Title: CATCH-UP Vaccines: Extension of Community - Engaged Approaches to Testing in Community and Healthcare Settings for Underserved Populations (COVID-19)

NCT Number: NCT05236270

Document: Informed Consent

Document Date: 03/08/2022

Consent Form to Participate in a Research Study
University of Oklahoma Health Sciences Center (OUHSC)

Study Title: CATCH-UP Vaccines

Extension of CATCH-UP (Community - engaged Approaches to Testing in Community and Healthcare Settings for Underserved Populations)

(Full Implementation)

Sponsor: National Institutes of Health (NIH)

Principal Investigator: Judith James, MD, PhD

Phone Number: Amanda Janitz, PhD (Project Director), 405-271-2229

KEY INFORMATION ABOUT THE RESEARCH STUDY

You are being asked to participate in a research study. Research studies are voluntary and include only people who choose to take part. This consent form begins with a 'Key Information' section to provide important information to help you decide whether or not to participate in this study. More detailed information is provided after the key information. Please take your time, discuss this with family and friends, and ask the investigator and study team any questions you may have.

WHY HAVE I BEEN ASKED TO PARTICIPATE IN THIS STUDY?

You are being asked to participate in this research study because you are present at a CATCH-UP Vaccines community event.

WHY IS THIS STUDY BEING DONE AND HOW LONG WILL IT LAST?

The purpose of this study is to understand factors related to COVID-19 vaccine hesitancy and compare the effects of interventions to see whether these interventions increase uptake of the COVID-19 vaccine. The interventions include receiving a text message, taking an interactive survey on an electronic device and discussing antibody test results with study personnel.

We think that you will be in the study for about 15-30 minutes total. We will contact you through text message or email to follow-up on your intention to get vaccinated and your COVID-19 vaccination status in 30 days and 60 days. We will also ask some participants to participate in an interview after the interventions are complete to help us understand what did and did not work well during the project. The interview will last 30 minutes to one hour.

WHAT WILL I BE ASKED TO DO IN THIS STUDY?

If you decide to participate in this study, you will be asked to let us take a blood sample from you using a finger stick. From the sample provided, we will perform a point of care COVID-19 serology antibody test. You are not required to have an antibody test to participate in the study. You will also be randomized to receive up to three interventions:

1. Text message or no text message
2. Vaccine educational messaging through an electronic device or healthy lifestyle educational message
3. Interpretation of antibody test results using either the 5A's strategy (Ask, Advise, Assess, Assist, Arrange) or standard interpretation of antibody test results.

We will also ask you to fill out a survey, including but not limited to questions about your basic demographic information, possible symptoms consistent with COVID-19, attitudes towards COVID-19, and intention to be vaccinated against COVID-19.

WHY MIGHT I WANT TO PARTICIPATE IN THIS STUDY?
If you agree to take part in this study, there may not be direct medical benefit to you. We hope that the information learned from this study will benefit other people in the future.

WHY MIGHT I NOT WANT TO PARTICIPATE IN THIS STUDY?
You may experience slight discomfort associated with blood drawing. Possible risks include occasional hematoma (bruise) or infection at the blood drawing site. You may not want to be randomized to an intervention. Also, it will take some time to complete the study activities and the survey.

WHAT OTHER OPTIONS ARE THERE?
You do not have to participate in this study to get a COVID-19 vaccine.

HOW WILL PARTICIPATING IN THE STUDY AFFECT ME FINANCIALLY?
There is no additional cost to you if you participate in this study.

You will receive a $20 gift card for participating in this study if you are a United States citizen. If you would like a gift card, you will complete a separate form that will collect your name, phone number, email address, and residency status after completing the survey. If you are not a United States citizen, you will not be eligible to receive a gift card.

DETAILED INFORMATION ABOUT THE RESEARCH STUDY

The following pages of the consent form will provide you with more information about this study. Please take your time in reviewing this information and ask the investigator and study team any questions you may have.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
About 2000 people will take part in this study in Oklahoma.

WHAT IS THE STATUS OF THE PROCEDURE USED IN THIS STUDY?
This COVID-19 serology antibody test has received an Emergency Use Authorization (EUA) from the FDA.

WHAT IS INVOLVED IN THE STUDY?
If you decide to participate in this study, you will be asked to let us take a blood sample from you using a finger stick. From the sample provided, we will perform a point of care COVID-19 serology antibody test. You will get the results of the test today **BUT**

- This testing has not been ordered by a physician and is being done for your own use and not for medical diagnostic or treatment purposes;
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a more standard test should be considered if infection is suspected;

- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status;
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E, or past or present infection with SARS virus (no. 6). You will need to consult your healthcare provider to determine how best to care for you based on the test results along with medical history, and your symptoms.
- Results from this test will take approximately 15 minutes.
- We will also ask you to fill out a Patient Survey, including but not limited to questions about your basic demographic information, possible symptoms consistent with COVID-19, attitudes towards COVID-19, and intention to receive a COVID-19 vaccine.

You will also be randomized to receive up to three interventions:

1. Text message or no text message
2. Vaccine educational messaging through an electronic device or healthy lifestyle educational message
3. Interpretation of antibody test results using either the 5A's strategy (Ask, Advise, Assess, Assist, Arrange) or standard interpretation of antibody test results.

All study components will be conducted over a 15-30-minute window. We will follow-up with you on your intent to be vaccinated and vaccine status in 30 and 60 days after the intervention. We will also ask some participants to participate in an interview after the interventions are complete to help us understand what did and did not work well during the project. The interview will last 30 minutes to one hour.

You will be randomized to receive either all, some, or none of the interventions. Randomization means that you are put in a group by chance. A computer program will make this random assignment. Neither you nor the study investigators will choose which group you will be in. The study team will know which group you have been assigned to.

