Cover Page for Study Protocol

Official Title: Rural Tailored COVID-19 Communication and SARS-CoV-2 Antibody Testing Evaluation and Uptake

NCT Number: NCT06085547

Date: February 24, 2023

3. * **Brief description:**

African Americans were infected and died from SARS-CoV-2 more than any other racial group in United States, including cities such as Flint, MI. Yet, connections to inflammatory biological processes in COVID-19 disparities remains unknown. This study aims to identify and compare inflammation among those with and without confirmed SARS-CoV-2 infection via antibody testing & conduct cross-race comparisons of inflammatory factors. The main objective is to encourage understanding and uptake of antibody testing. The central hypothesis is that African Americans will be receptive to antibody testing when benefits and limitations are communicated in a culturally effective manner. We will provide an opportunity to engage in salivary antibody screening - a non-invasive route to antibody testing that is highly suited to disparities-oriented COVID-19 research.

For the Set-Aside portion of the study: Rural Americans are at greater risk of many COVID-19 outcomes, and these disparities are likely to endure given lower vaccination uptake in many rural communities. Better understanding and addressing these rural disparities could be aided by SARS-CoV-2 antibody testing. However, implementing antibody testing education and outreach is challenged by the racial and regional diversity of rural contexts, as well as skepticism towards COVID-19 testing and treatments in many rural communities. The proposed "set aside" research assembles two disparities-focused SeroNet U01 teams – Michigan State University and the University of Arkansas for Medical Sciences. Together, these teams will adapt and extend their existing SeroNet projects to consider whether video communication for diverse rural populations can effectively encourage understanding and uptake of SARS-CoV-2 antibody testing in rural contexts.

4. * **What kind of study is this?**

IRB Submission

5. * **Will an external IRB act as the IRB of record for this study?**

○ Yes ● **No**

6. * **Local principal investigator:**

Todd Lucas

7. * **Does the investigator have a financial interest related to this research?**

○ Yes ● **No**

8. * **Is the activity a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge?**

● **Yes** ○ No

9. * **Does the activity involve a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information?**

● **Yes** ○ No

10. * **Is this project being conducted to fulfill the requirement of an education/training program?**

○ Yes ● **No**

Study Scope

1. * **Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**
   ○ Yes ● **No**

2. * **Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**
   ○ Yes ● **No**

Additional Study Information

1. * **Describe the research procedures that involve obtaining information or biospecimens about a living person through interaction or intervention and/or by obtaining their identifiable private information or identifiable biospecimens. If subjects will participate in or undergo an intervention, fully describe the intervention.**

Human subjects in the proposed research will be engaged in an experimental study involving exposure to either standard (i.e., generally applicable) or culturally-targeted
informational videos materials about salivary testing for SARS-CoV-2 antibody. These brief videos in conjunction with the survey questions will be distributed via qualtrics to the Flint community. The Flint Registry will provide contact information and demographics of eligible subjects to the SeroNet team. The SeroNet team will be recruiting participants via email/phone/mail. In collaboration with leading salivary bioscience experts, we will also furnish an opportunity to engage in salivary antibody screening – a non-invasive route to SARS-CoV-2 antibody testing that is highly suited to disparities-oriented COVID-19 research. Video materials will be developed in collaboration with clinical and community advisory committees that are highly suited to the proposed research, and we will present materials as professionally prepared online modules. Participants will also have the option to complete a spit kit in which their collected saliva will be used to enable assays for a dozen salivary cytokines, which we will link to antibody status.

In addition, we will offer an additional opportunity for eligible participants to complete up to 2 more SARS-CoV-2 antibody test kits. Eligible participants are those that have completed a SARS-CoV-2 antibody test kit in our study, have received the COVID-19 booster shot, and are eligible to receive and plan/are scheduled to receive a second COVID-19 booster shot. These qualified participants will be asked to complete a second SARS-CoV-2 antibody test kit before their second COVID-19 booster shot and a third SARS-CoV-2 antibody test kit within 2 weeks after receiving their second COVID-19 booster shot. Participants will receive two additional $50 electronic gift cards for completing the second and third SARS-CoV-2 antibody test kits. Recruitment will be conducted using the phone, text, and email contact information we have on file for eligible participants. Participants will be asked if they'd like to participate in this opportunity as explained above. Only participants that completed our 'spit kit' consent form will be contacted to complete 2 additional tests. The processes used to complete the additional two antibody test kits will follow the same protocols used for the initial spit kit test. Eligible participants will be contacted via phone/text/email to see if they would like to complete two additional test kits and receive two additional $50 electronic gift cards for doing so.

2. * Describe the subject population.

