Charles R. Drew University of Medicine and Science
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
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Title of the Study: 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

Principal Investigators: Dr. Sheba George, Dr. Omolola Ogunyemi, Dr. Lauren Daskivich

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Key Information about this Research Study

You are being invited to take part in the Rapid Acceleration in Diagnostics (in) Underserved Populations program (RADxUP) with Charles Drew University, a NIH funded research study about COVID-19 testing and vaccination being provided to African American and Latino patients in the Los Angeles County Department of Health Services (LACDHS).

WHAT IS THE NIH AND RADX-UP?

The NIH stands for the National Institutes of Health, a part of the United States Department of Health and Human Services. The NIH's purpose is to find new knowledge that will lead to better health for everyone. The NIH is our funder for the RADx-UP program, and the Duke Clinical Research Institute (DCRI) is our collaborator with the NIH, who will help collect and manage the data gathered from this project.

This program is a health research program to learn more about COVID-19. If you join RADx-UP, we will gather some information about you by talking to you. We will look at the information we get from you, along with information from other people who join the program to understand how to help more people at risk for or with COVID-19.

Why is this research study being done?

This study is being done to provide African Americans and Latinos, who are patients with LACDHS, information about COVID-19 testing, vaccination, and health care resources in Los Angeles County.

What will I be asked to do and how long will I be in the study?

If you decide to join this six-week study, we will ask you to complete the consent process and gather information from you from a basic demographic survey (such as age, gender, race, income, health insurance status, job status, education level, and housing status) before randomly assigning you to either group:

Group 1 –

- Complete two surveys by phone call, six weeks apart
- Each survey will take about 30-60 minutes to complete per phone call.
- Complete an additional demographic (common data element) survey at the end of the study, that will be sent via email, and you may complete it on your own time

Group 2 –

- Participate in an online class, via Zoom, and one-on-one Zoom or phone calls with a Community Health Worker (CHW) on a weekly basis, for six-weeks.

- Each online class will take around 90 minutes – 2 hours each, and the phone calls with the CHW will take between 30 minutes to an hour.
- You will be asked to complete surveys and participate in group discussions.
- The group classes and the Zoom or phone calls with the CHW will include discussions where you will be asked to share your thoughts, feelings, and experiences with COVID-19 testing, vaccination, and healthcare.
- Complete an additional demographic (common data element) survey at the end of the study, that will be sent via email, and you may complete it on your own time

Remember, the information we gather about you that could identify you will be removed from the information we keep to protect your privacy.

What are some reasons why I might want to take part in this study?
Information provided in the study will help create a health education class to overcome barriers to COVID-19 testing, vaccination and health care for African American and Latino patients in LACDHS. The findings from this study will help create a strong health education course for Community Health Workers in LACDHS. The study may also inform the challenges faced by African American and Latino patients in similar county health care systems in other cities.

What are some reasons why I might <u>not</u> want to take part in this study?
The time commitment will be 3 hours weekly at most, over the course of six weeks.

Do I have to take part in the study?
Taking part in research study is voluntary. You do not have to take part of the study and you can stop at any time.

What if I have questions or concerns?
Please contact Dr. Sheba George, Department of Preventive and Social Medicine at Charles R. Drew University of Medicine and Science at (323) 249-5733, who is in charge of this study. Additional contact information can be found on the last page of this informed consent.

Additional Information about this Research Study

The researchers will tell you about this study. It is your decision to take part or not take part in the research. Before you decide to volunteer for this study, you should:

1. ask questions you do not understand;
2. learn as much as you can about the study; and
3. talk it over with your family, friends, and doctor.

WHY AM I BEING ASKED TO TAKE PART IN THE STUDY?

You are being asked to take part in this research study because you are either Latino or African American, 16 years of age or older, speak English, and you are a Los Angeles County Department of Health Services patient whose records indicate you have not completed a COVID-19 test or vaccination. Your participation in this study is entirely **VOLUNTARY**. Please read the information below, and ask questions about anything you do not understand, before deciding whether to participate.

