Charles R. Drew University of Medicine and Science
Office of Research Integrity and Compliance
Institutional Review Board

Application for Study Review

Date: April 25, 2022	Federal Funding:	☐ No ☒ Yes
IRBNet#: 1838914-1	FDA-regulated Study:	☒ No ☐ Yes
CDU IRB#: N/A	IND/IDE Study:	☒ No ☐ Yes
Initial Approval Date:	Clinicaltrials.gov Registration Required?	☐ No ☒ Yes
Principal Investigator is a ☒ Faculty ☐ Resident ☐ Staff ☐ Student ☐ Other:		
This is a ☒ New Project ☐ Amendment ☐ Other:		

Check all that applies:

☒ This is a Principal Investigator (PI)-initiated project.

☐ This is a Sponsor-initiated project.

☐ This project is a course requirement. Describe:

☐ This project is a graduation requirement. Describe:

I. Project Information

Project Title: A Community Health Worker Intervention to Identify and Decrease Barriers to COVID-19 Testing and Vaccination among Los Angeles County Department of Health Safety-Net Patients – Aim 3

Principal Investigator (PI): Sheba George, PhD	
Phone: 323-249-5733	E-mail: shebageorge@cdrewu.edu
Faculty Sponsor (required if PI is a resident, staff, or student):	
Phone:	E-mail:
Primary Contact Person (in addition to PI): Denisse Ruiz, MPH	
Phone: 323-947-8045	E-mail: denisseruiz@cdrewu.edu

II. Study Personnel

Please use Appendix A to list all personnel involved in this project.

☒ Attached ☐ Not attached

III. IRB Review and Reliance for Multi-institutional Projects

1. Are you collaborating with researchers (or have faculty sponsor) from other institutions or organizations that have their own Institutional Review Board (IRB)?

☐ No ☒ Yes

2. If yes, please check the IRB reliance mechanism that might be applicable to the project.

☐ CTSI MOU (CDU to rely on IRB review by UCLA, CSMC, LA BioMed/HUMC, USC)

☐ RTRN IAA (CDU to review or rely with any of the 18 RCMI institutions)

☒ DHS MOU (CDU to review or rely with many of the LA County DHS facilities)

☐ WIRB (CDU to rely on commercial Western IRB for industry-sponsored, multi-center studies)

☒ SMART IRB (CDU to review or rely with many of the SMART IRB participating institutions)

☐ Not applicable. Please obtain IRB approval from the collaborating institution or organization.

3. If you are requesting single IRB to review a multi-institutional project, please call 323-563-4966 or write to irb@cdrewu.edu for consultation.

IV. Research Site(s)

1. List all research site(s) that will be used to conduct this project.

Educational intervention and access to ORCHID electronic health record from LAC Department of Health Services (DHS)

2. You should have the necessary letters of support, approvals, or permissions from the research site(s). Research sites might include external facilities, agencies, hospitals, clinics, schools, community organizations and centers, community health fairs, internal departments, programs, dean's office, Ministry of Health, internet chat rooms, *etc*.

Number of letters of support, approvals, or permissions attached: 0

V. Project Types and Methods

If the project involves any of the following, check the appropriate box(es).

- [x] Audiotapes/videotapes/**Zoom recordings**
- [ ] Alcohol and drug abuse research
- [ ] Behavioral observations
- [ ] Biohazardous waste
- [x] Children **(Ages 16 and 17)**
- [ ] Clinical trial (Phase I)
- [ ] Collection of biological specimens for banking
- [ ] Collection of data for repository
- [ ] Collection of surgical or biological specimens
- [ ] Controlled substances
- [ ] Data Safety Monitoring Board (DSMB)
- [ ] Deception
- [ ] Education records
- [ ] Genetic research
- [ ] HIV/AIDS
- [ ] HIV screening
- [ ] International research
- [x] Internet
- [ ] Interviews, focus group
- [ ] Investigational new drugs (IND)
- [ ] Investigational device exemption (IDE)
- [ ] Multicenter clinical trial
- [ ] Magnetic Resonance Imaging (MRI)
- [ ] National Cancer Institute Trial (NCI)
- [ ] NIH Cooperative Groups (i.e., RCMI)
- [x] Other, describe: Non-clinical Trial (non-FDA), health educational presentations and handouts
- [ ] Participants who may be vulnerable to undue influence or coercion
- [ ] PI or co-PI is the treating clinician
- [ ] PI is sponsor and investigator
- [ ] Placebo
- [ ] Pregnancy testing
- [ ] Pregnant women, fetuses, neonates
- [ ] Prisoner research
- [x] Protected Health Information (PHI)
- [ ] Radiation (CT or DEXA scans, X-rays)
- [ ] Reportable information or disease
- [ ] Social media use
- [x] Surveys, questionnaires, psychological testing

VI. Protocol Summary

Purpose, Background, and Design

1. Purpose of the study: What are the scientific aims of this study?

With the current pandemic, COVID-19 testing for patients has become an essential first step in the provision of critical procedural care. However, the range of reasons why patients refuse COVID-19 testing and vaccination is little understood. To this end, we propose to explore the obstacles to COVID-19 testing and vaccination, and provide COVID-19 specific training to LACDHS Community Health Workers (CHWs) from these same communities to effectively increase COVID-19 testing and vaccination for individual patients, and to facilitate needed healthcare in a timely manner for the safety net health system, and to develop a sustained public health presence in these communities to build trust and preparedness for critical COVID-19 related future needs.

This study has the following specific aims:

Aim 1- Utilize machine learning methods to assess whether there are characteristics that define African American and Latinx LACDHS safety-net patients who engage in or refuse COVID-19 testing and vaccination;

Aim 2 - Conduct in-depth interviews with African American and Latinx LACDHS patients who either declined or accepted COVID testing and vaccination to explore contextual, behavioral, and attitudinal factors shaping patient circumstances and concerns;

Aim 3 - Develop, implement, and pre-test a CHW intervention with the information from Aims 1 and 2, utilizing a randomized control design among African American and Latinx safety net patients to assess the effect of the CHW hypothesis-driven intervention on trust, self-efficacy, and intent to participate in COVID-19 testing and vaccination

This IRB application will address Aim 3 only. The data obtained from Aims 1 and 2 informed the researchers on the Aim 3 design and methodology.

2. Background: State the background of the study, including a critical evaluation of existing knowledge and the information gaps that this research proposes to fill. Describe previous work in animal and/or human studies that provides a basis for the proposed research and that supports the expectations of obtaining useful information without undue risk to research participants. Please include relevant citations.

COVID-19 testing and vaccination uptake have remained sparse in many low-income/minority neighborhoods, even though African American and Latinx communities in the U.S. bear a disproportionate COVID-19 burden of positive cases and deaths.1 Members of these communities are also not taking part in COVID-19 testing for a wide range of understudied reasons, even though it has been universally established that early and widespread COVID-19 testing is essential to help identify, treat, or isolate people who are infected and to identify and isolate contacts of infected people. Testing is also important for public health mitigation efforts to characterize the prevalence, spread, and contagiousness of the disease. Any plan to contain the virus will depend on fast and accurate testing, which can identify newly infectious people before they set off new outbreaks, as well as widespread vaccinations to tame the spread of the virus and the emergence of newer more dangerous variants. Vaccination uptake in African American and Latinx communities lags other US communities. The Kaiser Family Foundation/KFF states that “As of September 21, 2021, CDC reported that race/ethnicity was known for 59% of people who had received at least one dose of the vaccine. Among this group, nearly two thirds were White (60%), 10% were Black, 17% were Hispanic, 6% were Asian, 1% were American Indian or Alaska Native, and <1% were Native Hawaiian or Other Pacific Islander, while 5% reported multiple or other race. However, CDC data also show that recent vaccinations are reaching larger shares of Hispanic, and Black populations compared to overall vaccinations. Among vaccines administered in the past 14 days, 23% have gone to Hispanic people and 14% to Black people. [Source: https://www.kff.org/coronavirus-covid-19/issue-brief/latest-data-on-covid-19-vaccinations-race-ethnicity/]

The Importance of COVID-19 Testing and Vaccination in the Los Angeles County Department of Health Services (LACDHS): LACDHS is the second largest publicly operated safety net health care system in the United States, serving more than 750,000 patients annually.[3] Timely access to health care in this under-resourced, high-need setting has been an ongoing challenge for its majority Latinx and African American patients.[4,5] With the current pandemic, COVID-19 testing for patients has become integral to receiving critical health care, from treatment for symptomatic disease to the first step in providing procedural care. Because racial and ethnic minority patients with underlying chronic conditions make up

a large percentage of LACDHS patient populations, LACDHS has a growing challenge of managing and addressing the healthcare needs of such patients who are especially vulnerable in the pandemic.[6] It is thus an invaluable site for engaging in research to understand how to improve patient acceptance and uptake of COVID-19 testing and vaccination.

Our community partner from LACDHS, MPI on this project, Dr. Lauren Daskivich, has experienced growing concern from County physicians about patients' declination rates for COVID-19 testing and vaccination. From the reports of her colleagues, Dr. Daskivich estimates that about 68% of empaneled LACDHS patients do not have a completed COVID-19 vaccination status for undocumented reasons. Based on the number of LACDHS empaneled patients, Dr. Daskivich estimates about 289,400 patients over the age 16 do not have a completed COVID-19 vaccination status. However, the reasons for declination have not been clearly documented and understood at an actionable level. Patient refusal to complete either lab orders for COVID-19 testing or vaccinations can have serious consequences for both patient health outcomes and for the health system's efficient management of resources. Understanding COVID-19's effect on patients' decisions to either complete COVID-19 testing and vaccination is critical for reaching herd immunity and reducing the spread of the virus in vulnerable communities[7].

Low vaccination and testing rates among typically comorbid chronic conditions among such patients could result in an avoidable worsening of patient health status, a heightened patient vulnerability to developing COVID-19. Understanding and addressing the reluctance of African American and Latinx patients to be tested and vaccinated can have profound implications in safety-net health care settings like LACDHS where such patients oftentimes come from low-socioeconomic communities.

