RESEARCH PROTOCOL OUTLINE

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

Principal Investigator: Judith James, MD, PhD, Oklahoma Medical Research Foundation

Co-Principal Investigator: Amanda Janitz, PhD, Biostatistics and Epidemiology

Abstract

Our proposal is an extension of the Oklahoma Shared Clinical Translational Resources (OSCTR) project CATCH-UP (Community-engaged Approaches to Testing in Community and Healthcare settings for Underserved Populations) in partnership with the Oklahoma State Department of Health, Southern Plains Tribal Health Board, Latino Community Development Agency, County Health Improvement Organizations, Public Health Institute of Oklahoma, and the Center for Applied Social Research. We will build on existing strengths and infrastructure to improve SARS-CoV-2 vaccine uptake in these highly susceptible populations.

A. Specific Aims

Aim 1 (Preparation). Identify SARS-CoV-2 vaccination barriers/facilitators and assess acceptability and feasibility of a suite of evidence-based vaccine intervention strategies among Oklahoma's rural, minority, and high-risk populations to inform a targeted multicomponent intervention.

We will conduct up to 10 focus groups including participants from communities with low levels of vaccine uptake and/or high levels of vaccine hesitancy and communities holding events where SARS-CoV-2 testing or vaccination is offered in partnership with the CATCH-UP program (IRB #12582). Focus groups will: (1) explore vaccine-related concerns and motivators, (2) evaluate NIH Community Engagement Alliance (CEAL) educational resources for local and cultural acceptability; and (3) examine outreach and communication intervention strategies detailed in the NIH COVID-19 Vaccination Communication for feasibility at later testing events.

Aim 2 (Optimization). Develop and optimize a multicomponent intervention to improve SARS-CoV-2 vaccination among Oklahoman's seeking SARS-CoV-2 testing at CATCH-UP testing events.

Aim 2.1. Pilot Implementation. In a pilot implementation, we will randomize participants to either receive a text message (yes/no) and an educational intervention through a tablet compared to a control message. We will also pilot messages for motivational interviewing in tandem with SARS-CoV-2 antibody test results and observe how participants respond to the messages. As part of this study, we will collect

information on demographics, COVID-19 testing, and vaccine status and hesitancy as required by NIH for the RADx-UP projects.

Aim 2.2. Full implementation. Participants will be randomized to a 2 x 2 x 2 fully crossed factorial design, creating eight conditions to evaluate the contribution of each intervention component. Feedback from Aim 1 and Aim 2.1 will inform the selection and development of three intervention components, which address three primary areas to improve vaccination uptake in the catchment area of the community: (1) process improvement; (2) teachable moment messaging; and (3) barrier elicitation and reduction.

B. Background and Significance

This proposal unites academic and community partners to solve a dire need for SARS-CoV-2 vaccine uptake in rural, underserved minority, and at-risk populations. Oklahoma has high COVID-19 incidence, high vaccine hesitancy, and signs of a slowing SARS-CoV-2 vaccine uptake. As of April 30, 2021, 448,305 cases of COVID-19 and 8,263 deaths have occurred in Oklahoma.[1] Oklahoma's cumulative incidence is higher in rural (12,065 per 100,000) compared to urban (10,973 per 100,000) counties.[2] AI people have a higher incidence of COVID-19 compared to white populations in Oklahoma (22% higher). In the US, Hispanic (100% higher), AI (48% higher), and Black (8% higher) populations have higher incidence rates compared to NH Whites, though non-white race/ethnicity is likely underestimated due to racial misclassification.[2-4] Over one third (34%) of AI adults aged 18-64 years are at risk of serious illness from COVID-19 due to comorbidities, which is also elevated for Black (27%) and Native Hawaiian/Pacific Islander (23%) people, with lower percentages among White (21%), Hispanic (20%), Asian (12%) people.[5, 6]

Despite high incidence, as of April 2021, an estimated 54% of Oklahomans who have not yet been vaccinated (approximately half of those surveyed) reported unwillingness to receive the SARS-CoV-2 vaccine.[7] Vaccine hesitancy was even greater in AI people (62%).[7] The most common concerns were vaccine side effects and safety (30%).[8] Other reasons for hesitation included waiting for more data/information (15%), lack of trust in government (13%), and concerns about how rapidly vaccines were developed (10%).[8] As of April 30, over 2.6 million SARS-CoV-2 vaccines have been administered in Oklahoma, with 38% of the population having received one dose and 30% fully vaccinated.[2] Despite this early progress, all signs point to waning interest in receiving a vaccine, with many vaccine clinics unable to fill all available slots, particularly in tribal and rural areas.

C. Preliminary Studies/Progress Report

The OSCTR has extensive experience collaborating with clinical healthcare providers in Oklahoma and collaborating with tribal populations. As noted above, OSCTR is a grantee of the RADx^{SM}-UP program to identify and improve upon barriers to obtain testing for COVID-19. Initial findings from our patient survey during testing events (n=96) found that of those that had not been vaccinated, more than 50% indicated they were unlikely to be vaccinated, while nearly 15% were unsure. The most common reason respondents would get a COVID-19 vaccine is to keep their family (77%) and community (71%) safe. The most common concern was side effects from the vaccine (51%) followed by lack of

knowledge about how well a COVID-19 vaccine works (34%) and lack of trust in vaccine safety (30%).

