



Consent to Participate in Research

Study Title: Arizona CEAL COVID Consortium: Promoting Health Equity during the COVID Pandemic

Principal Investigator: Sairam Parthasarathy, MD

Sponsor: National Institutes of Health

Summary of the research

This is a consent form for participation in a research study. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

You are being asked to participate in a study about raising awareness about Coronavirus Disease 2019 (COVID-19) among members of Arizona's Latino, American Indian, African American, and other race/ethnicity communities to help improve understanding of your experiences, concerns, needs, wants, trust, and knowledge about COVID-19 testing, prevention, participation in research studies involving COVID treatments, prevention including vaccination. The study will last 6 months where you will be asked to complete study questionnaires and receive information regarding prevention and treatment of COVID-19 by phone, handouts, text, or social media. There is very low risk of loss of privacy and confidentiality. The direct benefit to you may be improved understanding of COVID-19 that could help prevent you from suffering from COVID. An alternative is to not participate in this study. Your time commitment is 5-10 minutes each week for 6 months duration. You may discontinue participation at any time.

The University receives compensation from the sponsor of this study for the conduct of this study. If you have any questions, please discuss this with your study staff.

Why is this study being done?

The COVID-19 pandemic has caused greater risk for hospitalizations and deaths in individuals belonging to racial/ethnic minorities and individuals with fewer resources. Such greater risk may be due to lack of resources, health information, or mistrust in minority populations. Ending the COVID-19 pandemic needs quick action to improve knowledge about how to prevent COVID-19 and information regarding personal tips for prevention and availability of research studies of vaccines and treatments. The purpose of the study is to raise awareness about Coronavirus Disease 2019 (COVID-19) among members of Arizona's Latino, American Indian, and African American communities to help improve understanding of your experiences, concerns, needs, wants, trust, and knowledge about COVID-19 testing, prevention, participation in research studies involving COVID treatments, prevention including vaccination.

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What will happen if I take part in this study?

The study will last 6 months where you will be asked to complete study questionnaires and receive information regarding prevention and treatment of COVID-19 by phone, handouts, text, or social media. There is very low risk of loss of privacy and confidentiality. The direct benefit to you may be improved understanding of COVID-19 that could help prevent you from suffering from COVID.

If you do not have access to internet and/or smartphone, you will be able to receive questionnaires by mail. If you receive the questionnaire by mail, you will be asked to return the questionnaire after you mark your responses by a stamped return envelope. You will receive information regarding COVID-19 prevention and treatment, availability of vaccines, and other research studies in your area by mail or text.

If you have access to internet and/or smartphone, you will be able to receive both the questionnaires and information by texts to your smartphone or email address. You will receive information regarding COVID-19 prevention and treatment research studies (including vaccine trials), and the availability of vaccines, and COVID-19 prevention and treatments in your area by mail or text. You will receive surveys and questionnaire up to once per week for a 6-month duration. Each survey and information package will take up to 5-10 minutes of your time to review.

If you are one of the early participants in the study, you may be asked to participate in focus groups. During the focus groups, we will ask you questions about your knowledge and feelings about COVID-19, prevention and treatment, and participation in research studies that test vaccines, medications, and other device treatments for COVID-19, and willingness to take a vaccine for COVID-19. Focus groups will take 90 minutes of your time and be conducted via Zoom video platform and/or telephone. You will be asked to complete brief questionnaires along with your participation in focus groups.

All focus groups including community members and community health workers will be conducted and recorded via Zoom video platform and/or telephone.

I give permission for audio recording to be made of me during my participation in this research study.

I do not give permission for audio recording to be made of me during my participation in this research study.

How long will I be in this study?

You will remain in the study for 6 months.

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How many people will take part in this study?

Locally we plan to enroll up to 150 people and 550 individuals across the state.

What benefits can I expect from being in this study?

You will receive information that may help you better understand how to improve your confidence, knowledge, trust, and ability to learn and take steps to prevent COVID. Such knowledge may allow you to prevent developing COVID. You may learn how to receive new treatments or prevention (such as vaccines) as part of routine care of other ongoing research studies. In all, such new knowledge may allow you to reduce your personal risk of developing COVID-19 or complications related to COVID-19.

What risks, side effects or discomforts can I expect from being in the study?

There are no risks associated with our research study because we are giving you health information about COVID and getting to understand your opinions about COVID. There is a very small risk of loss of privacy and confidentiality when we store your information. Every possible step will be taken to prevent any chances for breach or loss of privacy or confidentiality. If participating in a focus group there is minimal risk of psychological discomfort associated with answering questions surrounding your knowledge and personal experiences with COVID-19.

If you are Native American and agree to participate in this study, there may be risks associated with the research that impact your community. Health information can be applied to more than just you. Risks may include legal, financial, social, or physical harm. Information may be published that conflicts with your communities' culture, traditions, creation stories, or spiritual beliefs.

If there are significant new findings that may affect your participation, you will be informed immediately.

What other choices do I have if I do not take part in this study?

If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona. If you are a student or employee at the University of Arizona, your decision will not affect your grades or employment status.

When may participation in the study be stopped?

If you decide to take part in the study, you may leave the study at any time.

What are the costs of taking part in this study?

There are no anticipated additional costs for you to be in this study, except for your time.

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Will I be paid for taking part in this study?

There will be no compensation offered in our study for individuals who respond to questionnaires during the 6-month period of time. However, individuals who participate in focus groups will be compensated \$45 for their participation.

Compensation for participation in a research study is considered taxable income for you. If your compensation for this research study or a combination of research studies is \$600 or more in a calendar year (January to December), you will receive an IRS Form 1099 to report on your taxes. For any compensation or reimbursement you receive, we are required to obtain identifiable information such as your name and address for financial compliance purposes. Identifiable information collected for financial compliance purposes will not be linked to your research data. If you do not want us to collect this information, you can still participate in the study, but you will not be able to receive any payment for your participation.

Will my data be stored for future research?

The data obtained during this study will be analyzed after removing identifiers that connect the data to you. The data will be kept securely and analyzed for the duration of the study. Information collected will not be used or shared with future research studies.

Will my data be sold for commercial profits?

Your data will not be sold for commercial profit.

Will I hear back on any results that directly impact me?

You will receive any clinically relevant results discovered about the general population.

Will my study-related information be kept confidential?

The information that you provide in the study will be handled confidentially. However, there may be circumstances where this information must be released or shared as required by law. The University of Arizona Institutional Review Board; other federal, state, or international regulatory agencies; or the sponsor of the study, if any, may review the research records for monitoring purposes.

NIH Certificate of Confidentiality: To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except that the Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects

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or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Who can answer my questions about this study?

If at any time you feel you have questions, concerns, or complaints about the study you may contact Sairam Parthasarathy, MD at 520-626-8309.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program Director at 520-626-8630 or online at <http://rgw.arizona.edu/compliance/human-subjects-protection-program>.

A description of this clinical trial 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.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject

Signature of subject

Date

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