How our proposal will address potential testing and vaccination barriers with a CHW intervention

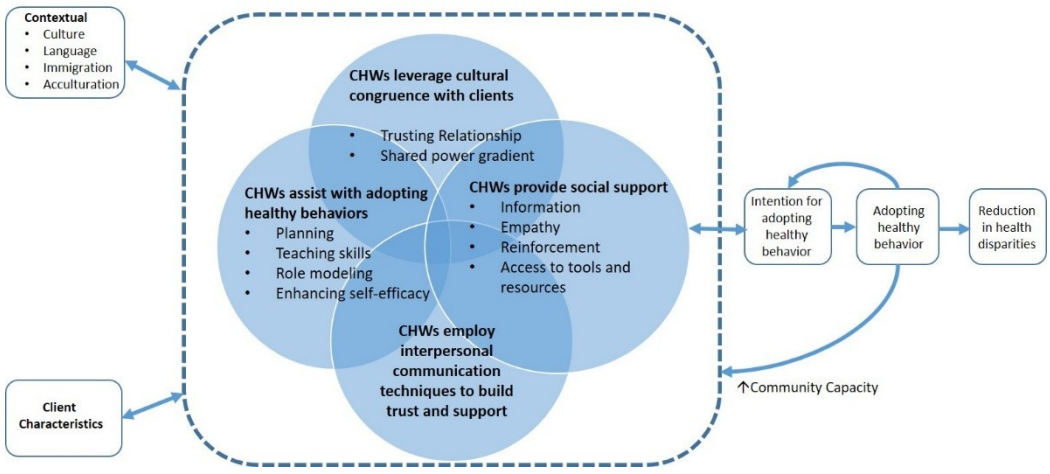
To address the barriers to COVID-19 testing and vaccination for safety net patients, we propose to train and use LACDHS CHWs from these same communities to engage safety net African American and Latinx patients, aiming to address the barriers outlined above as well as others we may identify through our exploratory mixed-methods research. There is a strong body of scientific research, both nationally and internationally, that has demonstrated the effectiveness of CHWs in improving not only health outcomes,[30,31] quality of care,[32] addressing social determinants of health and cost effectiveness,[33] but also in effectively engaging marginalized populations in disease testing and screening for a range of diseases[34] and in immunization.[35] Our team has contributed to this evidence base of CHW research with a variety of projects led by Co-I Balcazar and MPI George.[36-44] CHWs have a long history of functioning as frontline public health staff who conduct outreach and build trust with vulnerable populations in federally qualified health centers (FQHCs), hospitals, public health agencies, and through community-based organizations. They have played an increasingly important role in health interventions/programs, often bridging the gap between clinic and community by facilitating care coordination,[45,46] health promotion,[47] and communication between clinicians and patients/program participants[48] in a manner that is generally assumed to be more acceptable to the care recipients and ultimately improving health outcomes.[49-51] CHW interventions have been identified as an essential strategy to address health disparities for patient-centered medical home (PCMH)[52-54] by the NHLBI[55] and the Centers for Disease Control and applauded for their contributions to the Institute for Healthcare Improvement's Triple Aim objectives.[46,56-58] Thus, with the onset of COVID-19, on March 19, 2020, the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency issued a memorandum which included CHWs in the list of "essential critical infrastructure workers who are imperative during the response to the COVID-19 emergency for both public health and safety as well as community well-being."[59] Sen. Kirsten Gillibrand (D-NY) and Sen. Michael Bennet (D-CO) have proposed creating a national Health Force, inspired by the Depression- era Works Progress Administration, to recruit, train, and employ

"hundreds of thousands" of community health workers to perform contact tracing and testing and provide a range of services.[60]

Because CHWs are often embedded in the community and are uniquely able to bridge the gap between healthcare organizations and the safety net patients in the community, CHWs are in a great position to address known potential obstacles to COVID-19 testing and vaccination. From our recent systematic review of patient feedback on CHWs' care provision[36] and from other related literature, is it evident that CHWs are well positioned to build trust surrounding COVID-19 testing and vaccination, provide credible testing, vaccination, and healthcare information, address testing and vaccination barriers related to the social determinants of health, and facilitate patient access to telehealth environments. One of the key criteria for CHWs is that they come from the same communities as those they serve and thus CHWs tend to be *trusted* by their patients because of shared backgrounds (culture, religion, language),[61] shared life experiences, such as immigration experiences,[62] shared health conditions,[63] etc. Second, the health information provided by CHWs was seen as *credible* because CHWs, while representatives of the health system, had more time with patients than physicians to answer questions,[62,64] had direct access to physicians to clarify patient questions and had continuity with patients.[65] [66]Third, when it came to *social support,* CHWs, unlike anyone else on the healthcare team, had the lived experience to uniquely understand challenges faced by patients, well beyond the medical realm and consequently, patients shared challenges with CHWs that they may not have shared with physicians.[66,67] Consequently, CHWs not only provided various types of instrumental social support to patients (assisting them with accessing food, transportation, childcare etc.), [68,69] but they were also able to provide empathetic support [70,71] and model healthy behaviors.[72,73] Finally, CHWs have also helped patients with *technological literacy*, by modeling the use of technology for health education (digital storytelling for health promotion,[74] using tablets for health education,[75]) and by helping patients who experience the digital divide use technology to better access and manage care.[76,77]

Conceptual Framework: The research study is guided by a conceptual framework[78] to explicate the processes through which CHWs facilitate the adoption of healthy behaviors among their patients. In this framework shown in **Figure 1**, there are four components that synergistically influence patients' intention to adopt healthy behaviors: (1) CHWs leverage their cultural congruence with patients, (2) CHWs employ interpersonal communication techniques to build trust and rapport, (3) CHWs provide social support, and (4) CHWs assist with adopting healthy behaviors. Much like The CHWs and Patient Partners in Health Study Framework, our intervention also will leverage the same four components in using CHWs to influence safety-net patients' intention to participate in COVID-19 testing and vaccination.

Fig 1: Conceptual framework of community health workers (CHWs) and patient partners in health.



With this project, we will provide a training for CHWs already working in the LACDHS to enhance
their abilities to 1) build trust when communicating virtually with patients based on their shared identities, geographies, and histories; 2) provide accurate and credible health information about COVID-19 testing, vaccination, prevention, and care, 3) provide social support based on specific understanding of patient socioeconomic challenges and concerns surrounding COVID-19 testing and vaccination, and d) address their patients' gaps in technological literacy and help them maneuver through new health care processes in a telehealth environment. Once they have received our enhanced training, they will, in turn, facilitate a series of six group classes on COVID-19 testing and vaccination related barriers/facilitators to intervention patient groups and six personalized support sessions to intervention patients to address obstacles to COVID-19 testing and vaccination.

Summary of the Significance of our Approach: The research project is timely and important because 1) while COVID-19 testing is essential for public health mitigation efforts of the pandemic, vulnerable safety-net minority patients are not completing lab orders for COVID-19 testing and vaccination; 2) research on barriers suggests potential leverage points; and 3) linguistically and ethnically matched Community Health Workers working in the safety net health system are in ideal positions to lead intervention efforts. The project will draw on these data, resources, and opportunities to use multiple methods to enhance and test a proven community-engaged approach for addressing obstacles to COVID-19 testing for safety net patients.

References

Please note references 1-29 were also referenced in IRB Application #1682977 for Aims 1 and 2.

1. Servick K. 'Huge hole'in testing data blurs racial, ethnic disparities. In: American Association for the Advancement of Science; 2020.
2. reference removed – because of change of scope
3. About Los Angeles County Department of Health Services. https://dhs.lacounty.gov/more-dhs/aboutus/. Published 2020. Accessed August 27,, 2020.
4. Iyer SP, Jones A, Talamantes E, et al. Improving Health Care for the Future Uninsured in Los Angeles County: A Community-Partnered Dialogue. *Ethn Dis.* 2015;25(4):487-494.PMC4671431
5. Daskivich LP, Vasquez C, Martinez C, Jr., Tseng CH, Mangione CM. Implementation and Evaluation of a Large-Scale Teleretinal Diabetic Retinopathy Screening Program in the Los Angeles County Department of Health Services. *JAMA Intern Med.* 2017;177(5):642-649.PMC5818774
6. COVID-19 in Racial and Ethnic Minority Groups. U.S. Centers for Disease Control and Prevention; 2020. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html
7. reference removed – because of change of scope
8. Corbie-Smith G, Thomas SB, St George DM. Distrust, race, and research. *Arch Intern Med.* 2002;162(21):2458-2463
9. Dula A. African American suspicion of the healthcare system is justified: what do we do about it? *Cambridge Quarterly of Healthcare Ethics.* 1994;3(03):347-357
10. Gollin LX, Harrigan RC, Calderon JL, Perez J, Easa D. Improving Hawaiian and Filipino involvement in clinical research opportunities: qualitative findings from Hawai'i. *Ethn Dis.* 2005;15(4 Suppl 5):S5-111-119.PMC1473039
11. Hussain-Gambles M, Atkin K, Leese B. Why ethnic minority groups are under-represented in clinical trials: a review of the literature. *Health Soc Care Community.* 2004;12(5):382-388
12. Shavers-Hornaday VL, Lynch CF, Burmeister LF, Torner JC. Why are African Americans underrepresented in medical research studies? Impediments to participation. *Ethn Health.* 1997;2(1-2):31-45

13. Roberson NL. Clinical trial participation. Viewpoints from racial/ethnic groups. *Cancer.* 1994;74(9 Suppl):2687-2691
14. Nápoles-Springer AM, Grumbach K, Alexander M, et al. Clinical Research with Older African Americans and Latinos Perspectives from the Community. *Research on Aging.* 2000;22(6):668-691
15. Moreno-John G, Gachie A, Fleming CM, et al. Ethnic minority older adults participating in clinical research: developing trust. *J Aging Health.* 2004;16(5 Suppl):93S-123S
16. Herrera AP, Snipes SA, King DW, Torres-Vigil I, Goldberg DS, Weinberg AD. Disparate inclusion of older adults in clinical trials: priorities and opportunities for policy and practice change. *Am J Public Health.* 2010;100 Suppl 1(Suppl 1):S105-112.PMC2837461
17. Areán PA, Gallagher-Thompson D. Issues and recommendations for the recruitment and retention of older ethnic minority adults into clinical research. *Journal of Consulting and Clinical Psychology.* 1996;64(5):875
18. Jones CP. Levels of racism: a theoretic framework and a gardener's tale. *Am J Public Health.* 2000;90(8):1212-1215.PMC1446334
19. Byrd WM. *An American health dilemma: A medical history of African Americans and the problem of race: Beginnings to 1900.* Vol 1: Routledge; 2000.
20. Fong M, Braun KL, Tsark J. Improving Native Hawaiian health through community-based participatory research. *Californian journal of health promotion.* 2003;1(1):136-148
21. Jaiswal J, LoSchiavo C, Perlman DC. Disinformation, Misinformation and Inequality-Driven Mistrust in the Time of COVID-19: Lessons Unlearned from AIDS Denialism. *AIDS Behav.* 2020;24(10):2776-2780.PMC7241063
22. Rumala BB, Campos-Dominquez, T., Rabbani. R.S., & Matos, S. . Global and Local Community Health Workers as a lifeline for communities facing inequities in the midst of COVID-19 and beyond. In *Community Health Workers and COVID-19 Writing Group.*2020.
23. Campos-Dominquez T, and Rumala, B.B. . Case Study - Role of Community Health Workers in addressing inequities and systems transformation during COVID-19 and beyond: An opportunity for health department and organizational practices. In. *Community Health Workers and COVID-19 Writing Group.* 2020.
24. COVID-19 in Vulnerable Communities: An Examination by Race and Ethnicity in Los Angeles and New York City. Center for the Study of Latino Health and Culture, David Geffen School of Medicine, University of California, Los Angeles; 2020. https://ph.ucla.edu/sites/default/files/attachments/LPPI-LAv-NY-Report.pdf.
25. Report from Charles R. Drew University of Medicine and Science, Los Angeles County Department of Health Services, Martin Luther King Jr. Outpatient Center, and Los Angeles County Fire Department COVID-19 Testing Site. 2020. https://www.cdrewu.edu/newsroom/comprehensive-report-charles-rdrew-university-covid-19-testing-site.
26. Mann DM, Chen J, Chunara R, Testa PA, Nov O. COVID-19 transforms health care throughtelemedicine: evidence from the field. *Journal of the American Medical Informatics Association.* 2020. PMC7188161
27. Ramsetty A, Adams C. Impact of the digital divide in the age of COVID-19. *J Am Med Inform Assoc.* 2020;27(7):1147-1148.PMC7197532
28. Telehealth and COVID-19 Policy Considerations to Improve Access to Care. 2020. https://latino.ucla.edu/research/telehealth-covid-19-policy-considerations-to-improve-access-to-care/ Accessed July 2, 2020.
29. Van Winkle B, Carpenter N, Moscucci M. Why Aren't Our Digital Solutions Working for Everyone? *AMA Journal of Ethics.* 2017;19(11):1116-1124.
30. Viswanathan M, Kraschnewski J, Nishikawa B, et al. Outcomes of community health worker interventions: evidence report/technology assessment no. 181 (Prepared by the RTI International-University of North Carolina Evidence-based Practice Center under Contract No. 290 2007 10056 I.) AHRQ publication no. 09-E014. Agency for Healthcare Research and Quality. 2009
31. Zhou K, Fitzpatrick T, Walsh N, et al. Interventions to optimise the care continuum for chronic viral hepatitis: a systematic review and meta-analyses. Lancet Infect Dis.