D. Research Design and Methods (What, When, How, Where)

Aim 1 (Preparation). Identify SARS-CoV-2 vaccination barriers/facilitators and assess acceptability and feasibility of a suite of evidence-based vaccine intervention strategies among Oklahoma's rural, minority, and high-risk populations to inform a targeted multicomponent intervention.

Study Design. We will conduct up to 10 focus groups including participants from communities with low levels of vaccine uptake and/or high levels of vaccine hesitancy and communities holding events where SARS-CoV-2 testing or vaccination is offered in partnership with the CATCH-UP program (IRB #12582). We will recruit focus group participants in conjunction with testing events and through conversations with community leaders prior to testing events. Focus groups will: (1) explore vaccine-related concerns and motivators, (2) evaluate NIH Community Engagement Alliance (CEAL) educational resources for local and cultural acceptability; and (3) examine outreach and communication intervention strategies detailed in the NIH COVID-19 Vaccination Communication for feasibility to be implemented at later testing events.

Focus Group Procedure. Focus groups will be conducted virtually (via teleconferencing/telephone) or in-person. The focus group guide will be developed in conjunction with our collaborative team. Focus groups will examine barriers and facilitators to vaccination within each community (e.g., perceptions of COVID-19 severity, vaccine concerns, vaccine availability/accessibility, competing priorities, etc.). NIH Community Engagement Alliance (CEAL) educational resources will be examined for local and cultural acceptability. Participants will be presented with several vaccine interventions selected by the team for demonstrated efficacy as well as likely acceptability among Oklahoma communities. Responses to selected interventions will be elicited, with special attention to perceived effectiveness and acceptability within their respective communities, barriers to/facilitators of implementation, and needed modifications for local/cultural relevance. We will also have participants complete a brief demographic survey that will be completely de-identified. Although our goal is 6 participants per focus group, only one participant is required for a focus group.

We expect to enroll a maximum of 60 focus group participants.

Aim 2 (Optimization). Develop and optimize a multicomponent intervention to improve SARS-CoV-2 vaccination among Oklahoman's seeking SARS-CoV-2 testing at CATCH-UP testing events.

Overall Study Design: Interventions will address three primary areas to improve vaccination uptake: (1) process (text messages); (2) teachable moment messaging (motivational interviewing); and (3) barrier elicitation and reduction (electronic survey with tailored questions/prompts). In our selection of potential interventions, we will use the Community Preventive Services Task Force (CPSTF)[9] and the NIH Behavior and Social Sciences Research-Coordinating Committee Rapid Working Group on COVID-19 Vaccine Communication guide, among other resources.[10] We will work with the NIH RADx[SM]-UP Coordination and Data Collection Center (CDCC) to ensure collection of Common Data Elements.

Table 2. Experimental conditions in the 2^3 factorial design for the COVID-19 vaccine intervention

	Factor		
Condition	Process Improvement	Teachable Moment Messaging	Barrier Elicitation and Reduction
1	No	No	No
2	No	No	Yes
3	No	Yes	No
4	No	Yes	Yes
5	Yes	Yes	Yes
6	Yes	Yes	No
7	Yes	No	No
8	Yes	No	Yes

Outcome metrics characterizing SARS-CoV-2 vaccine uptake. Our **primary outcome** will be intention to receive a COVID-19 vaccine post-intervention. We will measure this with the question "How likely are you to get an approved COVID-19 vaccine?" and "If you have received 1 dose of the Janssen vaccine or 2 doses of the Moderna or Pfizer vaccine, how likely are you to get an approved booster shot?" We will compare intention to receive a COVID-19 vaccine or booster among those receiving the interventions compared to those not receiving the intervention (see details on analysis below).

Our **secondary outcome** will be vaccine uptake, including self-report of receiving an initial dose of any approved vaccine, two doses of Pfizer or Moderna vaccines, or a booster of any approved vaccine. We will request the manufacturer of the vaccine and the approximate dates the vaccine was received from the participant.

Aim 2.1. Pilot Implementation.

Study Design. Participants at the pilot sites will be randomized to receive a text message and/or education message (detailed below) delivered through a tablet or no intervention. We will also conduct a pilot of motivational interviewing messages that are tailored based on antibody test results (or lack of testing if the participant declines an antibody test).

We will collect a survey using Research Electronic Data Capture (REDCap) software (Nashville, TN) to allow for descriptive statistics, assessment of study outcomes, and ensure the randomization is balanced regarding these characteristics.

Intervention Procedure

1. Screening Form to identify eligibility for the study. This will include age, ability to read and speak English, vaccine status and dose information (see eligibility criteria), and having symptoms of COVID-19 or positive test for COVID-19 infection in the previous 14 days. The screening form will include the following symptoms as having active COVID-19: fever, chills, cough, shortness of breath, difficulty breathing, lack of energy/general tired feeling, muscle or body aches, headache, new loss of taste or smell, sore throat/congestion/runny nose, nausea, vomiting, or diarrhea, abdominal pain, or skin rash.