BIOSPECIMENS:
This research involves use of your biospecimens. Unless you separately provide consent to be involved in broader COVID-19 studies, blood samples collected for serology studies will not be used for other purposes and will be immediately destroyed after testing.

Your samples may be used to develop new drugs or other products for commercial purposes. If these products make money, there are no plans to share the money with you.

WHAT ARE THE RISKS OF THE STUDY?

Possible risks, inconveniences, and side effects for you include: occasional slight discomfort associated with blood drawing and occasional hematoma (bruise) or infection at the blood drawing site. Rarely, you may experience fainting or dizziness.

TO WHAT EXTENT WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. You will be asked to sign a separate authorization form for use or sharing of your protected health information.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations may include the US Food & Drug Administration and other regulatory agencies, the National Institutes of Health. The OUHSC Human Research Participant Program office, the OUHSC Institutional Review Board, OUHSC Office of Compliance, and other University administrative offices may also inspect and/or copy your research records for these purposes.

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

Certificate of Confidentiality:
To help protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. This Certificate means that the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. government that is used for checking or evaluating federally-funded projects or for information that must be disclosed in order to meet the requirements of the US Food and Drug Administration.

The protection offered by the Certificate of Confidentiality does not prevent us from being required by applicable state law to report information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The Certificate, however, 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, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. This means that you and your family should actively protect your own privacy.

Storing and Sharing Your Information:
We will keep your data securely (which means with extra protection), along with the data from all the other people who take part in the RADx-UP program. RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. RADx-UP is a health research program to learn more about COVID-19 disease. Researchers will use the data to learn more about COVID-19 or other diseases and conditions.

The Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies. The DCRI will build a RADx-UP database (systems that hold electronic information). This database will not hold information to identify you. It will hold all the nonidentifiable information you agree to give.

- You will be assigned a study code and you will only be identified in this database by this study code. Only the researcher for this study will have access to the code.
- It will not contain your name or other information that could easily identify you.

- We plan to transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
- When using the data from this database, researchers will only have access to your non-identifiable data and cannot link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.

CAN I WITHDRAW FROM THE STUDY?
You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first. There are no consequences to your decision to withdraw from the study.

There may be circumstances under which your participation may be terminated by the investigator without your consent, for example, the study is stopped by the sponsor or the investigator feels that it is in your medical best interest to stop your participation.

WHAT IF I AM INJURED OR BECOME ILL WHILE PARTICIPATING IN THIS STUDY?
In the case of injury or illness results from this study, emergency medical treatment is available. You or your insurance may be charged for this treatment.

No other funds have been set aside by the University of Oklahoma Health Sciences Center to compensate you in the event of injury, illness, or for other damages related to your event of injury or illness.

WHAT ARE MY RIGHTS AS A PARTICIPANT?
Taking part in this study is voluntary. You may choose not to participate. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.

If you agree to participate and then decide against it, you can withdraw for any reason and leave the study at any time. However, at certain times during the treatment, it may be harmful for you to withdraw, so please be sure to discuss leaving the study with the principal investigator or your regular doctor. You may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled.

You have the right to access the medical information that has been collected about you as a part of this research study. However, you may not have access to this medical information until the entire research study has completely finished. You consent to this temporary restriction.

Results of research testing on your sample will be returned to you.

DO I HAVE ANY OTHER RIGHTS OVER MY DATA?
Depending on where the sponsor for your study is located and other factors, you may have additional rights over your personal data collected in this study. For example, the European Union General Data Protection Regulation (GDPR) and some state privacy laws might apply. If the GDPR applies, generally you may have the following rights:

1. The right to request the information collected to be corrected.
2. The right to withdraw your consent for the use of your personal information at any time.

3. The right, in some circumstances, to receive your personal information in a structured, commonly used and machine-readable format and the right to provide your information to a third party.
4. The right to strict confidentiality of your personal data when it is used/shared.
5. The right to limit the use/sharing of your personal information in certain circumstances.
6. The right under some circumstances to request the erasure of your personal data.
7. The right to file a complaint with a privacy protection regulator if you believe any of the rights above have been violated.

You can receive more information regarding these rights in the Privacy Notice for Research Participants, located on the OUHSC Office of Human Research Participant Protection (HRPP) website at *https://compliance.ouhsc.edu/HRPP/Participant/Privacy-Notice*.

If you have any questions and requests, please contact the HRPP Office at 405-271-2045.

WHOM DO I CALL IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?
If you have questions, concerns, or complaints about the study or have a research-related injury, contact Principal Investigator, Judith James, MD, PhD, at (405) 271-4987 or Project Director, Amanda Janitz, PhD at (405) 271-2229 x48081.

If you cannot reach the Investigator or wish to speak to someone other than the investigator and for questions about your rights as a research participant, contact the OUHSC Director, Office of Human Research Participant Protection, at 405-271-2045.

1) I agree to let The Duke Clinical Research Institute collect only my zip code and no other identifiable information as stated above.

#1: Yes _____ Initials No _____ Initials

2) I agree to participate in an interview to help the study team learn what did and did not work during the project.

#2: Yes _____ Initials No _____ Initials

3) I agree to be contacted for future research studies.

#3: Yes _____ Initials No _____ Initials

SIGNATURE:

By signing this form, you are agreeing to participate in this research study under the conditions described. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

PARTICIPANT SIGNATURE OR ELECTRONIC SIGNATURE (age ≥18)	**Printed Name**	**Date**
SIGNATURE OR ELECTRONIC SIGNATURE OF PERSON OBTAINING CONSENT	**Printed Name**	**Date**