2016;16(12):1409-1422
32. Rhodes SD, Foley KL, Zometa CS, Bloom FR. Lay health advisor interventions among Hispanics/Latinos - A qualitative systematic review. American Journal of Preventive Medicine. 2007; 33(5):418-427
33. Vaughan K, Kok MC, Witter S, Dieleman M. Costs and cost-effectiveness of community health workers: evidence from a literature review. Hum Resour Health. 2015;13(1):71.PMC4557864
34. Shommu NS, Ahmed S, Rumana N, Barron GRS, McBrien KA, Turin TC. What is the scope of improving immigrant and ethnic minority healthcare using community navigators: A systematic scoping review. International Journal for Equity in Health. 2016;15(1):6.PMC4714538
35. Glenton C, Scheel IB, Lewin S, Swingler GH. Can lay health workers increase the uptake of childhood immunisation? Systematic review and typology. Tropical Medicine & International Health. 2011;16(9):1044-1053
36. George S, Dixon LZ, Carrasco E, Romo O, Vides L, Balcazar H. Talk to PAPA A Systematic Review of Patient/Participant (PAPA) Feedback on Interactions With Community Health Workers Using a Depth Analysis Approach. Journal of Ambulatory Care Management. 2020;43(1):55-70
37. Balcazar H, George S. Community Health Workers: Bringing a New Era of Systems Change to Stimulate Investments in Health Care for Vulnerable US Populations. Am J Public Health. 2018;108(6):720-721.PMC5944897
38. Balcazar H, Fernandez-Gaxiola AC, Perez-Lizaur AB, Peyron RA, Ayala C. Improving Heart Healthy Lifestyles Among Participants in a Salud Para Su Corazon Promotores Model: The Mexican Pilot Study, 2009-2012. Preventing Chronic Disease. 2015;12.PMC4362391
39. Balcazar H, Rosenthal L, De Heer H, et al. Use of Community-based Participatory Research to Disseminate Baseline Results from a Cardiovascular Disease Randomized Community Trial for Mexican Americans Living in a U.S.-Mexico Border Community. Education for Health. 2009;22(3):279-+
40. Balcázar H, Wise S, Rosenthal EL, et al. An ecological model using promotores de salud to prevent cardiovascular disease on the US-Mexico border: the HEART project. Preventing Chronic Disease. 2012;9:E35-E35.3310145
41. Balcazar HG, Byrd TL, Ortiz M, Tondapu SR, Chavez M. A Randomized Community Intervention to Improve Hypertension Control among Mexican Americans: Using the Promotoras de Salud Community Outreach Model. Journal of Health Care for the Poor and Underserved. 2009;20(4):1079-1094
42. Balcazar HG, Wise S, Redelfs A, et al. Perceptions of Community Health Workers (CHWs/PS) in the US-Mexico Border HEART CVD Study. International Journal of Environmental Research and Public Health. 2014;11(2):1873-1884
43. de Heer HD, Balcazar HG, Castro F, Schulz L. A Path Analysis of a Randomized Promotora de Salud Cardiovascular Disease–Prevention Trial Among At-Risk Hispanic Adults. Health Education & Behavior. 2011;39(1):77-86
44. Koniak-Griffin D, Brecht ML, Takayanagi S, Villegas J, Melendrez M, Balcazar H. A community health worker-led lifestyle behavior intervention for Latina (Hispanic) women: feasibility and outcomes of a randomized controlled trial. Int J Nurs Stud. 2015;52(1):75-87.PMC4277872
45. Collinsworth AW, Vulimiri M, Schmidt KL, Snead CA. Effectiveness of a community health worker-led diabetes self-management education program and implications for CHW involvement in care coordination strategies. Diabetes Educ. 2013;39(6):792-799
46. Findley S, Matos S, Hicks A, Chang J, Reich D. Community Health Worker Integration Into the Health Care Team Accomplishes the Triple Aim in a Patient-Centered Medical Home A Bronx Tale. Journal of Ambulatory Care Management. 2014;37(1):82-91
47. Terpstra J, Coleman KJ, Simon G, Nebeker C. The role of community health workers (CHWs) in health promotion research: ethical challenges and practical solutions. Health Promot Pract. 2011;12(1):86-93.PMC3748275
48. Brownstein JN, Bone LR, Dennison CR, Hill MN, Kim MT, Levine DM. Community health workers as interventionists in the prevention and control of heart disease and stroke.

American Journal of Preventive Medicine. 2005;29(5):128-133
49. Norris SL, Chowdhury FM, Van Le K, et al. Effectiveness of community health workers in the care of persons with diabetes. Diabet Med. 2006;23(5):544-556
50. Gibbons MC, Tyus NC. Systematic review of US-based randomized controlled trials using community health workers. Progress in community health partnerships: research, education, and action. 2007;1(4):371-381
51. Kangovi S, Mitra N, Grande D, et al. Patient-centered community health worker intervention to improve posthospital outcomes: a randomized clinical trial. JAMA Intern Med. 2014;174(4):535-543
52. Daaleman TP, Fisher EB. Enriching Patient-Centered Medical Homes Through Peer Support. Annals of Family Medicine. 2015;13(Suppl 1):S73-S78.PMC4648135
53. Rosenthal TC. The medical home: growing evidence to support a new approach to primary care. J Am Board Fam Med. 2008;21(5):427-440
54. Rogers EA, Manser ST, Cleary J, Joseph AM, Harwood EM, Call KT. Integrating Community Health Workers Into Medical Homes. Annals of Family Medicine. 2018;16(1):14-20.PMC5758315
55. The Community Health Worker Health Disparities Initiative National Heart, Lung and Blood Institute, National Institutes of Health. https://www.nhlbi.nih.gov/health/educational/healthdisp/chw-healthdisparities-initiative.htm. Published 2014. Accessed September 20, 2018, 2018.
56. Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. Health Aff (Millwood). 2008;27(3):759-769
57. Achieving the Triple Aim: Success with Community Health Workers. Massachusetts: Massachusetts Department of Public Health;2015.
58. Taking Innovation to Scale: Community Health Workers, Promotores, and the Triple Aim. California Health Workforce Alliance;2013.
59. Memorandum on Identification of Essential Critical Infrastructure Workers during Covid-19 Response 2020. https://www.cisa.gov/sites/default/files/publications/CISA-Guidance-on-Essential-Critical-Infrastructure-Workers-1-20-508c.pdf Retrieved August 21, 2020
60. US Senate. Press release, Gillibrand, Bennet announce “Health Force” to recruit, train, and employ Americans as United States battles coronavirus pandemic. 2020 Available from: https://www.gillibrand.senate.gov/news/press/release/gillibrand-bennet-announce-health-force-torecruit-train-and-employ-americans-as-united-states-battles-coronavirus-pandemic.
61. Islam NS, Zanowiak JM, Wyatt LC, et al. A randomized-controlled, pilot intervention on diabetes prevention and healthy lifestyles in the New York City Korean community. J Community Health. 2013;38(6):1030-1041.PMC3964609
62. Katigbak C, Van Devanter N, Islam N, Trinh-Shevrin C. Partners in health: a conceptual framework for the role of community health workers in facilitating patients' adoption of healthy behaviors. Am J Public Health. 2015;105(5):872-880.PMC4386525
63. Becker J, Kovach AC, Gronseth DL. Individual empowerment: How community health workers operationalize self-determination, self-sufficiency, and decision-making abilities of low-income mothers. Journal of Community Psychology. 2004;32(3):327-342
64. Battaglia TA, McCloskey L, Caron SE, et al. Feasibility of chronic disease patient navigation in an urban primary care practice. J Ambul Care Manage. 2012;35(1):38-49
65. Heisler M, Spencer M, Forman J, et al. Participants' Assessments of the Effects of a Community Health Worker Intervention on Their Diabetes Self-Management and Interactions with Healthcare Providers. American Journal of Preventive Medicine. 2009;37(6):S270-S279
66. Collinsworth A, Vulimiri M, Snead C, Walton J. Community health workers in primary care practice: redesigning health care delivery systems to extend and improve diabetes care in underserved populations. Health Promot Pract. 2014;15(2 Suppl):51S-61S
67. Nguyen TU, Tran JH, Kagawa-Singer M, Foo MA. A qualitative assessment of community-based breast health navigation services for Southeast Asian women in Southern California: recommendations for developing a navigator training curriculum. Am J Public Health.

