

## FDA OMMHE Extramural Research Data Collection

### 1. Project Title:

Co-creation of digital tools to enhance young adult minority participation in COVID-19 trials

### 2. Project Summary: (300-500 words)

Increasing young adult racial and ethnic minorities' participation in COVID-19 clinical trials are essential to reducing health disparities in the uptake of COVID-19 vaccinations and treatment burden. Yet, several obstacles hinder racial/ethnic minority participation in trials, including structural barriers associated with a lack of financial resources, access, transportation issues, and group-specific problems such as mistrust of the medical/research community or concerns about medical experimentation. The proposed project is novel and fills a critical research and innovation gap by directly addressing the complex intersectionality of COVID-19 clinical trials and health equity using several interdisciplinary methods of inquiry. The objective of the proposed project is to utilize novel approaches involving big data, machine learning, data science, and community-driven qualitative research to develop and evaluate a digital tool to encourage young minority adults to participate in the clinical trial process. Through data mining and geospatial analysis of ClinicalTrials.gov, insights into which communities in the United States are underrepresented in the context of access to COVID-19 clinical trials will be developed (Aim 1), while big data and machine learning approaches will be used to characterize user self-reported knowledge, attitudes, and lived experiences related to COVID-19 on social media platforms (Aim 2). Focus group discussions will be used to deeply explore specific rationalities, cultural norms, and historical influences related to COVID-19 clinical research engagement with minority young adults (Aim 3). Data collected from these multiple sources will serve as the basis of a protocol to ideate, co-create, and jointly design a digital health tool to encourage clinical trial participation among young adult minority populations through co-design sessions and pilot testing held with racial/ethnic minority young adults (Aim 4). The efficacy of the digital health tool will be evaluated by conducting a controlled before-and-after study among a population of young adult college students at a university designated as a Minority Serving Institution (Aim 5). The proposed project will result in a digital health tool to increase young adult participation in COVID-19 clinical trials.

### 3. Investigators and Affiliated Institution:

Investigator Names	Affiliated Institutions
<i>MACKEY, TIMOTHY KEN</i>	<i>S-3 Research</i>
<i>YANG, JOSHUA</i>	<i>CALIFORNIA STATE UNIVERSITY FULLERTON</i>

### 1. Publications/Presentations/Abstracts/Posters (directly related to OMMHE funded project):

	Type	Title	Journal/Conference
1	Publication (Paper)	COVID-19 Pediatric Vaccine Misinformation on Twitter: Analyzing Themes and User Interactions Among Racial and Ethnic Minority Twitter Account Users (FDA Review)	Journal TBD
2	Publication (Paper)	Demographic Disparities of COVID-19 Clinical Study Site Proximity in the United States: A Geospatial Analysis (Under Review)	PLOS ONE
3	Conference Poster	Leveraging a Digital Mixed Methods to Develop Tools to Encourage Young Minority Participation in COVID-19 Clinical Trials	SOCRA 2022

4	Conference Poster	Leveraging Multiplatform Infodemiology to Detect and Characterize Barriers to COVID-19 Vaccine Clinical Trial Participation	APHA 2022
5	Conference Poster	Characterizing Twitter Public Sentiment on COVID-19 Clinical Trials Using Unsupervised Machine Learning and Longitudinal Analysis	APHA 2022
6	Conference Poster	Identifying Spatial Disparities in Online Discussions About Clinical Trials for COVID-19 Vaccines	APHA 2022
7	Conference Poster	Demographic Disparities And Spatial Variability of COVID-19 Clinical Trials in the United States	APHA 2022
8	Conference Poster	Utilizing Social Listening to Detect and Characterize COVID-19 Clinical Trial Barriers Among Minority Populations	PMSA 2022
9	Conference Oral Presentation	Envisioning a Future Where Technology Serves Global Health Equity: Multistakeholder Perspectives	APHA 2022
10	Conference Oral Presentation	Characteristics of Interventional and Observational Studies on COVID-19 Therapies in the United States	APHA 2022
11	Conference Oral Presentation	Communications for Evidence- Based Impact	Preventive Medicine 2022
12	Conference Oral Presentation	Leveraging Infodemiology, Big Data, and Machine Learning to Characterize Barriers to Minority Clinical Trial Participation	Stanford- Building a Culture of Health Equity Summit 2022
13	Conference Oral Presentation	Leveraging Digital Mixed Methods to Develop Tools to Encourage Young Racial and Ethnic Minority Participation in COVID-19 Clinical Trials	APHA 2023
14	Conference Poster	Data mining of twitter posts associated with COVID-19 clinical trials and racial minority topics	APHA 2023
15	Conference Poster	Leveraging a Digital Mixed Methods to Develop Digital Tools to Encourage Young Minority Participation in COVID-19 Clinical Trials	PMSA 2023
16	Conference Poster	New Approaches to Encourage Young Minority Participation in Clinical Trials - Digital tools developed by leveraging Mixed Methods	PMSA 2023