Your doctor may be an investigator of this research study. Before taking part in this study or at any time during the research, you may ask about your health care from another doctor who is not involved in this study. You do not have to take part in any research study offered by your doctor.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

142 people will take part in this research study. Of these participants, 36 will be African American and 106 will be Latino patients. They will take part in this research study remotely by a combination of video-conference calls and/or telephone calls.

WHERE WILL THE RESEARCH TAKE PLACE?

The study will be conducted at CDU but your participation will be remote, over zoom meetings and by telephone calls, by Charles R. Drew University study staff.

HOW LONG WILL I BE IN THE STUDY?

You will be in this study for six-weeks, where you will be randomly assigned to one of two groups:

Group 1:
You will need to participate a minimum of two phone calls during the study. Each of the phone calls will take about 30-60 minutes, six weeks apart, in which you will be asked to complete a survey. The total amount of time you will be asked to take part in the study is about 1-2 hours over 6 weeks.

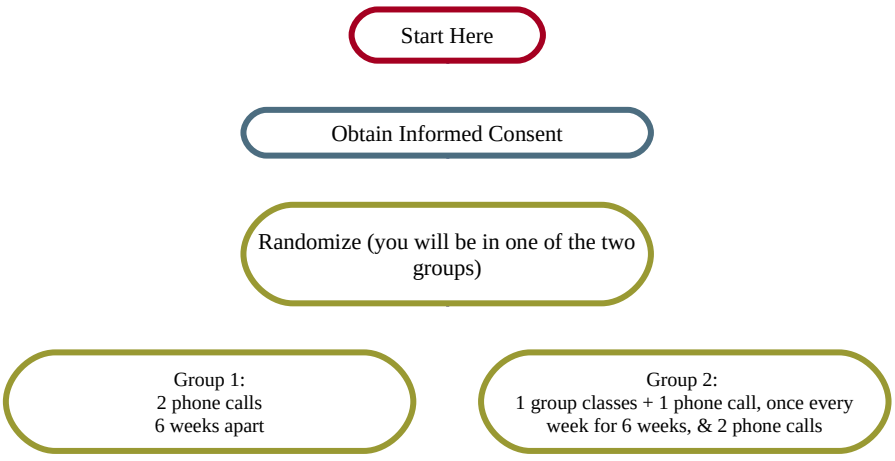
Group 2:
You will need to participate in:

- 2 phone calls before and after the study,
- 6 group classes **and** 6 meetings with a CHW during the study.

The 6 online group classes and 6 Zoom phone calls will be done with a CHW over the course of six weeks. The total amount of time you will be asked to take part in the study is up to 20 hours (6 two hours group class, + 6 one hour personal sessions, + 2 one hour phone calls), over the next 6 weeks.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Here is a chart that shows what you can expect:



If you decide to take part in this study, we will ask you to do the following:

- Complete this informed consent process.
- Complete a demographic questionnaire about general information about your background.
- Wait to be randomly assigned to one of the two groups:
- Complete the required activities in the group you were randomly assigned to.
    - **Group 1**: Complete two phone calls with a CDU staff member to complete two separate surveys, 6 weeks apart
    - **Group 2**: participate in 6 group classes and 6 phone calls with a CDU CHW, and 2 survey phone calls with CDU staff. A timeline would look like:
        1. Complete survey via phone call with CDU staff
        2. Complete a group class and phone call with a CHW on a weekly basis for 6 weeks
            - If assigned to this group, you must have a reliable WIFI connection to join the Zoom classes. A tablet will be available to you if you do not have access to a device with a large enough screen (7 inches or bigger)
            - During the group class, a CHW will provide you with information about COVID-19 testing, vaccination, other COVID-related resources in LA County, and complete other questionnaires about the material discussed during the group session.
            - During the Zoom phone call with the CHW, the CHW will ask if you had additional questions or concerns about the material discussed during the group session, and provide additional resources in LA County you may benefit from.
        3. Complete a second survey via phone call with CDU staff

WHAT RISKS OR DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?