2011;101(1):87-93.PMC3000717
68. Cabral L, Strother H, Muhr K, Sefton L, Savageau J. Clarifying the role of the mental health peer specialist in Massachusetts, USA: insights from peer specialists, supervisors and clients. Health Soc Care Community. 2014;22(1):104-112
69. May ML, Contreras RB. Promotor(a)s, the organizations in which they work, and an emerging paradox: How organizational structure and scope impact promotor(a)s' work. Health Policy. 2007;82(2):153-166
70. Driskell JR, O'Cleirigh C, Covahey C, et al. Building Program Acceptability: Perceptions of Gay and Bisexual Men on Peer or Prevention Case Manager Relationships in Secondary HIV Prevention Counseling. J Gay Lesbian Soc Serv. 2010;22(3):269-286.PMC3660956
71. Gimpel N, Marcee A, Kennedy K, Walton J, Lee S, DeHaven MJ. Patient perceptions of a communitybased care coordination system. Health Promot Pract. 2010;11(2):173-181
72. Albarran CR, Heilemann MV, Koniak-Griffin D. Promotoras as facilitators of change: Latinas' perspectives after participating in a lifestyle behaviour intervention program. Journal of Advanced Nursing. 2014;70(10):2303-2313
73. McCorkle BH, Dunn EC, Yu Mui W, Gagne C. Compeer friends: a qualitative study of a volunteer friendship programme for people with serious mental illness. Int J Soc Psychiatry. 2009;55(4):291-305 74. Cueva M, Kuhnley R, Revels LJ, Cueva K, Dignan M, Lanier AP. Bridging storytelling traditions with digital technology. Int J Circumpolar Health. 2013;72(1):20717.PMC3752288
74. Arvey SR, Fernandez ME. Identifying the core elements of effective community health worker programs: a research agenda. Am J Public Health. 2012;102(9):1633-1637.PMC3415604
75. Paasche-Orlow MK, Schillinger D, Greene SM, Wagner EH. How health care systems can begin to address the challenge of limited literacy. Journal of General Internal Medicine. 2006;21(8):884-887
76. Braun R, Catalani C, Wimbush J, Israelski D. Community health workers and mobile technology: a systematic review of the literature. PLoS One. 2013;8(6):e65772.PMC3680423
77. Katigbak C, Van Devanter N, Islam N, Trinh-Shevrin C. Partners in health: a conceptual framework for the role of community health workers in facilitating patients' adoption of healthy behaviors. Am J Public Health. 2015;105(5):872-880.PMC4386525

3. Study Design: Describe the study design (e.g., double blind, crossover, etc.) and sequentially list all procedures, drugs or devices to be used on research participants. Describe any use of placebos and indicate whether participants will be randomized in this study. If there are any investigational drugs or biologic agents used in this study, please complete and include Form-132 (Investigational Drug Information) with this application.

A key objective of this study is to use the results from the combination of machine learning and qualitative methods to implement a CHW-based intervention among African American and Latinx safety-net patients who declined COVID-19 testing and/or vaccination. Specifically, we will use a CHW-led health education intervention to provide information on COVID-19 resources and services in LA County to LACDHS safety-net patients and to address barriers to knowledge and access, and improve perceptions and intentions on COVID-19 testing and vaccination.

This aim will be a randomized control study; the control arm will consist of the standard treatment of LACDHS Vaccine Hesitancy Outreach Group calling participants to remind them to get COVID-19 vaccinated; the intervention arm will consist of a CHW-based health educational program via Zoom, where participants will be provided with information about COVID-19, COVID-19 resources and services in Los Angeles County, and engagement with LACDHS CHWs who will be available to answer the questions of the patients in the intervention arm.

Study Population

4. Study Population: Describe the characteristics of the participant population including, anticipated number, age range, gender, ethnic background and health status. Provide a candid discussion of potential problems related to the study population. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, prisoners, or other vulnerable populations. If women, minorities or children are excluded, provide written justification.

a. Anticipated number of participants to be enrolled:

Aim 3: We will recruit a total of 142 patients to allow for approximately 10% attrition from each group. The final number of enrollees we require to successfully complete the study is **128** LACDHS patients composed of 32 African American and 96 Latinx patients who have not completed COVID-19 testing and/or vaccination, according to LACHDS records.

Each arm will have at least 64 LACDHS patients, comprised of at least 16 African American and 48 Latinx patients who have not completed COVID-19 testing and/or vaccination

b. Age range: 16 years old and older for Aim 3

c. Gender: all genders for Aim 3

d. Racial/ethnic background: African American and Latinx for Aim 3

e. Describe health status: LACDHS patients who did not complete a lab order for COVID-19 testing or COVID-19 vaccination from Aims 1 and 2

f. Foreign language translation and interpreter required? None

g. Other population characteristics: None

h. Potential problems related to study population: None

i. Vulnerable populations included in the study and the rationale: None

j. If excluding women, minorities, and children, please provide justification:

We will exclude children (those under the ages of 16) from this study.

Moreover, we are excluding patients under the age of 16 because a) they were not yet eligible for COVID-19 vaccination as of April 19, 2021 and b) decision making on COVID-19 testing and vaccination for children is usually made by their adult caregivers.

5. Inclusion/Exclusion Criteria: Indicate the criteria for exclusion and inclusion and explain the system for equitable selection of participants.

Aim 3

Inclusion Criteria:

- Age 16 years and older
- Self-identify as African American or Latinx
- English Speaking
- Receives primary or specialty care treatment at an LACDHS facility
- Has either not completed lab orders for COVID-19 testing and/or vaccination at an LACDHS facility
- Have reliable internet access

Exclusion criteria:

- Not meeting the inclusion criteria listed above

6. Eligibility: How and by whom will it be determined that interested individuals meet the inclusion and exclusion criteria?

Our community partner and Multiple PI (MPI) Dr. Daskivich, along with the LACDHS Vaccine Hesitancy Outreach Group, will generate a list of LACDHS patients who have been offered but not taken up the opportunity to get the COVID-19 test and/or vaccine, and who meet other inclusion/exclusion criteria from LACDHS ORCHID. This list will include names of patients and contact information such as phone number, email, address, etc. which study staff will use to ensure that selected patients meet our inclusion criteria by a) cross referencing our data list from Aim 1 to ensure they are LACDHS empaneled patients, b) checking each potential candidate's medical record to see if they meet the inclusion criteria, and c) calling each potential candidate by telephone to confirm eligibility for inclusion before presenting the opportunity for participation in the study.

7. Participant Identification and Recruitment: Describe the methods used to identify and recruit potential participants. This section should include how, where, when, and by whom the potential participant is approached. Attach a copy of all planned scripts, advertisements, flyers and letters, etc. to the potential participants.

Table 1 below gives our recruitment goals for Aim 3 with a breakdown of the number of participants that will be assigned to the case and control arm:

Table 1.

	Patients not vaccinated	Patients who did not complete lab orders for COVID test	Total
Control	32	32	64
Intervention	32	32	64
		Total Study Participants	**128**

Identification Strategy

We will need to enroll at minimum total of 128 participants to successfully complete the study, with a breakdown of 32 African American and 96 Latinx patients to reflect the LACDHS patient population in our study.

Our community partner and Multiple PI (MPI) Dr. Daskivich, along with the LACDHS Vaccine Hesitancy Outreach Group, will generate a list of LACDHS patients who have been offered an appointment to be vaccinated and who have not taken the COVID-19 test and/or vaccine, and who meet all other inclusion criteria. The patient list from the DHS Vaccine Hesitancy Outreach Group, is a filtered list of the empaneled patients we obtained from Aim 1. The patient list provided by the DHS Vaccine Hesitancy Outreach Group a list of current patients from DHS County records showing which patients who do not have a completed vaccination status on their record.

Our study staff (Denisse Ruiz, project coordinator and Jacqueline Carranza, research assistant), will work with the support of our two consultant-specialist LACDHS CHWs, who will provide additional insight on recruitment strategies.

For our recruitment process: The two CHW specialists and the intervention CHWs will help us identify and recruit participants by assisting in circulating the patient recruitment flyer within their CHW networks and DHS facilities. By using the CHW's existing CHW and DHS network, it can assist with quick identification and recruitment of vaccine-hesitant patients. CHWs who work with these identified vaccine-hesitant patients can talk to the patients about the study and validate our research project is a legitimate study to overcome any initial patient skepticism.

The study team will work with the Intervention CHWs and CHW specialists, and follow a standardized referral process. By having a standardized referral process with the CHW network, CHWs can assist with a soft hand off for patients that are interested in learning more about the study. Using CHWs in the referral process can also assist the study team, where the

CHWs can measure and assess the patients' interest in wanting to join the study and help with patient retention.

CHW's can confirm if patients they work with are not vaccinated. CHW-identified patients will most likely be in the vaccine hesitant list provided by the LACDHS Vaccine Hesitancy Outreach Group, as their records are obtained from ORCHID and updates from California Immunization Registry System (CAIRS). After streamlining the referral process, the study team will cross reference the referred patient with the patient list provided by the LACDHS Vaccine Hesitancy Outreach Group and the patient list from Aim 1. This will work in tandem with the process we have identified with the vaccine outreach group list because the CHWs that work with them will be able to do a soft hand off. The hand off will provide a stronger connection between the patient and the study, and will validate the project simultaneously.

In addition to using CHWs as the preferred source of identification and recruitment of patients for the study, we will have an additional process of recruiting patients by virtual communication methods such as phone calls, texts, and emails. Using the list of vaccine-hesitant patients from the LACDHS Vaccine Hesitancy Outreach Group, the study staff will filter the list of LACDHS patients to ensure only include patients who meet the inclusion criteria (16 years and older, self-identify as Latinx or African American) are on the list.

Preferred method:

- CHW network will assist in identifying vaccine-hesitant and non-vaccinated people they work with at LACDHS facilities
- CHWs will talk to patients they work with about the study and provide them a flyer in case they are interested in participating. If a patient expresses they are interested in the study, the CHW will notify the study team with the patient's contact information.
- Study team will cross reference the lists of vaccine-hesitant patients provided by LACDHS Vaccine Hesitancy Outreach Group and Aim 1 data pull.
- If the patient is in the list, the study team can follow up with the referred patient to talk to them about the study and provide them additional details about the study.
- If the patient is interested in participating in the study, the study team will send them the consent forms and continue with study enrollment process.

Recruitment Strategy – telephone script

Our study staff will contact the patients via telephone, ascertain their self-reported eligibility to participate in the study, present the study and invite them to participate in our 6-week study, where they will be randomly assigned to one of two groups. The study staff will explain what will be required of the participant, and answer any questions the potential participant may have about the study. If participants agree to be in the study, the study staff will send the participant a copy of the consent forms and follow up with them at a separate time to provide them time to review the consent forms with family or friends. During the phone call, the study staff will notify the participant they will be randomly assigned to one of two following groups:

- Group 1 (Control Arm): will consist of two phone calls where participants are to complete a total of 4 surveys (demographic, pre-study and post-study survey, and CDE survey). The pre- and post- surveys will be completed six weeks apart at a time that is convenient for them.
- Group 2 (Intervention Arm): in addition to the surveys listed in Group 1, the group will consist of a six-week COVID-19 educational program, where participants will participate in a weekly 1.5 – 2-hour virtual classroom, and weekly 30-60 minute personal session with an assigned and IRB-approved Intervention CHW.
    - Only the weekly group session will be recorded for further analysis and program evaluation, the personal session with the CHW will not be recorded. The Zoom recording feature asks participants to consent to being recorded. If participants do not agree to being recorded, the Zoom feature automatically disconnects the

participant from the Zoom meeting. As such, participants must agree to being recorded during the consent phone call if they are randomly assigned to this group. Therefore, we will only include one option on the consent form saying they *agree to being recorded during the weekly group only if they are assigned to Group 2.*

The approach for recruitment is based on our previous consultation with the LACDHS partners. The study staff created telephone recruitment scripts, patient recruitment flyers, and a recruitment strategy to illustrate what the study staff will be communicating with participants, and attached to the IRB application. The approaches below are overviews and will refer to the recruitment materials.

Our primary and strongest recruitment effort will be for CHW specialists and their CHW network to introduce the study to potential participants and then let them know that if interested, the patient can contact the study team.