2. Obtain consent and HIPAA authorization and allow an opportunity for questions.
3. Brief demographic questionnaire (race, ethnicity, sex, county of residence) and questions to assess intention to receive a COVID-19 vaccine.
4. Conduct interventions. All participants will have the opportunity to receive antibody testing using a finger stick (using the same methods as in the CATCH-UP Study, IRB #12582). After the antibody test is done and participants are waiting for the results (about 15 minutes), the participants will receive the interventions. If participants decline the antibody test, the interventions will begin once consent, HIPAA, and the brief demographic questionnaire are complete.
    a. **Text message.** Participants will be randomized to either receive 1) a text message encouraging COVID-19 vaccination (treatment) or no text message (control). This factor will last less than 1 minute.
    b. **Tailored messaging.** Participants will be randomized to receive 1) educational messaging about COVID-19 vaccines (treatment) or 2) an attention control educational message not related to COVID-19 (control). This will be delivered on a tablet through RedCap. This factor will last around 10 minutes.
    c. **Motivational interviewing.** As part of CATCH-UP (IRB #12582), participants currently receive feedback on their antibody test results. Based on focus group findings, we will use a semi-structured script that encourages participants to take actions tailored to their individual test results. The procedure will be as such: Participants are given their test results in line with current CATCH-UP procedures. As part of this protocol, participants will be shown examples of anonymized antibody test results (e.g., results with low and high antibody tests). The key personnel will follow a script in REDCap to interpret the results (or address refusal to receive antibody testing).

       These interactions will be observed by key study personnel who will take notes on the participants' reactions to the messages following a checklist directing them to note the antibody results, verbal and non-verbal reactions, as well as fidelity to the semi-structured script. In addition, we will observe the responses of the personnel delivering antibody test results to participants even if they are not using the semi-structured script. The study team will use this information to revise the messaging for full implementation in a future IRB modification. We expect this factor to last approximately 5 minutes.
5. Once the interventions are complete, the participants will complete a brief exit survey that includes questions about their intention to receive a COVID-19 vaccine or booster and to request their contact information for future follow-up surveys and mailing/distribution of gift card (if mailing or emailing is needed). Participants will also be asked to complete a survey required by NIH to report common data elements, with a link sent through text message or email, with follow-up daily for up to three days after the initial survey invitation is sent, and at 30 and 60 days post intervention if the participant has not responded (in tandem with the follow-up survey in #6 below). This will complete the intervention.

6. We will send participants a RedCap survey link through text message or email 30 days and 60 days after the intervention to assess intent to be vaccinated for COVID-19 and vaccine uptake, allowing time for both doses of the Pfizer and Moderna, single dose of Jansen's COVID-19 vaccine, or boosters of vaccines to be delivered. We will also send up to three daily reminders to the participant to complete the common data elements survey if they did not complete it after the intervention.
7. For participants who agree, we will contact up to 60 participants to participate in an evaluation interview to help the personnel determine what did and did not work well during the intervention. This will be a 30 minute to one hour interview.

Aim 2.2. Full implementation.

Study Design. Participants will be randomized to a 2 x 2 x 2 fully crossed factorial design, creating 8 conditions to evaluate the contribution of each intervention component in an initial pilot/feasibility study. For each intervention site, we will collect a brief demographic survey through Research Electronic Data Capture (REDCap) software (Nashville, TN) to allow for descriptive statistics and ensure the randomization is balanced regarding these characteristics.

Intervention Procedure

All interactions with participants will occur through a tablet or through verbal communication.

1. Screening Form to identify eligibility for the study. This will include age, ability to read and speak English, vaccine status and dose information (see eligibility criteria), and having symptoms of COVID-19 or positive test for COVID-19 infection in the previous 14 days. The screening form will include the following symptoms as having active COVID-19: fever, chills, cough, shortness of breath, difficulty breathing, lack of energy/general tired feeling, muscle or body aches, headache, new loss of taste or smell, sore throat/congestion/runny nose, nausea, vomiting, or diarrhea, abdominal pain, or skin rash.
2. Obtain consent and HIPAA authorization and allow an opportunity for questions.
3. Brief demographic questionnaire (race, ethnicity, sex, county of residence) and questions to assess intention to receive a COVID-19 vaccine.
4. Conduct interventions. Participants will be randomized to receive or not receive each of the interventions described below. Participants may be randomized to receive all three factors (treatment), all three control factors, or any combination of treatment/control as defined below (see Table 2). All participants will have the opportunity to receive antibody testing using a finger stick (using the same methods as in the CATCH-UP Study, IRB #12582). After the antibody test is done and participants are waiting for the results (about 15 minutes), the participants will receive the interventions.
    a. **Text message.** Participants will be randomized to either receive 1) a text message encouraging COVID-19 vaccination (treatment) or no text message (control). This factor will last less than 1 minute.

a. **Tailored messaging.** Participants will be randomized to receive 1) educational messaging about COVID-19 vaccines (treatment) or 2) attention control educational message not related to COVID-19 (control). This will be delivered on a tablet through RedCap. This factor will last around 10 minutes.

b. **Motivational interviewing.** Participants will be randomized to receive feedback on their antibody tests in these two methods: 1) receive a motivational interview following the 5A's strategy (Ask, Advise, Assess, Assist, Arrange) following a semi-structured format (treatment) or 2) interpretation of antibody test results and encouragement of vaccine uptake (as per usual standard practice) (control). Personnel will make notes regarding any deviations from the semi-structure script or assigned treatment arm (e.g., some participants may decline to discuss the vaccine). This factor will last around 5 minutes.