There is a possibility that you may feel embarrassed while discussing personal beliefs and behaviors. We understand some topics may be sensitive when it comes to events that were caused by the COVID-19 pandemic. If you are uncomfortable, please let the CHW know to notify the researchers. The CHWs are there to listen to participants' concerns and feelings and provide resources that will assist your concerns. You do not have to answer any question that makes you feel uncomfortable, your decision to not answer or not participate will not affect any services you receive from LACDHS.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You may not get direct benefit from taking part in this study.

Information provided in the study may change your thoughts and feelings about COVID-19 testing and vaccination, and may influence your decision to be COVID-19 tested and/or vaccinated. This study was designed to address and overcome barriers to COVID-19 testing, vaccination, and other resources for African American and Latino LACDHS patients. The study may also help in similar county health care systems in other cities address challenges with COVID-19 related services.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

The alternative to participating in this study is to not participate.

WILL I BE PAID?

You will be paid a between $100 to $599 in gift cards for your participation (depending on the group you are assigned to).

If assigned to Group 1 – you will be paid $100 *at the end of the study*, after you complete your second telephone survey.

If assigned to Group 2 – you will be paid $99 after the first week, and then $100 for *every week* you successfully complete a group session and a personal phone call with the Community Health Worker, for a total of $599.

If you cannot complete the study for Group 1, or if you must drop out because the researcher asks you to even though you want to continue, you will be paid $50 for your time and effort.

If you cannot complete the study for Group 2, (all six group classes and all six personal sessions) or if you must drop out because the researcher asks you to even though you want to continue, you will be paid $50 for your time and effort.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There is no cost to you for participating in this research.

WHAT WILL YOU DO WITH MY DATA?

If you agree to join this study, we will keep your information you share with us today, along with information from other people like you who participate in this study, so that researchers can use the information to learn more about protecting us from COVID-19 or other diseases and conditions.

Some of the information collected for this study, **which does not directly identify you**, will be saved in a secure electronic system with the funder, and will not identify you and will not be linked to you in any way. Other researchers working on COVID-19 research may want to use this information for their studies, but they will not be able to identify you or link this information to you.

Some of the information collected for this study **can directly identify you**, such as your name, address, email, and gender, which we need in order to send you consent forms, gift cards, and other study information. Our collaborator at Duke University would also like us to share your identifiable information with them, so that other researchers can call you to ask you if you would be interested in participating in their studies. **You do not have to agree to provide this information and you can still be in the study and your care at LACDHS will not be affected. If you do not want to be contacted for future research studies, you can initial below under "No."**

I agree to be contacted for future research

____ Yes ____ No

Initials Initials

HOW WILL MY PRIVATE INFORMATION BE KEPT CONFIDENTIAL?

The researchers will do their best to keep your personal information confidential. Any personal information that could identify you will be removed from your information to protect your privacy.

However, researchers cannot guarantee total privacy.

We will make every effort to prevent unauthorized access to any information that identifies participants from anyone not part of the study team by:

1) using a secure password protected computer and allowing only IRB certified study team members to access the information;
2) stripping all confidential identifying information from all data collected (e.g., name, medical record number, address, etc.) that could directly connect it back to a patient/participant;
3) assigning unique ID code so that the data are de-identified for data analysis and participants names are not directly connected to the data;
4) having all study staff who have any contact with study participants or analyzing collected data have completed online training on human subject research and receive training in how to ensure privacy of study participants and confidentiality of any identifiable data.
5) the funder issuing a Certificate of Confidentiality, meaning it protects your privacy by blocking the release of identifiable, sensitive research information to anyone not connected to the research except when you agree, or in a few other specific situations listed below.

Members of the research team will know that you are a research participant. Your personal information may be given out without your written approval,

- if necessary to protect your rights or welfare (for example, child abuse and neglect, elder and dependent adult abuse, and domestic violence); or
- if required by law

When the results of the research are published or discussed in meetings, no information will be used that would identify you.

