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

Study Title: Community-engaged Approaches to Testing in Community and Healthcare settings for Underserved Populations (CATCH-UP)

Sponsor: National Institutes of Health (NIH)

Principal Investigator: Judith James, MD, PhD
Phone Number: (405) 271-4987

Practice Name: _____

Consent Obtained from: ☐ Practice Owner/Decision-Maker ☐ Practice Member

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 own this medical practice or have the authority to make decisions on behalf of this medical practice, or you are employed by this practice as a clinician or staff member.

If you are the owner of the practice or making the decision on behalf of the practice, you are being asked to provide consent for the practice to participate in the study.

If you are a member of the practice, you are being asked to provide consent to participate in the study activities and surveys.

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

The goal of this project is to provide technical support to Oklahoma primary care practices to help them implement a culturally-responsive approach to SARS-CoV-2 testing based on best available evidence and current guidelines. The approach will include development of implementation support resources for testing and risk mitigation strategies to meet the needs of vulnerable populations. We will assist practices to integrate tailored SARS-CoV-2 testing protocols and resources into their workflows through academic detailing from peer-physician experts, practice change facilitation through QI implementation professionals, and health information technology support.

There may be anticipated circumstances under which your practice's participation may be terminated by the investigator without regard to your consent if your practice is unable or unwilling to participate in the use of practice performance measures for quality improvement or the study is stopped by the sponsor.

WHAT WILL I BE ASKED TO DO IN THIS STUDY?
You and your practice will enter into a training and practice transformation process that will build capacity for practice measurement, quality improvement, and implementation of the CATCH-UP Project protocol.

WHY MIGHT I WANT TO PARTICIPATE IN THIS STUDY?
We hope that the information learned from this study will benefit your professional capabilities and your practice's quality improvement capacity.

WHY MIGHT I NOT WANT TO PARTICIPATE IN THIS STUDY?
It will take some time to complete surveys and help the Practice Facilitators and Technical Advisors collect performance data. In addition, the level of clinician and practice performance will be known to the study team, which, if below average, might make practice staff feel uncomfortable.

WHAT OTHER OPTIONS ARE THERE?
You may choose not to participate in this study.

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

Your practice will be reimbursed at the rate of $300 for completing surveys at baseline and $300 for completing end of study surveys. In addition, at the end of the study we will reimburse the practice an additional $1,000 for study related extra work and research participation, including the time of practice members for assisting study staff with data access and extractions, research meetings, etc.

Practices will also receive $3,400 for testing supplies, point of care tests, and equipment if they decide to implement point of care testing at the practice.

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 *750* people from approximately 50 medical practices will take part in this study.

WHAT IS THE STATUS OF INTERVENTIONS USED IN THIS STUDY?
Academic Detailing from peer clinicians, facilitation of practice process improvement by Practice Facilitators, and Technical Advisors have been demonstrated to speed the adoption of clinical guidelines, enhance joy in practice, connect practices to the community, and contribute to a practice's financial security.

WHAT IS INVOLVED IN THE STUDY?
For Your Practice

- Complete a Practice Characteristic Survey and a Building Blocks of Primary Care Survey at the beginning and end of the study.
- Develop a workflow to ensure patients offered COVID-19 testing are invited to participate in a Patient Survey.

- Provide data for performance measurement or permit access to Practice Facilitators or Technical Advisors to collect performance measurement data.
- Permit access to the practice electronic health record and/or Health Information Exchange systems, if available, for Practice Facilitators and Technical Advisors to facilitate deployment of evidence-based guidelines for COVID-19 screening, testing, and treatment.
- Complete a Practice Facilitator Assessment Survey after completing the intervention period. This survey will be used to elicit feedback on the practice's experience with the assistance provided through the CATCH-UP Project.

For Each Practice Member

- Complete a Practice Member Survey which will be used in aggregate to compare practice attitudes about the CATCH-UP Project and quality improvement processes used in the practice.
- Participate in the dissemination and implementation program by attending Academic Detailer discussions, taking training, and using the CATCH-UP Project toolkit.

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 your Practice Facilitator first. There are no consequences to your decision to withdraw from the study.

WHAT ARE THE RISKS OF THE STUDY?

Risks to participating practices are minimal. Likewise, risks to clinicians and staff are minimal. The main risk to the practice, clinicians, and office staff may be minimal loss of productivity and overall practice income, not individual income.

The risks of the research to patients are minimal as well. The risks are those associated with use of medical record data for measure calculation and temporary disruptions in services associated with efforts to improve care processes.

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.

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 Centers for Disease Control and Prevention, the Oklahoma State Department of Health, collaborating RADx-Up projects, and the National Institutes of Health (NIH), the funder of this program. 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.

Please note that we may release names of participating practices, but no individual-level data of these practices will be released.

Identifiable Private Information:

- All data collected will be identifiable through clinician and practice StudyID numbers.
- Your data may be used for future studies without your additional consent. We will remove direct identifiers from your information and assign a code. The key to this code will be kept separately and only the researcher for this study will have access to the code. If your information is shared with another investigator for research purposes, they will not have access to the key code and will not be able to re-identify you.

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.

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. We will provide you with any significant new findings developed during the course of the research that may affect your health, welfare, or willingness to continue your participation in this study.

WHOM DO I CALL IF I HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?
If you have questions, concerns, or complaints about the study, contact the Principal Investigator, Judith James, MD, PhD, at (405) 271-4987.

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.

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