A second approach will be the study team introducing the study with a patient recruitment flyer by mail from our LACDHS MPI and follow-up with a phone call using the telephone recruitment script the study team will use to introduce the study to interested potential participants.

A third approach is to distribute the flyer in LACDHS facilities and have participants call the study staff if they are interested in participating. After a screening and determination if the patient qualifies for the study, research staff will send the consent forms via email or mail and begin the consenting and enrollment process.

Our recruitment strategies are detailed below:

- We will distribute the patient recruitment flyer among the LACDHS CHW networks. CHWs will hand their patients a recruitment flyer (**see attached**) to assist with the recruitment for Aim 3. When they hand the flyer to their patients, they will explain to their patients this is a legitimate study, and their decision to participate or not will not affect the care they receive from the CHWs or LACDHS; we want the CHWs to emphasize that patients should not feel coerced to participate in the study if they do not want to. If participants express that they are interested in learning more about the project, they will be asked to contact the study staff on the phone number in the flyer for more information. After a line of communication is established between the prospective participant and research staff, the research staff will cross-reference the list from Aim 1 Data Pull to confirm if this is a patient that meets study inclusion criteria and continue explaining what the study entails. If the patient qualifies for the study, research staff will send a copy of the informed consent form via mail or email, according to the patient's preference. Study staff will follow up with the patient one-week later and review the consent form, answer questions, and obtain verbal consent. A summary of this recruitment strategy is found in **Figure 1 Document: "Aim 3 Patient recruitment strategy – flow chart."**
- Create a patient recruitment flyer and distribute the flyers by mail to potential candidates identified from Aim 1 data pull. After one week, study staff will follow up with the potential candidates via phone call, and using the telephone recruitment script (**see attached**), re-introduce the research study to see if the patient is eligible and interested in participating in the study. In this strategy, we aim to reach out to at least 600 potential candidates for the study to account for patient retention rates. We are estimating about a third of potential candidates will answer the phone. Within that group of potential study participants, we estimate about half of the group will agree to participate and consent to the study.
- Similarly, to the approach above, we will reach out to patients via text messaging (using a non-personal phone number such as Google Voice) with a link to the patient recruitment flyer. If participants are interested to learn more, they can text back or call the number from where it was sent. In this strategy, we aim to reach out to at least 600

potential candidates for the study in case they are not as receptive to phone calls and mail. We are estimating about a quarter of participants will respond (150) and potentially half of those who respond will enroll (75)

- Distribute the patient recruitment flyer around LACDHS facilities and have participants call study staff if they are interested. If patients call study staff, study staff will establish a line of communication. The research staff will cross-reference the list from Aim 1 Data Pull to confirm if the patient meets criteria, study staff will continue to explain what the study entails using the telephone recruitment script. If the patient qualifies for the study, research staff will send a copy of the informed consent form via mail or email, according to the patients' preference. Study staff will follow up with the patient one-week later and review the consent form, answer questions, and obtain verbal consent.

Our approach for recruitment may be modified based on additional input from the LACDHS CHWs considering the dynamic nature of COVID-19 in communities of color. If our recruitment materials or approach are modified, we will submit any additional or modified recruitment materials as an IRB amendment (e.g. scripts, flyers, any –mail or letter to be sent by the LACDHS, etc. to notify the patient.)

Research Methods and Procedures

8. Methodology and Procedures: Describe the research procedures that will be followed. Please indicate those that are experimental and those that may be considered to be standard treatment. Describe all activities involving research participants and explain the frequency and duration of each activity.

Recruitment of CHWs:

Currently, there are 76 CHWs working across the LACDHS health system and officially they are allowed to work 24 hours/week outside of their allotted weekly County work hours. Using our MPI's and CHW networks, we will recruit 3 African American and 9 Latinx CHWs from the pool of currently employed LACDHS CHWs to participate and provide the intervention in this study. We estimate that each CHW will spend 24 hours over 2 weeks for the enhancement training pre-intervention, 6 hours/week for group classes with patients and 10 -14 hours/week for personalized patient encounters over the two months of intervention implementation.

Training of CHWs:

We developed a training curriculum for the Intervention CHWs on how to implement the patient modules that address COVID-19 testing, vaccination, and care overall. The patient modules are based on our preliminary findings from Aims 1 and 2.

Leveraging the resources of the CDU CHW Academy, study staff will train the Intervention CHWs virtually via Zoom. The training will take about 24 hours and will be delivered over the course of a month, allowing flexibility to CHW participants. Intervention CHWs will receive CITI training to ensure that they are compliant with IRB protocols and be IRB approved.

Table 2 provides the training outline of how some barriers will be addressed systematically in the CHW training, in terms of the content of the curricular modules and the learning objectives. We developed the training curricula and with input from our two CHW specialists, they provided their assessments in tandem with the implementation and analysis of Aims 1 and 2.

Table 2: CHW Training Plan

Identified Barriers to COVID-19 testing and vaccinations from Aims 1+2	How CHW Training Addresses Barriers	Curriculum Content	Learning Objectives
Barrier #1 Patient Mistrust of	Demonstrate ways of **building trust virtually** with patients based on their shared identities,	Building Trust in Virtual Communication Settings/ Historical Mistrust and	1. Explain why trust is important in the patient relationship 2. Review and apply the steps for

Health Care Organizations and Providers	geographies, and histories	Addressing Barriers to Trust	building-trust virtually
Barrier #2 Patient Lack of Reliable COVID-19 Health Information	Highlight the importance of timely, accurate, credible **health information about COVID-19** testing, vaccination, prevention, and care	COVID-19 health information challenges and sources of culturally relevant COVID-19 information for all reading levels	1. Address frequently asked questions and explain the facts and myths about COVID-19 2. Use information from official sources, including local, state, and federal health agencies
Barrier #3 Patient Lack of Social Support and Resources Compounded by COVID-19	Demonstrate ways of providing **Social support** based on a better understanding of patient socioeconomic challenges and concerns with COVID-19 testing and vaccination	Description of Social Support Resources for COVID-19 testing, vaccination, and care specific needs and other health-related needs.	1. Identify specific social determinants of health that are obstacles to COVID-19 testing, vaccination and access to care. 2. Review community resources available for referrals
Barrier #4 Patient Lack of Facility with Accessing Health Information Technology	Address **gaps in technological literacy** and help them maneuver through new health care processes	Description of digital divide related inequities for safety-net patients, changes in telehealth environment and practice using and explaining use of Health Technology Tools	1. Discuss patients' challenges with accessing & using health information technologies 2. Identify local telehealth resources that assist patients. 3. Review and apply the steps for building technological literacy.

After completing the intervention training, each Intervention CHW will be assigned to support 5-8 patients, who were randomly assigned to the case arm, by delivering a remote intervention of hosting a health class on COVID-19, at a time that is convenient for the both the participants and the Intervention CHW.

Intervention Design:

We will utilize a randomized control design consisting of one treatment arm and a control arm. African American and Latinx patients who did not complete COVID-19 testing or vaccination will be recruited from the patient list obtained from Aim 1 data pull of the LACDHS EHR. The patient list obtained by the data pull will be filtered by the patient list provided by the LACDHS Vaccine Hesitancy Outreach Group. Based on the inclusion criteria, we will recruit a total of 142 patients to allow for approximately 10% attrition from each group. Patients who meet the inclusion criteria and agree to participate in the 2-month intervention will be randomly assigned to either the intervention or control arm.

We will stratify the randomization on the basis of race/ethnicity and we will use permuted blocks **(see table 3).** We will use a scheme such as found at randomization.com. Here we will define a block size of 4 subjects and determine a random permutation of 2 treatment and 2 control assignments employed the scheme in question. This is repeated to cover the request number of blocks in each stratum in order to randomize the total number of required subjects. We expect our study sample to reflect LACDHS patient population race/ethnicity stratification (9% African American and 68% Latinx).

Table 3 – Stratified Random Sampling

Block	Category	Number of participants to enroll
Block 1	African American + control	18
Block 2	African American + case	18
Block 3	Latinx + control	53
Block 4	Latinx + case	53

We will refer the control arm as "Group 1" and the intervention arm as "Group 2" for the purposes of explaining to prospective participants they will be randomly assigned to a group without compromising the integrity of the study.

Participants will need to complete the consenting process, complete a basic demographic survey, and wait to be randomly assigned to either Group 1 or 2. Once assigned to a group, the study staff will notify the participant of which group they were assigned to. The methodologies of

each respective group are detailed below after the participants are notified which group they were randomly assigned to.

Control Arm- Standard Treatment (Group 1):

The standard care for the control arm will be: the LACDHS Vaccine Hesitancy Outreach Group calling patients once every month to remind patients of the need to be vaccinated and tested if needed. During the duration of the six weeks, the study participants will be exposed to the call from the LACDHS Vaccine Hesitancy Outreach Group.

Participants will receive two phone calls six-weeks apart, where they will complete a pre-survey in the first phone call, and 2 surveys (post-survey and CDE survey) in the second phone call. The survey will measure their trust in medical institutions, rate their self-efficacy, and intention, knowledge, and perceptions on COVID-19 testing and vaccination. Each survey will take about a half hour to complete, with the total time commitment for participants in Group 1 is about 1-1.5 hours. A copy of the surveys will be sent to the study participant either by email (preferred) or postal mail, prior to the telephone call.

An outline of the activities in Group 1 will look like:

1. Complete the pre- survey
2. Wait 6 weeks, where the LACDHS Vaccine Outreach Group will call one time in the month to remind them about getting the vaccine
3. After the 6 weeks have passed, the study staff will follow up with the participant to complete the post-survey and the CDE survey.

Study staff will use the REDCap Calendar feature to track events (such as when to administer the pre- and post- surveys) and will be used for data entry. The filters and reminders on the calendar feature assist study staff with adding events to adhere to study follow up times for study staff to call participants six-weeks later. If participants do not answer the phone calls to complete the post-survey, we will add a note on the patient's chart, follow up three times to provide additional opportunities for patients to complete the study, and mark the patient's chart as "Incomplete". Once phone calls and post- surveys are complete, study staff will mark the participants' charts as "Complete."

Intervention Arm – CHW-led curriculum (Group 2)

Participants assigned to the intervention group will be asked to participate in the virtual intervention, consisting of six-weekly group classes via Zoom, and six-weekly personalized teleconsultations (via phone call or Zoom) at a suitable time for both participants and CHWs. Study participants will receive 6 linguistically and ethnically concordant weekly two-hour group classes and personalized teleconsultations led by CHWs. The total time commitment for Group 2 will be a maximum of 20 hours (6 two-hour group classes, + 6 one hour personal session, + 2 half hour phone calls), over the next 6 weeks.