5. Once the interventions are complete, the participants will complete a brief exit survey that includes questions about their intention to receive a COVID-19 vaccine or booster and to request their contact information for future contact and mailing/distribution of gift card (if mailing or emailing is needed). Participants will also be asked to complete a survey required by NIH to report common data elements, with a link sent through text message or email, with follow-up daily for up to three days after the initial survey invitation is sent, and at 30 and 60 days post intervention if the participant has not responded (in tandem with the follow-up survey in #6 below). This will complete the intervention.
6. We will send participants a RedCap survey link through text message or email 30 days and 60 days after the intervention to assess intent to be vaccinated for COVID-19 and vaccine uptake, allowing time for both doses of the Pfizer and Moderna, single dose of Jansen's COVID-19 vaccine, or boosters of vaccines to be delivered. We will also send up to three daily reminders to the participant to complete the common data elements survey if they did not complete it after the intervention.
7. For participants who agree, we will contact up to 60 participants to participate in an evaluation interview to help the personnel determine what did and did not work well during the intervention. This will be a 30 minute to one hour interview.

At all events, key personnel will also conduct a field observation of how the events flow, including external factors such as weather or logistical problems and where challenges to implementing the study or recruiting participants occurred. We will also conduct evaluation focus groups with event site staff to determine what did and did not work during the event.

We expect to recruit 2000 participants over the entire study period (Aim 2.1 and 2.2).

Factorial design. In a factorial research design, two or more independent variables are concurrently examined within the same trial. The three factors are crossed with one another to create a total of eight experimental conditions. An equal number of participants are randomly assigned to each condition, using a random number generator. This is not an 8-arm randomized controlled trial, but instead allows for an efficient examination of main effects for each variable in a sample of 2000 participants (including Aim 2.1 and Aim 2.2).

This approach allows examination of three key treatment development questions in a much more time-efficient and economical manner by simultaneously performing three studies within the single trial. This achieves power to detect between-group differences that is equivalent to performing three separate randomized trials. Investigators who are providing the intervention and conducting analysis will be not be masked to study assignment due to challenges in maintaining the masking in an educational intervention. For all sites, including Aims 2.1 and 2.2, we expect to recruit 2000 participants.

Identifiers might be removed and the de-identified information may be used for future research without additional informed consent from the subject.

Evaluation. Global questions will be explored in the program evaluation, including: 1) What are potential barriers and facilitators to "real-world" implementation of the interventions?; 2) What problems are associated with delivering the interventions, and how might they translate to improving implementation processes?; 3) What potential modifications to the interventions could be made to maximize implementation?; and 4) Among the interventions that were implemented, which appeared most promising? *Implementation process metrics* will be assessed by conducting a process evaluation for deployment of interventions to increase vaccine uptake. To organize process findings, we will generate a comprehensive list of patient and community implementation outcomes aggregated through the common taxonomy of the Proctor et al. evaluation framework.[11, 12] The evaluation also will incorporate measures from CFIR,[13] which has been shown to be effective for guiding successful implementation.[14, 15]

Research team members will visit the community sites or meet through videoconference to conduct five additional focus groups with multiple respondents, including the community members involved in the intervention, to assess acceptability, cultural relevance, and possible barriers. We will also interview participants who agreed to an interview in the consent form for evaluation of the intervention. Findings will help clarify processes of care and perceptions of barriers and facilitators. The focus group guide will prompt participants to discuss their practice context as it relates to their experiences with implementing each of the intervention components, and participants will be probed regarding challenges and facilitators they face when implementing each component. To evaluate whether the selected intervention(s) improved vaccine uptake in the pilot study, our team will evaluate aggregate vaccination data for the catchment area of the community site through the Oklahoma State Department of Health. The final product will summarize barriers and facilitators for implementation and provide a thorough picture of the implementation process, including feasibility, acceptability, and fidelity of intervention implementation that can inform future large-scale research.

For the community site evaluation, we will have participants complete a brief demographic survey that will be completely de-identified. Although our goal is 6 participants per focus group and one focus group per intervention site, only one participant is required for a focus group. We expect to enroll a maximum of 60 focus group participants.

We expect to interview up to 60 Aim 2 participants for an evaluation interview.