**2. Communication materials (Please include those that are planned to be developed e.g., videos, apps, websites)**

	<b>Communication Materials Developed</b>	<b>Status (attach product/link)</b>
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1	<b>Website:</b> Trial Match	<a href="https://tmackeys3.wixsite.com/u01site">https://tmackeys3.wixsite.com/u01site</a> username: <a href="mailto:test@gmail-s3.com">test@gmail-s3.com</a> password: test
2	<b>Mobile app:</b> Trial Match	<a href="https://www.justinmind.com/usernote/tests/30839629/73060321/73231473/index.html">https://www.justinmind.com/usernote/tests/30839629/73060321/73231473/index.html</a> password: CTPW123

### 3. Study Demographics:

#### A. Race and Ethnicity

Ethnic categories	Number of study participants (if none, please enter zero)
Hispanic	46 (39 from focus groups, 7 from co-design sessions)
Non-Hispanic	135 (81 from focus group, 16 from co-design sessions)
<i>Total number of study participants</i>	181 (158 from focus groups, 23 from co-design sessions)

Racial categories	Number of study participants (if none, please enter zero)
American Indian or Alaska Native	0
Asian	45 (41 from focus groups, 4 from co-design sessions)
Black or African American	39 (focus groups)
Native Hawaiian or Other Pacific Islander	0
White	48 (39 from focus groups, 16 from co-design sessions)
<i>Total number of study participants</i>	181 (158 from focus group, 20 from co-design sessions; 3 individuals from co-design sessions categorized themselves as bi- or multi-racial and are not included in the racial category counts above)

#### B. Gender and Sexual Identity

Sex	Number of study participants (if none, please enter zero)
Male	81 (76 from focus groups, 5 from co-design sessions)
Female	99 (82 from focus groups, 17 from co-design sessions)
Another identity	1 (co-design sessions)
<i>Total number of study participants</i>	181 (158 from focus groups, 23 from co-design sessions)

**If applicable, please also include the following information**

Gender categories	Number of study participants (if none, please enter zero)
Cisgender man	Unknown
Cisgender woman	Unknown
Transgender man	Unknown
Transgender woman	Unknown
Non-binary	Unknown
Another identity	Unknown
<i>Total number of study participants</i>	181 (158 from focus groups, 23 from co-design sessions)
Sexual categories	Number of study participants (if none, please enter zero)
Heterosexual, straight	Unknown
Gay or lesbian	Unknown
Bisexual	Unknown

Pansexual	Unknown
Queer	Unknown
Another identity	Unknown
<i>Total number of study participants</i>	181 (158 from focus groups, 23 from co-design sessions)

C. **Geographic Study Locations** (e.g., state or zip code)

<b>Geographic locations</b>	<b>Number of study participants</b> (if none, please enter zero)
California	181 (158 from focus groups, 23 from co-design sessions)
<i>Total number of study participants</i>	181 (158 from focus groups, 23 from co-design sessions)

D. **Age**

<b>Age groups</b>	<b>Number of study participants</b> (if none, please enter zero)
25 years and under	140 (120 from focus groups, 20 from co-design sessions)
26 to 41 years old	41 (38 from focus groups, 3 from co-design sessions)
42 to 57 years old	0
58 to 64 years	0
65 to 74 years old	0
75 to 79 years old	0
Over 80-year-old	0
<i>Total number of study participants</i>	181 (158 from focus group, 23 from co-design sessions)