Table 4 outlines the group classes that will be used in the intervention. The findings from Aims 1 and 2 are incorporated in the curriculum and address the four barriers to COVID-19 testing and vaccination (mistrust, COVID-19 knowledge, social support, and health & technological literacy). The list of topic areas for the group sessions, which incorporate findings from Aim 1 and 2, were validated by the study CHWs specialists. The complete list of topics and learning goals under each module is found in **"Attachment 2 – Aim 3 Curriculum Module Outline."** These topic areas are grouped into curricular tracks as summarized below:

Table 4: Summary of Group Classes for Intervention Arm	
Week 1	1**) Introduction and Exploration** CHWs will introduce process, build rapport and elicit the key needs/ concerns of the patient group (topics: previous pandemics, current pandemic, how

	current pandemic affected them)
Week 2	**2) <u>Misinformation, Information, and Prevention</u>** (topics: where do they get their news, understanding misinformation, social distancing in housing contexts with limited space, mask wearing and handwashing, contact tracing, vaccination etc.)
Week 3	**3) COVID-19 <u>Testing, and General Vaccine Information</u>** (topics: types of tests, locations and processes around testing and vaccination, fears about testing, and general vaccination information.)
Week 4	**4) <u>COVID-19 Vaccination</u>** (topics: types of vaccines, locations and processes around vaccination, fears about vaccination etc.)
Week 5	**5) <u>Building Social Support</u>** (topics: caring for a sick member of the family; managing self-isolation; social services and mental health resources; hospitalization and treatment; managing chronic illnesses, accessing specialty care, accessing telehealth-based care etc.).
Week 6	6) **<u>Closure</u>**: CHWs will ask patients to reflect on their learning and address any additional concerns

Barriers to COVID-19 testing and vaccination:

1) Misinformation, Information, and Prevention (topics: identifying misinformation, mask wearing and handwashing, vaccination, etc.)
2) Testing and Vaccination (topics: types of tests and vaccines, locations and processes around testing and vaccination, fears about testing and vaccination etc.)
3) Building Social Support (topics: caring for a sick member of the family; managing self-isolation; social distancing in housing contexts with limited space, social services and mental health resources; hospitalization and treatment etc.),
4) Ongoing healthcare in the age of COVID-19 (topics: managing chronic illnesses, accessing specialty care, accessing telehealth- based care etc.).

Furthermore, participants will receive six one-hour weekly teleconsultations via phone calls, after they attend the group class (at a time that is both convenient for the participant and CHW) from their assigned CHWs to discuss progress toward personalized goals, the social support group experience, and resolve barriers to testing, vaccination, and accessing care. The Intervention CHWs will be asked to complete a patient encounter form on REDCap (**See attached: Patient Encounter Form**) after each of the six personalized patient interactions, documenting the nature of the interaction, the types of concerns raised by the patient and the types of information and support that was provided by the CHW. These forms will capture the participants' behavior and willingness to be open with the CHW and to document the participants' behavioral progress throughout the program. The forms will also be used as an evaluation tool, where study staff and PIs will review to provide the CHWs with feedback and support.

An outline of how the activities in the intervention group will be performed are the following:

- Complete pre-survey
- Complete intervention activities:
  - Attend weekly group online classes, via Zoom. Each online class will take around 90 minutes – 2 hours each.
  - Participants will be asked to complete surveys (**See attached: Knowledge Checks**) and participate in group discussions
  - Attend a weekly personal session with the Intervention CHW (via phone call or Zoom). Each personal session with the CHW will take between 30 minutes to an hour. The CHW will facilitate a discussion for the participant to share their thoughts, feelings, and experiences with COVID-19 testing, vaccination, and healthcare.
- Have participant complete the post-survey and the CDE survey

Once there are groups of 5-8 participants assigned to the intervention arm, the groups of participants will be assigned to an Intervention CHW to start the intervention. Depending on recruitment of participants, the intervention arm start dates will be staggered.

A note for the Intervention Group:

Participants will be notified during the consent process that if they are randomly assigned to Group 2 (intervention group), then participants will need to have a reliable internet connection and a device with a screen larger than 7 inches to attend the classes.

To remove any barriers to connecting to the group classes, if participants state they do not have a large enough device to use to log into the zoom meetings, participants will be provided with an android tablet with the Zoom application installed. The study staff will not require the participants to return the tablets. The study staff do not believe giving the tablets might inflict a sense of unfairness to the participants that end up being in the control arm. It is not unfair to provide the tablets to the participants in the intervention arm for the following reasons:

1. The time commitment is different, 20 hours for intervention and up to 2 hours for the control arm.
2. Intervention arm participants need the tablet to join the classes, the control arm participants don't need a tablet to complete the activity.

In addition, the tablets would be an older model and are worth $100 each, not an expensive device such as an iPad. The tablets would quickly lose their values and would not be able to be repurposed for another study. We believe it is best that we give the tablets to the participants so they can feel they can be trusted and it can help with participant retention in the study.

A note about the NIH's Common Data Element Survey

Once the project is completed, both groups will be asked to complete a Common Data Element Survey as requested by the NIH's terms and conditions. A priority of the RADx initiative is to build the RADx Data Hub, the NIH's resources of RADx-generated research data that can help other researchers and public health officials better understand the impact of the COVID-19 pandemic, including outcomes, disparities, and possible solutions. RADx-UP projects collect data for the RADx Data Hub and simplify the analysis of that data, the NIH defined a set of Common Data Elements (CDEs). The NIH RADx-UP CDEs provide a standard set of study questions that RADx-UP projects are required to use in their COVID-19 studies. Additional information can be found at https://radx-up.org/learning-resources/cdes/

9. Surveys, questionnaires, or psychological tests: If your study uses surveys, questionnaires, or psychological tests, please list and describe the setting, mode of administration, the length of administration time, number of repeats, and if special training or qualifications are necessary to administer the study instruments. Describe provisions for maintaining privacy and confidentiality.

All the following surveys and questionnaires will be comprehensible to participants by ensuring readability checks on the type of language used, simplicity of language, and additional explanation of concepts.

A basic demographic survey (**see attached: Basic Demographic Survey**) will be administered on a phone call when the patient has been consented and enrolled in the study. In this demographic survey, the survey consists of demographic questions such as age, race and ethnicity, education level, and other sociodemographic questions and will take about 10 minutes to complete.

Pre- and post- surveys (**see attached: Pre- and Post- RADxUP Survey**) will be administered telephonically by study staff to enrolled study participants. These surveys will be provided to both control and case arms, to measure three key measures: trust, self-efficacy,

and intent to participate in COVID-19 testing and vaccination. Secondary measures included will use brief measures from the RADxUP and Phenx database of COVID protocols such as worry about COVID-19, knowledge, attitudes, behaviors, social support, perceived COVID-19 threat, and sources of information about COVID-19.

- **Pre- surveys** will be administered by IRB-approved study staff, after study participants are consented and enrolled into the study and at a convenient time for the study participant. The survey should take about 30-60 minutes to complete **(see Pre- and Post- RADxUP Survey)**. The survey questions and answers will be sent via email or mail prior to the phone call, and read and answered over the phone by the study staff to overcome any misinterpretation of the survey questions. The participant's response will be input by the study staff directly into REDCap under the subject ID#. No special training will be required to administer the survey.
- **Post- surveys** will take between 30-60 minutes to complete **(see Pre- and Post- RADxUP Survey).** The survey questions and answers will be read and answered over the phone by study staff to overcome any misinterpretation of the survey questions. The participant's response will be input by the study staff directly into REDCap under the subject ID#. No special training will be required to administer the survey.
  - The post survey will be administered by study staff telephonically (similar to the pre-survey process) after:
    - Control arm – 6 weeks from the first survey
    - Case arm – after they complete the 6th group class and 6th personal phone call with the CHW

As part of the intervention arm, the modules will incorporate weekly formal "Knowledge Checks" **(see Knowledge Checks)** a comprehension questionnaire administered via email survey (sent by REDCap) sent after each module, which all participants will complete before their personal phone call with the CHW. The purpose of these Knowledge Checks is for the study team to measure patients' comprehension after each group session and throughout the course of the study. If patients score low in the Knowledge Checks, the CHW will review with the patients during their personal sessions to increase comprehension of the materials presented during the group session. There will be a total of 5 Knowledge Checks for Modules 1-5 (the Post- survey will be administered in lieu of a Knowledge Check for Module 6), each with 5-10 multiple-choice questions.

The study team will administer the **Common Data Elements (CDE) Survey** as provided by the funding partner, RADxUP (**see RADxUP CDE Survey attached**), the survey will be sent via email at the end of the project. Participants will be asked to complete it once. The survey can take up for 45minutes to an hour, no special training is required. In the RADxUP website, the reason for collecting the CDE's is "… to ensure consistency in how RADx-UP projects collect data for the RADx Data Hub and simplify the analysis of that data, the NIH defined a set of Common Data Elements (CDEs). The NIH RADx-UP CDEs provide a standard set of study questions that RADx-UP projects are required to use in their COVID-19 testing studies." More information can be found at https://radx-up.org/learning-resources/cdes/

10. Data Collection, Storage and Confidentiality: Please complete the following questions regarding data.

a. How will the data be collected and recorded? How will the data be coded to protect personal privacy?

Data Collection:

The different types of data that will be collected in this aim are:

- Verbal Consents
- Basic Demographic Survey
- CDE survey (NIH's required survey)

- Pre- and post- surveys
- Knowledge Checks (comprehension questionnaires for intervention arm)
- Patient Encounter Forms (CHW reports for personal encounters in intervention arm)

Verbal consents – will be obtained telephonically by study staff before participants are enrolled in the study, and will be reviewed, recorded, and collected at a time that is convenient for the study participant. The study staff, who are IRB approved, will save the audio recordings on REDCap under the subject ID# with a date and time stamp, documenting when the participant provided their verbal consent.

Basic Demographic Survey – The survey will be administered and obtained telephonically with study staff at the end of the study, and will be reviewed and collected at a time that is convenient for the study participant. The answers to the survey will be input directly into REDCap under the subject ID# with a date and time stamp, documenting when the participant completed the survey.

CDE Survey - The questions on this survey are required to be collected, as noted in the NIH's terms and conditions of funding the project. The project staff is in the process of requesting an exemption review for the Alcohol and Tobacco questions. However, the CDCC instructed the project staff to include all of the Common Data Elements as created by the NIH until our request is reviewed and approved. Selected CDE questions are used in the basic demographic survey that will be asked once (See Basic Demographic Survey). Additional information about the CDE's and a copy of the CDE survey can be found on the RADx-UP website at: https://radx-up.org/learning-resources/cdes/

Due to the sensitive nature of select questions, the study team will provide this survey to the study participants at the end of the project to give the project team additional time to have the questions reviewed and approved to be exempted. The study staff will notify the participants during the consent they will have to complete this additional survey at the end of the project. The survey will be sent out via REDCap to the participant's email and explain to participants they are also given the option to not answer any questions they do not want to answer. The answers to the survey will be saved on REDCap and shared via a secure portal to the NIH's RADxUP data sharing hub.

Pre- survey – will be administered telephonically with study staff after the study participant is consented and enrolled in the study, at a time that is convenient for the study participant. The study staff, who are IRB approved, will send the survey to the participant to review prior to data collection, and will read the questions and answer choices aloud and input the participant's answer directly into REDCap under the Subject ID#. If participants state they are comfortable with completing the survey on their own, the study staff will send the survey via REDCap to the email Participants enrolled in both control and case arm will complete this survey. Participants in the case arm will complete the survey before they attend the group classes and phone calls with the CHW.

