- Send in RFPs that can be used as examples

Representative Research Collaborative

- $9.25M to increase participation in biomedical research
  - 5-year interagency collaborative
  - study/develop best practices, create materials, host events
  - Commitments from nine public agencies

Priority Populations

1. Central Valley residents
2. Migrant workers
3. Residents north of I-80 (Sacramento and above, particularly the far northern regions of California)

Project Aims

1. Recruit and retain participants who reflect the rich diversity of the Federal Precision Medicine Initiative, otherwise known as *All of Us*.
   - Task leaders: OPR, Department of Public Health (one FTE health specialist through its Office of Health Equity)
   - Task participants: CA Mental Health Services, CA Institute for Regenerative Medicine, CA Dep of Developmental Services, CA Dep of Rehabilitation (one FTE program analyst), CA Dep of Aging, CA State Univ. Office of the Chancellor, USC (Hollywood Health & Society), CA Primary Care Association, CA Council of Community Behavioral Health Agencies, Association of CA Nurse Leaders, CA Pan-Ethnic Health Network
2. Engage researchers from diverse backgrounds to utilize the *All of Us* data resources. Target backgrounds are communities that CIAPM projects are tailored to, such as communities of color, rural residents, people with disabilities, older/younger Californians, and those who identify as LGBTQ+
   - Task leaders: CA State Univ. Office of the Chancellor, UC office of the President
   - Task participants: CA Institute for Regenerative Medicine
3. Collaborate with health care providers, specifically those who serve these underrepresented communities to engage them in conversations and to instill the value of engaging in research for those long-term benefits.
   - Task leaders: CA Primary Care Association, CA Council of Community Behavioral Health Agencies
   - Task participant: Association of CA Nurse Leaders
4. Develop novel assets that resonate with diverse groups by working with the NIH, *All of Us* consortium, and communications team to conduct multiple engagement,

enrollment, and retention campaigns (based on California's unique geographies and programmatic scientific priorities).
    - Task leaders: Department of Public Health
    - Task participants: CA Institute for Regenerative Medicine, CA Dep of Developmental Services, CA Dep of Rehabilitation, CA Dep of Aging, CA State Univ. Office of the Chancellor, Office of the California Surgeon General, CA Primary Care Association, CA Council of Community Behavioral Health Agencies, CA Pan-Ethnic Health Network
5. Contribute to the science of engaging, enrolling, and retaining UBR communities into research.
    - Task leaders: CA Institute for Regenerative Medicine
    - Task participants: CA Department of Public Health, CA Primary Care Association, CA Council of Community Behavioral Health Agencies

**Since this is funded by the state there will be a competitive RFP process to solidify external partners.*

<u>Timeline</u>

Sept-Dec 2022

1. Recruit candidates for two new positions: Equity Officer, Project Administrator
2. Initiate interagency agreements
3. Refine RFP for external partners

Jan-June 2023

1. RFP and selections for external partners
2. Finalize MOU with NIH *All of Us* program
3. Recruit candidates for new Public Health Graduate Student Fellowships

Jul 2023-Jun 2027

1. Launch annual conferences
2. Project implementations

Jul 2027-Jun 2028

1. Project Evaluation

Establishing a Project Steering Committee

Purpose: Provide guidance on the development of the project with a very hands-on approach

- Refine project goals
- Set deliverables and timeline
- Review selection process for funded partners
- Assess progress
- Recommend changes and connections

Meeting Frequency

- Twice-monthly meetings for first 6 months
- Monthly from 6 months onward

Composition [proposed]

- 7-9 members
  - 2 State officers from OPR and CDPH Office of Health Equity
  - 3-4 Representatives from Statewide, University Community Engagement, Clinical/Research network
  - 1-2 Representatives from CBOs or Direct service providers
    - Ysabel: Direct service providers are different from CBOs, so I would recommend more representatives from this section. Direct service providers have street experience and can provide a lot of insight. Think we need to put out broader net. Maybe we need a more regional representation. The more members you have representing, the more confidence you feel to share.
    - Clara: Like the idea and want to make sure that we keep the group tight knit.
    - Bonnie: We have some concern in regard to certain underrepresented groups in terms of trust and ability to move forward with what seems like data mining. A good idea to make sure the representation and element that goes into the project is very clear upfront. Gave an example of centralized *All of Us* data, and challenges with autonomy and ownership.
    - Fatima: Precision medicine is not a norm in many underserved populations. We may want to look into community health centers. Direct service providers and community-based organizations will have different perspectives, so it would be great to have community health centers perspectives as well.
    - Hakan: When we say underserved populations, what populations do we really mean? Can the number of members be increased? We may need to consider a larger group.
    - Ken: When we say top-tier versus middle-tier? The tiers were referring to funding, right? There are several private sector clinical trial sites that focus on enrolling minority populations, and currently they aren't represented. We should find a way to include.

Julianne will encourage we continue the conversation with any other suggestions or concerns via email. JM will follow up about advisors' guidance via email. JM will take all the feedback and incorporate into current process proposal, etc.

Working Group report-back: Data Integration

The Data Integration Working Group met and welcomed guest speaker Mike Valle, the HCAI Information Officer. Valle discussed about the goals of the program and welcomed data-focused public committees.

Looking Ahead

The Data Integration Working Group will next meet in January when the Chief Health Equity Research & Statistics, Peter Oh, will join for a discussion about linking data across Social Determinants of Health measures.

Working Group report-back: Equitable Consent

Website: Equitable Engagement and Consent in Clinical Research

Provide resources and best practices for clinical research stakeholders to increase participation by underrepresented subpopulations. Stakeholder groups include:

- Sponsors
- Researchers
- Research staff
- Potential and current research participants
- Health care providers/Clinics

Phased rollout of website content: new schedule

PHASE 1- expected fall 2022

Introduction
Existing Laws and Policies
For existing and potential research participants, excluding stories

PHASE 2- expected winter 2022

For researchers, excluding population-specific guidance
For research staff

PHASE 3- expected spring 2023

History and case studies
Population-specific guidance

PHASE 4- expected summer 2023

For Sponsors
For Healthcare providers
Stories of participants

Review of Website Model- Climate Assessment Webpage

- Web design is being led by OPR web design team; however, they are at capacity and welcoming in new staff therefore there should be more bandwidth to take over EC web design.
- To facilitate review, we will skip Miro board review and go straight into test site review
- Timeline is slightly extended due to the OPR web team needing to build out certain features to make the EC webpage more engaging, and aesthetically pleasing for our audience
- Current OPR website is very nuts and bolts and straight to the point, therefore lacks the mechanism for some of the features we hope to have on our EC webpage

Public Comment

Ben Rubin, UCSF

Really impressive to see progress on multiple fronts and appreciate how this group holds certain values that are not typically in the precision medicine ecosystem.

Depression Research: Appreciate the discussion about authentic engagement and appropriate tailoring to special populations. Recommend paying special attention to guidance for the selection committee and how much to weight portfolio considerations vs. merit of individual proposal to select proposals.

> Ysabel Duron: Truly critical that everyone understands, especially when we are working on DEI. I reiterate why one CBO voice may not be enough.

Next Steps

Next council meeting will be dependent on health climate at the time but would like to welcome new staff at that time.