E. Inclusion / Exclusion Criteria

Aim 1.
The following inclusion criteria will apply:

1. 18 years of age and older
2. Leadership/membership role in community organization or staff at CATCH-UP testing event (IRB #12582)
3. English speaking

Aim 2.1 and Aim 2.2.
The following inclusion criteria will apply:

1. 18 years of age and older
2. Must be eligible to receive a COVID-19 vaccine dose at the time of consent based on the following criteria:
    a. Eligible for one bivalent mRNA vaccine
        i. No previous doses of any COVID-19 vaccine
        ii. At least 8 weeks since a previous vaccine dose of any manufacturer
    b. Eligible for second bivalent mRNA vaccine
        i. Adults 65 year of age and older can receive one additional bivalent mRNA vaccine at least 4 months after the first dose of a bivalent mRNA vaccine.
        ii. Those who are immunocompromised can receive one additional bivalent mRNA vaccine at least 2 months after the first dose of a bivalent mRNA vaccine.
3. Ability to read and speak English

Exclusion criteria:

1. Those who have received all eligible doses of any approved COVID-19 vaccine.
2. Those with active COVID-19 disease (either through self-reported positive test within the last 10 days or viral test at the event if available).

Vaccine criteria are based on CDC recommendations as of April 13, 2023 obtained here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html#recommendations

Evaluation of Aim 2 (focus group with intervention site staff or volunteer)
The following inclusion criteria will apply:

1. 18 years of age and older
2. Community volunteer or staff at a CATCH-UP Vaccines intervention site.

F. Gender/Minority/Pediatric Inclusion for Research

Both men and women will be included in the focus groups (Aim 1) and in the intervention (Aim 2).

We will enroll adults 18 years of age and older for Aim 1 and Aim 2. Focus groups will include community leaders who are adults working/volunteering in a leadership role or at CATCH-UP testing events. The intervention will only include adults 18 years of age and older.

G. Recruitment and Enrollment

Aim 1.

Recruitment: Focus groups will include community leaders and staff/volunteers involved in community events. Included participants will be able to provide insights into the barriers faced within their communities in Oklahoma in partnership with the CATCH-UP program (IRB #12582). We will work with Laura Ross at Public Health Institute of Oklahoma to assist with recruitment of focus group participants. We will recruit focus group participants through emails and advertisements to the community organizations and will use REDCap to register interested potential participants. If a participant recommends including other potential participants in future focus groups, we will provide the participant with the study team's contact information to allow any potential participants to obtain more information about the study while maintaining confidentiality between participants.

We will advertise for the focus groups through social media, websites, email, and flyers. Testing event partners will disseminate flyers during community team meetings and at CATCH-UP testing events and in partnership with Public Health Institute of Oklahoma. Potential participants will be directed to contact the study team listed on the flyer for questions or interest in participating in the focus groups. At the time of contact, we will explain the purpose of the project and the nature of the study. Participants will receive a $40 gift card as compensation for their participation. We expect the focus groups to last one hour.

Consent Procedures: We will obtain oral consent from participants prior to beginning the focus groups by reading a consent script. Once we have identified key informants who are eligible and agree to participate, we will schedule a meeting virtually through Zoom/conference call or in-person. The informed consent process will include the audio and/or video recording of the interview.

Location where consent/interviews will take place: Focus groups will be held in-person or virtually through telephone or Zoom using a password-protected meeting that requires a free Zoom account to ensure privacy. In-person focus groups will take place at Tabitha Baptist Church in Oklahoma City, OK; Sertoma Center in Pryor, OK; and OUHSC campus at the OSCTR.

Recruitment of non-English speaking participants: We will only recruit English-speaking participants.

Measures to decrease participant coercion: The study personnel conducting interviews will not be supervisors of the focus group participants. Participants will be informed that they have the opportunity to leave the focus group or skip questions at any time.

Aim 2.1.
Recruitment: We will recruit participants through the community health events in partnership with the Public Health Institute of Oklahoma. We will recruit through flyers, emails, and direct contact during events. Participants will be eligible for a $20 gift card at the completion of the study, which will either be given to participants on-site, mailed to the participants, or emailed as an e-gift card.

Consent Procedures: After completing a screening form, eligible participants who are interested in the study will review and sign the consent and HIPAA authorization form if they decide to participate in the study. The consent form will include questions about sharing zip code with the Duke Clinical Research Institute and contact for future research studies. Study staff will review the consent form and answer any questions. Consent and HIPAA authorization will be conducted either with paper forms or electronically through REDCap.

Location where consent and intervention will take place: The pilot events will occur in partnership with community organizations in Oklahoma. The events will be at a public location selected by the community organization in partnership with PHIO.

Measures to decrease participant coercion: Potential participants will be notified through the consent process that participating is optional and withdrawing from the study any time is allowed. Study personnel will not be supervisors of any potential participants.

Aim 2.2.
Recruitment: We will recruit sites through the CATCH-UP program testing events and as requested through community partnerships in collaboration with the Public Health Institute of Oklahoma. We will recruit through flyers, emails, and direct contact during events. Participants will be eligible for a $20 gift card at the completion of the study, which will either be given to participants on-site, mailed to the participants, or emailed as an e-gift card.

Consent Procedures: After completing a screening form, eligible participants who are interested in the study will review and sign the consent and HIPAA authorization form if they decide to participate in the study. The consent form will include questions about sharing zip code with the Duke Clinical Research Institute and contact for future research studies. Study staff will review the consent form and answer any questions. Consent and HIPAA authorization will be conducted either with paper forms or electronically through REDCap.