Post- survey – like the pre- survey, the post- survey will be administered telephonically with study staff, at a time that is convenient for the study participant. The study staff, who are IRB approved, will resend the survey out before the phone call to read the questions and answer choices aloud and input the participant's answer directly into REDCap under the Subject ID#. Participants enrolled in both control and case arm will complete this survey. Participants in the control arm will complete the post- survey 6 weeks after they complete the pre- survey. Participants in the case arm will complete the survey after they attend the 6th group class and 6th phone call with the CHW.

Knowledge checks – this survey will only be administered to study participants randomly assigned to the case arm on a weekly basis, after they attend a group session. The survey will be sent out via email using the REDCap survey feature. If participants are not able to complete the survey via email, study staff will follow up with the participants via phone call to complete the survey where study staff will read the questions and answers aloud. The

study staff will then enter the answers directly into REDCap. This survey will need to be completed before the participants complete their personal phone calls with the CHW.

Patient encounter forms – this data collection tool will only be used on study participants randomly assigned to the case arm during their weekly teleconsultations. Intervention CHWs will complete these forms after each of their teleconsultations (personal phone calls) with their assigned study participants and enter their notes on REDCap. Each participant will have six completed patient encounter forms in their subject file on REDCap by the end of the study. The teleconsultations will be scheduled at a time that is convenient for both the participants and the CHWs.

One of the MPI and software programmer will strip personally identifiable information from the clinic data and substitute with a random code (Subject ID#). A master code list will be created separately that will link the code with the patient. This master code list will reside in a separate file in REDCap.

b. Where will the data be stored and how will it be secured during the study?

The data from Aim 3 will be stored in REDCap electronic data capture resource administered by the Biomedical Informatics Core function of AXIS (Accelerating Excellence in Translational Research) and the UCLA Clinical and Translational Science Institute (CTSI). REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.

CDU's REDCap servers are hosted by the University of California, San Diego Supercomputer Center. Vanderbilt University, with collaboration from a consortium of institutional partners, developed REDCap specifically around HIPAA-Security guidelines. REDCap can be used to easily build and manage online surveys and databases and all web-based information transmission is encrypted. REDCap currently has over 4641 collaborating institution in 139 countries wide with over 1.5 million end-users conducting 1 million projects (www.project-redcap.org). CDU's implementation of REDCap can be found at https://redcap.cdrewu.edu.

[1]Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J. Biomed Inform, 2009 Apr; 42(2):377-81.

c. Who will have access to the data and/or the data codes? If data with participant identifiers will be released, specify the person(s) or agencies to whom this information will be released.

The core study team (the MPIs, Machine Learning Specialist, Study Coordinator, and Research Assistant) will have access to the data and the data codes. The Biostatistician will have access to the data for data analysis, but not the data codes.

We will not release data with participant identifiers.

d. What will happen to the data when the study is completed? How long will the data be kept and what kind of identifiers will be associated with the data for long-term storage?

The data will be stored in REDCap for continued analysis and publication of manuscripts for up to six years after the overall study has been completed. During the six years, the coded link

will be maintained, as well as the master code that identifies the code with a particular patient.

The data from Aim 3 will be shared with NIH RADxUP program, who has funded this study and requires that de-identified data be shared as part of a national database for collective learning. The data will be submitted to the RADx-UP CDCC on a regular schedule as required by the funder, the NIH. The RADx-UP CDCC has chosen the Duke Research Center Institute (DCRI) to manage the data and be responsible for submitting de-identified datasets to the RADx Data Hub. The following link describing an overview of this process can be found: https://radx-up.org/learning-resources/cdes/#files and the following link describes the DCRI as the data collaborator with the RADx initiative https://reporter.nih.gov/project-details/10233289 . Detailed information on this process can be found: https://radx-up.org/wp-content/uploads/2021/01/RADx-UP_Data_Harmonization_Guidance_CDEs.pdf

Risk/Benefit Assessment

11. Potential Risks and Discomforts: Describe any potential risks (physical, psychological, social, legal, or financial) and discomforts that may be associated with the study, including likely adverse effects of the drugs, biologics, devices, research procedures, or interventions. If possible, assess their likelihood (quantitative and qualitative descriptors) and seriousness (permanent or transient condition).

Aim 3

The level of risk associated with this study for Aims 3 is minimal; therefore, we do not anticipate any major risk as a result of participating in this study. However, the potential risk and discomfort for the participant may include inadvertent 1) breach of confidentiality and anonymity; 2) violation of privacy, 3) embarrassment, and discomfort. There is a risk that some of the conversations during the intervention may make participants feel uncomfortable, embarrassed, or upset. However, the risk is minimal. The intervention does not include any intrusive conversation or invasive procedure; thus the risk of harm is minimal. There is also some minimal risk to study participants feeling uncomfortable discussing reasons for why they did or did not accept COVID-19 testing and/or vaccination. Nonetheless, if the participants do become upset, they have the option to stop their participation. They also can stop answering any question that makes them feel uncomfortable. All investigators on the study have completed Human Subjects Training and any new staff hired to work on the study will have to undergo this training prior to commencing work.

12. Risk Classification: Please check the level of risk* associated with this study.

**HHS/FDA regulations defines minimal risk as, "The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." When the risks that are associated with a new procedure or product are unknown, they cannot be classified as minimal.*

☒ Minimal ☐ Greater than minimal ☐ Unknown

13. Safety Precautions for Minimizing Risks: Describe the procedures for minimizing any potential risks. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the participants. For greater than minimal risk studies, describe the data safety monitoring plan (DSMP) to monitor the data collected and to ensure the safety of the participants.

Please see the attached data safety monitoring plan (DSMP)

Aim 3 – Case-control study

In data collection activities in Aims 3 (group class discussions, personal discussions, comprehension questionnaires, demographic and pre/post surveys), there is a chance that respondents may be uncomfortable with some of the questions in the surveys or open-ended

interviews, which ask about their attitudes towards COVID-19 testing and vaccination. However, the interviewers, who will be study staff, will have the training to respond to such discomfort and provide respondents with the option to not answer a question. If participants do become upset, they will have the option to stop their participation. They also can stop answering any question that makes them feel uncomfortable.

We will make every effort to prevent unauthorized access to patient identifying information by using a secure password protected computer and limiting the number of study personnel who can access the list. Whenever possible and particularly once all data collection is complete, we will use participants' unique study ID code, so that they are de-identified for data analysis. All study staff, including CHWs and all those with any contact with study participants or with collected data will have met all ethics certification requirements of the CDU IRB and have received training in how to ensure confidentiality and privacy of study participants and any identifiable data.

For Aim 3, all data collected on the patients will be stripped of confidential identifying information (e.g., name, medical record number, address, etc.) that could directly connect it back to a particular patient. However, each patient will be assigned a unique study ID code that allows us to link the data back to a particular patient, so that during data cleaning, we can check for additional information. A separate file linking unique identifiers and information about a patient will be created, and stored securely in CDU's instance of REDCap. Only the MPI overseeing this aim, Project Coordinator, and Machine Learning Specialist will have access to this master code list with the linking unique identifiers.

Additional safeguards includes having a regular meetings with the study team to review subject safety and data integrity, data security plan, implementing DSMP (see attached), keeping close communication with the participants, and resolving adverse events in a timely manner.

14. Potential Benefits to Participants and Society: Describe the potential benefits to the participants by being in the research and the potential benefits that the society might expect from this study.

Aim 3

Participants who are patients in medically underserved settings at risk of COVID-19 could benefit from obtaining additional information about resources and services about COVID 19 including information on how to access COVID testing or vaccinations, get additional support from CHWs, including increased technological literacy. They may also not get direct benefit. But, we have minimized the risk and have safeguards in place. The principle risk is breach of confidentiality and discomfort or anxiety in sharing information with the investigators in group and personal session, and surveys. However, we aim to minimize the risk in several ways, (e.g. limiting who has access to the data, the use of REDCap to collect data, the use of unique study ID# on the participant's data and keeping the master code list in a separate location). We have additional safeguards in place, such as regular meetings with the study team to review subject safety and data integrity, data security plan, implementing DSMP, keeping close communication with the participants, and resolving adverse events in a timely manner. Therefore, the risk to participants are reasonable in relation to anticipated benefits.

Given the unprecedented nature of the disease and severity of health outcomes related to COVID-19, there is an urgent need to increase COVID-19 testing and vaccine uptake in communities of color. The LACDHS, one of the largest safety net systems in the country, is not unique in facing declination of COVID-19 testing and vaccination in their safety net patient population. We propose that development and testing of a community engaged, CHW- based intervention could be useful for other similar safety net settings. This proposal has the primary goal of a) increasing COVID-19 testing and vaccine uptake for individual patients, and the secondary goal of b) developing a sustained public health presence in these communities to build trust and preparedness for critical future needs.

15. **Therapeutic Alternatives:** What therapeutic alternative(s) are reasonably available to potential participants should they choose not to participate in the study? *These may be research or non-research-based alternatives.*

This study does not involve therapy. Therefore, there are no therapeutic alternatives.

16. Risk/Benefit Ratio: What is the risk benefit ratio of this research, compared with available alternatives?

The potential benefits of the research must justify the risks to research participants. The risk/benefit ratio of the research must be at least as favorable for the participants as that presented by standard treatments for their condition. When comparing the risk/benefit ratio of research with that of available alternatives, the alternative of doing nothing should be included in the analysis.

The risk/benefit ratio of this research is favorable, because this is a low risk study and we aim to minimize the risk in several ways, (e.g. limiting who has access to the data, the use of REDCap to collect data, the use of unique study ID# on the participant's data and keeping the master code list in a separate, secure location). While there is no direct benefit to the individual participant, there may be a benefit to society in that the information gained in the study. Findings from this study may help identify barriers to COVID 19 testing, vaccination, and health care for African American and Latino patients in the Los Angeles County Department of Health Services, which may also inform the challenges faced by African American and Latino patients in similar County health care systems in other cities. The risks to the participants are reasonable in relation to the importance of knowledge to be gained.

Financial Considerations

17. Payment for Participation: Describe all plans to compensate participants, including provision of services, and other reimbursements. Describe the conditions that participants must fulfill to receive full or partial payment.

Study participants in the case arm will receive a $599 compensation (71 participants), and study participants in the control arm will receive $100 compensation (71 participants) for their time and effort.

Control arm:
Participants in the control arm will be compensated with a $100 gift card at the end of the study, after they complete the basic demographic, CDE, pre- and post- surveys. If the participant starts the surveys and cannot complete the required pre-, post-, and demographic surveys, then the participant will get the partial payment of $50.

Case arm:
Participants will be compensated in weekly installments, after completing the first week of the 6-week program, the participant will receive a $99 gift card, and subsequent weeks with $100 gift cards for every successful week of completion (group session and personal session with CHW).

If the participant cannot complete participation requirements for the case arm of the study for any given week (completion of the group session and personal session, or if the study personnel decides that the participant cannot continue), then the participant will get the partial payment of $50. If the participant drops out the study, they will not receive further payment.