Your information may also be reviewed by those who gave us money for this project and those who are responsible for making sure that we do this project correctly. As a result, they may see your name; but they have to follow the rules of confidentiality and not to share your identity with others.

- National Institutes of Health (NIH)
- Office for Human Research Protections (OHRP)
- Safety monitors
- Authorized representatives of Charles R. Drew University of Medicine and Science

Any personal information that could identify you will be removed from the study information. After such removal, your information without any personal identifiers may be used for future research studies or shared with other researchers for future research studies without the investigator asking for your additional permission.

Photographs, Videos, Audio-Recording

You will be videotaped for the group classes (if assigned to Group 2) in this study because we are using Zoom to conduct these classes and also recording the sessions to evaluate them and learn how we can improve the classes. The digital video and audio recordings will be used for research purposes only and your identity will not be disclosed. The class video recordings will be kept in a password protected computer that is accessible only to CDU study staff until five years after the study is completed and they will be deleted after that.

Please check one of the boxes below and initial:

☐ _____ I agree to be video-recorded.
Initials

☐ _____ I do not want to be video-recorded.
Initials

CAN I STOP BEING IN THE STUDY?

Your participation in this research is VOLUNTARY. If you choose not to take part in the research study, that will not affect your relationship with the Los Angeles County Department of Health Services or your right to health care or other services to which you are otherwise entitled. If you decide to take part in the study, you are free to withdraw your consent and stop at any time without affecting your future care at the Los Angeles County Department of Health Services.

CAN THE RESEARCHERS REMOVE ME FROM THE STUDY?

The researcher may remove you from taking part in this research for several reasons. If you become sick during the study, you may have to drop out, even if you would like to continue. The researcher, Dr. Sheba George, will make the decision and let you know. The decision may be made because it is part of the research plan that people who miss scheduled meetings or phone calls, or did not follow instructions may not continue to take part in the study.

- If you do not attend the classes or complete the phone calls without letting the CHW or the study staff know ahead of time, or
- If you become sick during the program and cannot attend/complete the group class or phone calls, or
- If you are not able to follow instructions, you may not continue to take part in the study.

If you must drop out because the researcher asks you to, you will be paid $50 for your time and efforts.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any questions about the research, please feel free to contact:

- Sheba George, Ph.D. at Charles R. Drew University of Medicine & Science, shebageorge@cdrewu.edu; 323-249-5733.
- Denisse Ruiz, MPH at Charles R. Drew University of Medicine & Science, denisseruiz@cdrewu.edu; 626-534-6304
- Jacqueline Carranza, MPH at Charles R. Drew University of Medicine & Science, jacquelinecarranza@cdrewu.edu; 209-248-0416

Public Information about this Study

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

You may withdraw your consent at any time and end your participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research participant, please contact:

Charles R. Drew University of Medicine and Science
Institutional Review Board/Office of Research Integrity and Compliance
1731 East 120th Street, Los Angeles, CA 90059
Telephone: 323-563-5902
FAX: 323-563-4826
e-mail: irb@cdrewu.edu

VERBAL CONSENT OF RESEARCH PARTICIPANT

For COVID-19 safety-related reasons, this consent form will be discussed via telephone call and CDU staff will record your verbal consent.

If you agree to participating and enrolling in the study, please read the following statement with the CDU staff member recording your verbal consent.

"I, _ (name) _, have read, heard, and understood the information provided above. I have been given a chance to review a mailed/emailed copy of this consent form, to ask questions and to have all of my questions answered to my satisfaction. I am not giving up any of my legal rights by providing my verbal consent for this consent form.

"I agree to be video-recorded for this study, if assigned to Group 2.

"I _ (pick one: do or do not) _ agree to be contacted for future studies. I am aware my decision will not affect my care at LACDHS or my opportunity to participate in this study.

Today's date is __/__/___."