Location where consent and intervention will take place: We will conduct the intervention at multiple community events, which will be open to the public, as identified by community organizations as they are scheduled in partnership with PHIO.

Measures to decrease participant coercion: Potential participants will be notified through the consent process that participating is optional and withdrawing from the study any time is allowed. Study personnel will not be supervisors of any potential participants.

Aim 2 Evaluation with intervention event staff/volunteers

Recruitment: Focus groups will include community leaders and staff/volunteers involved in community events where CATCH-UP Vaccines interventions were held. We will work with Laura Ross at Public Health Institute of Oklahoma to assist with recruitment of focus group participants. We will recruit focus group participants through emails and advertisements to the community organizations and will use REDCap to register interested potential participants. If a participant recommends including other potential participants in future focus groups, we will provide the participant with the study team's contact information to allow any potential participants to obtain more information about the study while maintaining confidentiality between participants.

We will advertise for the focus groups through social media, websites, email, and flyers. Testing event partners will disseminate flyers during community team meetings and at CATCH-UP testing events. Potential participants will be directed to contact the study team listed on the flyer for questions or interest in participating in the focus groups. At the time of contact, we will explain the purpose of the project and the nature of the study. We expect the focus groups to last one hour.

Consent Procedures: We will obtain oral consent from participants prior to beginning the focus groups by reading a consent script. Once we have identified key informants who are eligible and agree to participate, we will schedule a meeting virtually through Zoom/conference call or in-person. The informed consent process will include the audio and/or video recording of the interview.

Location where consent/interviews will take place: Focus groups will be held in-person or virtually through telephone or Zoom using a password-protected meeting that requires a free Zoom account to ensure privacy.

Recruitment of non-English speaking participants: We will only recruit English-speaking participants.

Measures to decrease participant coercion: The study personnel conducting interviews will not be supervisors of the focus group participants. Participants will be informed that they have the opportunity to leave the focus group or skip questions at any time.

H. Risks and Benefits

Potential Risks

The potential risks to the participants in this study should be minimal. It is possible that participants may feel psychological stress associated with completing the focus groups. There is also a slight risk of a breach in data confidentiality. For those participating in the serology study, it remains a minimal risk study, where possible risks associated with blood draws include: occasional slight discomfort associated with blood drawing and occasional hematoma (bruise) or infection at the blood drawing site. Rarely, a participant may experience fainting or dizziness. Procedures will be implemented to minimize these potential risks as described below.

Due to the nature of the intervention and the minimal risks, we will not establish Data Safety Monitoring Board (DSMB) to monitor this study. Study data are accessible at all times for the Project Directors (PDs) to review. Dr. James will review the study conduct weekly and the investigators will review the study conduct on a monthly basis. Study conduct will include accrual, drop-outs, and protocol deviations. The PDs will review adverse events individually in real-time and in aggregate on a weekly basis. The PI, PD, and co-investigators will review serious adverse events in real-time. The PI and PD ensure all protocol deviations, AEs, and SAEs are reported to the NIH and IRB according to the applicable regulatory requirements.

Protection Against Risk

Psychological Stress: This stress will be minimized as focus group and intervention participants will be informed through the consent process that they do not have to participate, do not have to answer all questions, and do not have to complete the focus group or intervention if they are uncomfortable. The voluntary nature of the study will be emphasized and participants will have the option to participate in only some aspects of the study. Participants will have the option to withdraw from the study at any time.

Data confidentiality: Any written notes taken during the focus groups or at intervention sites and any paper forms will be stored in a locked filing cabinet in the office of the study personnel.

Blood draws: We will use a low-risk method of finger sticks to collect serum for the serology study. Participants will have access to bandages if needed and have the option to withdraw from the study at any time.

Potential Benefits of the Proposed Research to the Subjects and to Others

Subjects often experience a sense of satisfaction with their participation in research; however, the most obvious benefits of this work will be to others.

Importance of the Knowledge to be Gained

Oklahoma's IDeA-CTR, the OSCTR, and its long-standing community-engaged research programs and partnerships will contribute to the knowledge base necessary to improve SARS-CoV-2 vaccine uptake in underserved and vulnerable populations. We have developed robust community partnerships through the OSCTR Community Engagement and Outreach (CEO) Core and investment in the development of community-driven and responsive organizations developed primarily in rural counties. Oklahoma has high

COVID-19 incidence, particularly among underserved minority and rural Oklahomans. Oklahoman's are also reporting SARS-CoV-2 vaccine hesitancy and signs of slowing vaccine uptake, with increased hesitancy among American Indian and rural populations. The project aims to work with ongoing community testing events to implement interventions to improve vaccine uptake among Oklahoma's underserved populations.

I. Statistical Methods

Aim 1 Analysis. Digitally recorded focus groups will be securely uploaded to protected servers and transcribed using NVivo Transcription. Transcriptions will be team coded for conceptual themes using QSR NUDIST Vivo12 Pro for Windows.[16] Investigators will develop a code book. Throughout the coding process, qualitative data will be categorized, connections made between categories, and core categories identified and systematically linked to other categories. Focus group data will inform intervention selection and needed modifications for community acceptability/relevance.