18. Financial Obligations of Participants: Will participants have to pay for any of the tests or treatments that they receive as part of the research? *Please clarify who will pay for the procedures associated with the study as well as procedures that may be part of standard clinical care. Clarify that insurance and other third party payers may not cover standard procedures if they are associated with a research project.*

The participants do not have to pay to take part in this study. There are no financial obligations to the participants.

19. **Emergency Care and Compensation for Research-Related Injury:** If the research presents a greater than minimal risk, the financial liability for the costs of care associated with potential research related illness/injury must be specified. *(if no funds are available, please see the consent form template for the standard language to explain this to potential participants)*

Not applicable. This study is minimal risk.

Informed Consent

If you are requesting (1) waiver or alteration of consent, (2) waiver of parental permission, or (3) waiver of documentation of consent, please attach Form 115 to this application.

20. Capacity to Consent: Will all participants have the capacity to give informed consent? If not, describe the likely range of impairment and explain how, and by whom, their capacity to consent will be determined.

Aim 3: We expect that the participants will have the capacity to give informed consent. However, it is possible that older adults may have hearing problems. If they are not evaluated and considered incapable of giving consent due to hearing problem or if they are not able to confirm information given before, then we will move on to another participant. The person obtaining the informed consent will usually determine the potential participant's capacity to consent by using a teach-back approach and asking the participant to tell us what they understand to be the requirements for participation. If there are any issues, the final determination as to whether the potential participant is capable of consenting will be done by an MPI.

Lastly, this study aim has the potential to recruit participants ages 16 and 17. Due to their minor status, we will ask their parent or guardian to give their permission and informed consent for the minor to participate in the study. If the parent or guardian provides their informed consent, the person obtaining the informed consent will discuss describe the study and participation requirements with the minor participant and obtain their assent. However, if the minor refuses to participate after their parent or guardian provides their permission, the minor will not be recruited for the study.

21. Study Personnel Administering the Consent Process: Who will describe the research and invite the potential participants or their legally authorized representatives (LARs) to participate? Please identify the authorized individuals by name and describe their past training or experience in the research consent process. *To insure that participants give complete informed consent and are able to ask and have answered all questions regarding the nature of their participation, the personnel administering the consent must have appropriate training and background.*

Aim 3 - CDU study staff, who are IRB approved for this study, will describe the research project and obtain consent from potential participants. All study team members will have completed CITI online training on Human Subject Research, Health Information Privacy and Security, Good Clinical Practice For Behavioral Clinical Trials, and Conflict Of Interest training. The MPIs who have conducted collaborative research in the past and have experience in obtaining informed consent from potential participants will ensure that study team members obtaining informed consent will be trained and supervised for the study-specific processes of recruitment and obtaining of consent.

22. Process of Consent: Please discuss the consent process that promotes participants to make voluntary, informed consent without coercion or undue influence. Consider the following elements:

a. The environment and location where the informed consent will be solicited

The informed consent process will occur as follows:

1. Study staff will send the consent forms ahead of time to potential participants via mail or email before study staff follow up with the participants with a phone call.

2. Once the study staff confirms the study participants (or study participants' parents) have received and reviewed the consent form, we will answer any questions they might have and as a walkthrough of the consent form with them over the telephone. Study staff will also conduct a teach-back to ensure comprehension. After the teach back method, study staff will ask the participant to record the participants' consent to which we will ask them to state their name and agree to consent to being recorded for the following: initial recording of the consenting phone call, agreeing to being recorded during the group classes in Group 2 program (if assigned to the intervention arm), and to agree being enrolled in the study. The audio of the consent will be saved in REDCap as proof of consent.
    a. On the consent form, it will only provide that they agree to being recorded if assigned to Group 2. The recordings will be done via Zoom and the Zoom recording feature automatically disconnects participants from the meeting if they do not agree to being recorded. By design, participants cannot disagree with being recorded because if they are randomly assigned to Group 2 and do not agree with being recorded, they will not be able to participant in the group meetings via Zoom. The Zoom recordings will serve as a back-up to ensure participants are able to review the class if they find themselves unable to attend the group class with the CHW.
3. For minors, consent/assent will be reaffirmed when the interviewer calls the participants after obtaining parental consent. The study staff will review the assent form with the minor participants and to obtain assent, the study staff will also ask the participant to be recorded for the following items: assent phone call, they agree to being recorded during the study, and consent to being enrolled in the study. The audio of the consent will be saved in REDCap as proof of consent.

b. When the consent is solicited (*e.g.*, in relation to stressful events, hospital admission, surgery)

The consent will be solicited at a time of convenience to the potential participants

c. Opportunities for the potential participants to discuss their participation with family or others before signing the consent form

Study staff will send the consent and assent forms to participants via mail or email and allow some time for participants to discuss their participation with family or others before deciding to take part in the study by providing their verbal consent. Study staff obtaining verbal consent will specifically check with potential participants to see if they want to discuss their decision with family members or others before providing their verbal consent.

d. Use of individuals other than the investigators to explain the research

Only the investigators and study staff who are designated to obtain consent will contact the potential participants to explain the research project

e. Types of forms used (*e.g.*, adult consent form, assent form for ages 7-12, parental consent form, youth simplified consent form for ages 13 to 17, foreign language translations)

We will use a parental consent form and assent form for participants ages 16 and 17.

We will only use an English adult consent form.

The adult and parental consent form, and assent form will be comprehensible to participants by ensuring readability checks on the type of language used, simplicity of language, and additional explanation of concepts.

We request for a waiver of documentation of the consent form by the CDU IRB. Due to the COVID-19 pandemic, we will be conducting all research activities remotely. The

research is minimal risk and involves no procedures for which written consent is normally required outside of the research context. The procedures for this study involve demographic surveys, pre- and post- surveys, group and personal discussions. To obtain an effective verbal consent over the phone, we will send the consent form to the potential participants by e-mail or postal mail so that they can review the consent document before the phone call. After we go over every element of the consent, we will do a teach-back and/or Q&A to assess the individual's understanding of the study. We will ensure that all the individual's questions about the research have been answered to their satisfaction before they make their decision. The potential participant's decision to enroll or not enroll into the study will be recorded and logged into their study file along with the date and time.

23. Comprehension of the Information Provided: How will it be determined whether or not the participant or their legally authorized representatives understood the information provided?

We will use a "teach back" method to determine that the participants understood the information in the consent. In particular, we will ensure that the questions in the evaluation to provide verbal consent are clear to the participants by conducting a question-and-answer process as well.

24. Information Withheld from Participants: Will any information about the research purpose and design be withheld from participants? If so, please explain the non-disclosure and describe plans for post-study de-briefing.

No information will be withheld from the participants.

Data Analysis

25. Data Analysis: Please describe the data analysis plans for this study. Include planned statistical analyses and explanation of sample size determination.

Aim 3 - After data cleaning, we will assess psychometric properties of all scaled measures, calculate descriptive statistics to ensure quality of the data (check distributions, examine outliers) and to describe study participants. Bivariate analyses will include independent t-tests models (or their nonparametric equivalents, e.g. Wilcoxon rank-sum test, differences between the groups in trust and self-efficacy. Paired-tests (or Wilcoxon signed-rank test) will be used to assess change within groups. Contingency table analyses will address intention to participate in COVID-19 testing and vaccination. We will then fit multiple regression models predicting change in COVID-19 testing- and vaccine-related knowledge, trust, and self-efficacy as a function of intervention group, racial/ethnic group, and possible interactions. We will use covariate adjustment approaches such as multiple linear and logistic regression models for the three outcomes (trust, self-efficacy, intent to participate) while controlling for demographic characteristics (e.g. age, gender, education, health status) and other potential covariates that will be identified a priori. We do not anticipate many missing data, given the format of completion. However, if we do have 10% or more missing, we will impute data using SAS PROC MI and SAS PROC MIANALYZE to implement these multiple imputation procedures. With respect to sample size, with 64 subjects in each of the two study groups, it will be possible to detect an effect size of 0.5 standard deviations in a quantitative outcome (a medium effect size in Cohen's terminology) with 80% power and 2-sided 5% significance level.

VII. Funding

4. Check all types of funding sources for this study.

☒ Federal Grant/Contract	☐ Private
☐ State, Local Government	☐ Internal Grant Program
☐ International	☐ Departmental

☐ Industry	☐ Other:
2. Name of Funding Source (*e.g. NIH)*	NIH/National Library of Medicine
3. Grant/Contract Title*	A Community Health Worker Intervention to Identify and Decrease Barriers to COVID-19 Testing and Vaccination among Los Angeles County Department of Health Safety-Net Patients (Title of the Supplement to parent R01)
4. Grant/Contract #	We are submitting the IRB application as part of the Just in Time for NOT-OD-20-119 (NOSI: Emergency Competitive Revisions for Social, Ethical, and Behavioral Implications (SEBI) Research on COVID-19 testing among Underserved and/or Vulnerable Populations
5. PI of Grant/Contract	Omolola Ogunyemi, PhD (parent RO1), Sheba George, PhD, Lauren Daskivich, MD. This supplement is a Multiple PI (MPI) grant.
6. Funding Status	☒ Funded ☐ Pending ☐ No Funding
7. Expected Award Period	11/2020 to 11/2022
8. Is the funding received as part of a subcontract with another institution?	☒ No ☐ Yes, name of institution:
9. Please indicate whether the study under review is being conducted under the auspices of a larger umbrella grant.	☐ Center grant ☐ Training grant ☐ Program projects/multiple project grant ☐ Not applicable ☐ Other: Supplement to RO1
10. Name of larger umbrella grant (*e.g.*, AXIS, CTSI, RTRN): Supplement to R01 grant, Predicting Diabetic Retinopathy from Risk Factor Data and Digital Retinal Images (Parent Grant PI: Omolola Ogunyemi) (PA-20-135)	

VIII. Statement of Financial Interest or Commitment

1. Does the Principal Investigator or any personnel on this project or their spouses/domestic partners, or dependent children have any significant financial interests related to this research?

☒ No ☐ Yes (attach Form 133 Financial Disclosure Form)

2. Does the Principal Investigator or any personnel on this project or their spouses/domestic partners, or dependent children have any significant financial interest or commitment with any company, entity, or government agency that sponsors this research?

☒ No ☐ Yes (attach Form 133 Financial Disclosure Form)

IX. Ancillary Approvals

1. Identify the entity that provided scientific or scholarly review for this project.
   a. Name of reviewer/review committee: NIH/NLM
   b. Date of review or approval: 11-18-2020

2. Will you be requesting services from CDU Clinical and Translational Research Center (CTRC)?

   ☒ No ☐ Yes. Please contact CTRC for their services at (323) 568-3359.

3. Will you collect biological specimens from participants (*e.g.*, blood, tissue, urine, body fluids, *etc*.)?

   ☒ No

   ☐ Yes. Date application submitted to Institutional Biosafety Committee (IBC):

   or IBC approval period: (please attach approval notice)

4. Will you be using radioactive material or radio-emitting equipment?

   ☒ No

   ☐ Yes. Date application submitted to Radiation Safety Committee (RSC)/Radioactive Drug Research Committee (RDRC):

   or RSC/RDRC approval period: (please attach approval notice)