This study will recruit both male and female participants who are Black/African-American or White/Caucasian and enrolled in the Flint Registry. All participants will be 18 and over. We aim to recruit a total sample size of 500 individuals. We will stratify by age and recruit even sample sizes of N = 167 children 18-21, young adults 22-40; and older adults 40 and above (see Inclusion of Individuals Across the Lifespan). Each age group will be further stratified by race and gender. We will recruit a two-thirds African American sample (N = 110), and a one-third White sample (N = 57), both of which will be one-third to one-half male. The inclusion of both a one-third White sample and a one-third male sub-sample will ensure that we are able to conduct effective race and gender comparisons.

For the vaccination/boosting arm of research, we seek to recruit 200 total male and female participants who are Black/African-American or White/Caucasian. Participants must have received a SARS-CoV-2 vaccination booster within the past 24 hours to be enrolled. We aim to recruit a one-half African American sample (N = 100), and a one-half White sample (N = 100), both of which will be one-third to one-half male.

For the Set-Aside portion of the study: We will recruit 400 rural participants: 200 each from Arkansas and northern Michigan. Arkansas recruitment will be led by Dr. Nembhard. Arkansas inclusion criteria are resident African American, 18 years and over, and recruited from selected Arkansas rural counties and zip codes. Northern Michigan inclusion criteria are White American, 18 years and over, and recruited from counties considered rural based on the Economic Research Services' rural-urban continuum codes. In both recruitment locations, we will measure but not exclude based on prior SARS-CoV-2 natural infection and vaccination.

3. * Select the age range (select one).

Adults who are 18 or older

4. **Identify if your project involves any of the following: (check all that apply)**

Activities That May Require Additional MSU Reviews:

Biospecimens from humans (e.g. human blood, tissue, cell lines, buccal swab)

Activities That May Utilize MSU Resources

There are no items to display

Activities That May Be Subject To Additional Federal Requirements

Certificate of Confidentiality

Registration and/or reporting with clinicaltrials.gov (by you or the sponsor)

Activities That May Be Subject To Additional Requirements Based On Recruitment

There are no items to display

Activities That May Be Subject To International Requirements

There are no items to display

5. * **Is this a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes?**

(●) **Yes** ( ) No

* **Please select one of the options below:**

Other

6. * **Will any subject's insurance be billed as part of this project?**

( ) Yes (●) **No**

7. * **Are you aware of any individual who has a financial interest which may create an organizational conflict of interest? See HRPP policy 10-1, Conflict of Interest, for definitions and additional information.**

( ) Yes (●) **No**

8. * **Has any financial arrangement, including compensation, ownership interest, stock options, or other ownership interest, (e.g., compensation that is: explicitly greater for a favorable result; in the form of an equity interest in the sponsor of a covered study; or in the form of compensation tied to sales of the product, such as a royalty interest) been established whereby the value of compensation or ownership interest to investigators conducting the study could be influenced by the outcome of the study?**

○ Yes ● **No**

9. * **Do any investigators or research staff have a financial interest related to the research that has not otherwise been disclosed elsewhere in this submission?**

○ Yes ● **No**

10. * **Will the research be conducted outside the United States?**

○ Yes ● **No**

11. * **Will subjects be compensated for participation in the study (e.g. money, gift cards, coupons for free food)?**

● **Yes** ○ No

* **Provide details concerning payment, including the amount and schedule of payments including any terms and conditions and who will provide payment (e.g. MSU, another institution). Payment should be proportionate to participation.**

We will recruit 500 participants to conduct the proposed research. Each participant will be compensated $50 for one online session lasting approximately 45-60 minutes. This session will include completing prescreening, viewing educational materials, and filling out an initial immediate outcome survey measure. Participants can be compensated an additional $50 for completing a salivary assay kit for antibody testing, and for inflammatory profiles.

12. * **Will your research likely require non-exempt (expedited or full board) review?**

● **Yes** ○ No

*** (1) Describe the criteria for who will be included or excluded from the study, including how subjects will be screened for eligibility.**

The formal inclusion criteria broadly encompass Flint area community members who are Black/African-American or White/Caucasian, 18 years and above, and enrolled in the Flint Registry. We will exclude participants who do not meet age or race criteria. Although we will not intentionally exclude them, our sample will include individuals from the Flint community who have ready access to interest – the primary mode of enrolling in the Flint Registry.

For the Set-Aside portion of the study: We will recruit 400 rural participants: 200 each from Arkansas and northern Michigan. Arkansas inclusion criteria are resident African American, 18 years and over, and recruited from selected Arkansas rural counties and zip codes. Northern Michigan inclusion criteria are White American, 18 years and over, and recruited from counties considered rural based on the Economic Research Services' rural-urban continuum codes. In both recruitment locations, we will measure but not exclude based on prior SARS-CoV-2 natural infection and vaccination. We will exclude participants who do not meet age or race criteria.

*** (2) Identify materials that will be used to recruit subjects (select all that apply):**

Letter, email, flyer, postcards, CD, DVD

Use of websites or Apps (e.g. Facebook, ResearchMatch)

Other

*** Describe:**

Study team may also recruit participants via text message/phone.