Aim 2 Analysis. All analyses are intent-to-treat. Outcome measures will be assessed at baseline, 30 days, and 60 days follow-up. At the outset, we will examine the frequency distributions of all variables. We will compare the baseline characteristics to assess whether randomization distributed covariates evenly. We will determine whether there is differential dropout and consider developing probability-of-completion weights to obtain unbiased estimates of treatment effect.

The primary analysis will assess the effects of each intervention component in terms of its association with the primary outcome (intent to receive a COVID-19 vaccine immediately after the interventions are completed). Cross-sectional analyses will be conducted for outcomes assessed at 30 and 60 days. For binary outcomes, chi-square tests will be used to compare the outcomes between groups. For continuous outcomes, two-sample t-tests or Wilcoxon rank sum tests, whichever is more appropriate, will be used to compare between groups. A longitudinal analysis using Generalized Estimating Equations (GEE) techniques will also assess the overall impact of the intervention by including data from all follow-up time points.

As a secondary analysis, we will compare vaccine coverage among counties with an intervention compared to counties without intervention to see whether coverage increased in the study counties using a chi-square test. We will use publicly available data from the Oklahoma State Department of Health and/or Centers for Disease Control and Prevention for this analysis.

Sample size and power calculations. Power calculations are based on our primary analysis, which is to assess the effect of each intervention component on increased intention to receive a COVID-19 vaccine immediately after the intervention. This is a two-sample comparison between participants that receive one intervention component and those that receive the control. Our pilot implementation will include a single site with an estimated 500 participants.

Our outcome of interest is also assessed at 30 and 60 days follow-up to measure intention to receive a COVID-19 vaccine, which allows us to use a longitudinal generalized estimating equations approach wherein power is proportional to the within-site

correlation. Using PASS v16, we assume the intra-cluster correlation within each site is 0.01. Our power analysis is based on data from both pilot and full implementation of the study results. Assuming a minimum n=167 participants per site for a minimum of sites, a Type 1 error rate of 0.05, and an estimated standard deviation of 5, we have over 80% power to detect a mean difference of 20.

Data and Safety Monitoring Plan

Drs. James and Janitz assure that oral informed consent is obtained prior to conducting the focus groups (Aim 1) and written informed consent and HIPAA authorization are obtained for the intervention (Aim 2) prior to performing any research procedures, that all subjects meet eligibility criteria, and that the study is conducted according to the IRB-approved research plan.

Study data are accessible at all times for the PI/PD to review. Dr. James will review the study conduct weekly and the PI/PD will review the study conduct on a monthly basis. Study conduct will include accrual, drop-outs, and protocol deviations. The PI/PD will review adverse events individually in real-time and in aggregate on a weekly basis.

COLLECTION AND REPORTING OF SAEs AND AEs

For this study, the following standard AE definitions are used:

Adverse event: Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure.

Serious Adverse Event: Any AE that results in any of the following outcomes:

- Death
- Life-threatening
- Event requiring inpatient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity

AEs are graded according to the following scale:

Mild: An experience that is transient, & requires no special treatment or intervention. The experience does not generally interfere with usual daily activities. This includes transient laboratory test alterations.

Moderate: An experience that is alleviated with simple therapeutic treatments. The experience impacts usual daily activities. Includes laboratory test alterations indicating injury, but without long-term risk.

Severe: An experience that requires therapeutic intervention. The experience interrupts usual daily activities. If hospitalization (or prolongation of hospitalization) is required for treatment it becomes an SAE.

The study uses the following AE attribution scale:

Not related: The AE is clearly not related to the study procedures (i.e., another cause of the event is most plausible and/or a clinically plausible temporal sequence is inconsistent with the onset of the event).
Possibly related: An event that follows a reasonable temporal sequence from the initiation of study procedures, but that could readily have been produced by a number of other factors.
Related: The AE is clearly related to the study procedures.

AEs are identified by the study coordinator during weekly visits or by phone call throughout the study duration, and AEs will be assessed at time of study follow-up visits. SAEs and specific procedure-associated AEs are reported to the PDs within 24 hours. In addition, all AEs are reported according to the University of Oklahoma Health Sciences Center Institutional Review Board AE reporting guidelines.

MANAGEMENT OF RISKS TO SUBJECTS

Expected AEs
There are no expected AEs as a result of this study, as the intervention components will be standard and evidence-based strategies and non-therapeutic. Potential interventions strategies are educational in nature with a minimal risk finger stick for serology tests and are not anticipated to have AEs.

Expected SAEs
There are no expected SAEs as a result of this study, as the intervention components will be standard and evidence-based methods, primarily educational in nature with a minimal risk finger stick for serology tests.

AE and SAE Management
The research coordinator will monitor outcomes and make adjustments to the protocol if unanticipated problems arise.

J. Data Sharing

Sharing of primary epidemiological data that is generated as part of this project will occur as allowed by the University of Oklahoma Health Sciences Center IRB.

Aggregate data will be submitted to clinicaltrials.gov as required by NIH.

Identifiable data will be uploaded, with participant consent, to the RADx-UP data repository as required by the NIH grant terms and conditions. A data transfer agreement will be fully executed prior to sharing data with NIH. If participants decline to share their identifiers, including all identifiable information or zip code with the Duke Clinical Research Institute, only de-identified information will be shared for these participants.

Specifically, only aggregate data that cannot be linked back to individual people will be shared upon request in accordance with IRB. We will adhere to NIH Policy on sharing

biomedical research resources. We will make de-identified data available for users under a data-sharing agreement that requires the user to (1) agree to use the data for research purposes only; (2) have a plan in place to secure the data using appropriate computer technology; and (3) agree to destroy or return the data after analyses are completed.

K. Confidentiality

No one will have access to the data files and servers except the investigators. All data will be stored on Redcap or an OUHSC secured drive behind a firewall that requires a log-in and password. When the drive is not in use, the user will log off. The server is stored in a locked location. To transfer de-identified, aggregate data between OU Norman and OUHSC for development of research products (i.e., posters, manuscripts, dissertation), we will use a secure file transfer system/method. This will help safeguard the confidentiality and integrity of sensitive data in compliance with HIPAA and other regulatory requirements. We will encrypt the data prior to sending through the secure file transfer system. Published reports and presentations will not include any individually identifiable data and only aggregate statistics will be reported.

L. Literature Cited

1. Oklahoma State Department of Health. COVID-19. Accessed May 1, 2021, https://oklahoma.gov/covid19.html
2. Centers for Disease Control & Prevention. COVID Data Tracker. Accessed May 1, 2021, https://covid.cdc.gov/covid-data-tracker/
3. Services USDoHaH. Bridged-Race Population Estimates, United States July 1st resident population by state, county, age, sex, bridged-race, and Hispanic origin. . Accessed March 11, 2021, http://wonder.cdc.gov/bridged-race-v2019.html
4. Jacobs-Wingo JL, Espey DK, Groom AV, Phillips LE, Haverkamp DS, Stanley SL. Causes and Disparities in Death Rates Among Urban American Indian and Alaska Native Populations, 1999-2009. *Am J Public Health*. May 2016;106(5):906-14. doi:10.2105/ajph.2015.303033
5. Raifman MA, Raifman JR. Disparities in the Population at Risk of Severe Illness From COVID-19 by Race/Ethnicity and Income. *American journal of preventive medicine*. Jul 2020;59(1):137-139. doi:10.1016/j.amepre.2020.04.003
6. Koma W, Artiga S, Neuman T, et al. Low-Income and Communities of Color at Higher Risk of Serious Illness if Infected with Coronavirus. Accessed 7/29/2020, https://www.kff.org/disparities-policy/issue-brief/low-income-and-communities-of-color-at-higher-risk-of-serious-illness-if-infected-with-coronavirus/
7. Amber Integrated. *2021 Quarter 1 Poll*. 2021. https://static1.squarespace.com/static/60099f1f6ffad96a2d94bf98/t/6066423fe856f432ebb6234b/1617314367733/AI+OK+Statewide+-+Crosstab+Results+-+March+2021+-+Public+Results.pdf
8. Nguyen KH, Srivastav A, Razzaghi H, et al. COVID-19 Vaccination Intent, Perceptions, and Reasons for Not Vaccinating Among Groups Prioritized for Early Vaccination - United States, September and December 2020. *MMWR Morb Mortal Wkly Rep*. Feb 12 2021;70(6):217-222. doi:10.15585/mmwr.mm7006e3

9. The Community Guide. CPSTF Findings for Increasing Vaccination. Accessed April 18, 2021, https://www.thecommunityguide.org/content/task-force-findings-increasing-vaccination
10. Chou W-YS, Burgdorf CE, Gaysynsky A, Hunter CM. *COVID-19 Vaccination Communication: Applying Behavioral and Social Science to Address Vaccine Hesitancy and Foster Vaccine Confidence*. 2020. https://obssr.od.nih.gov/wp-content/uploads/2020/12/COVIDReport_Final.pdf
11. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health*. Mar 2011;38(2):65-76. doi:10.1007/s10488-010-0319-7
12. Proctor EK, Landsverk J, Aarons G, Chambers D, Glisson C, Mittman B. Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. *Adm Policy Ment Health*. Jan 2009;36(1):24-34. doi:10.1007/s10488-008-0197-4
13. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. Aug 7 2009;4:50. doi:10.1186/1748-5908-4-50
14. Escoffery C, Riehman K, Watson L, et al. Facilitators and Barriers to the Implementation of the HPV VACs (Vaccinate Adolescents Against Cancers) Program: A Consolidated Framework for Implementation Research Analysis. *Prev Chronic Dis*. 2019;16(180406)doi:http://dx.doi.org/10.5888/pcd16.180406
15. Garbutt JM, Dodd S, Walling E, Lee AA, Kulka K, Lobb R. Barriers and facilitators to HPV vaccination in primary care practices: a mixed methods study using the Consolidated Framework for Implementation Research. *BMC Fam Pract*. May 7 2018;19(1):53. doi:10.1186/s12875-018-0750-5
16. Research QSa. NUDIST Vivo 12 Pro for Windows (Version 12). QSR International Pty td. Accessed October, 2019. https://www.qsrinternational.com/nvivo/nvivo-products/nvivo-12-pro