Washington University in St. Louis

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Brief Title: Assessing Testing Strategies for Safe Return to K-12 Schools in an Underserved Population

Washington University in St. Louis

INFORMED CONSENT DOCUMENT - Adult

Project Title: RADx Up Safe Return to Schools: Strategies to increase vaccine uptake

Principal Investigator: Jason Newland, MD

Research Team Contact: Cindy Terrill, BS, CCRP
314 747-3396

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Washington University in St. Louis having to do with children and their educators. We are looking to understand COVID-19 and its impact on St. Louis school districts over the course of the 2022-2023 academic year and to understand two different strategies on their ability to increase vaccine uptake in these school districts.

You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participate, you will be asked a questionnaire regarding your beliefs on vaccination. You will then receive one of two interventions: (1) Text message + Video or (2) Phone call with a study team member. A research team member will follow up within two weeks of the intervention to check your vaccination status. You may then receive one of two interventions previously listed a second time with an additional follow-up questionnaire. Your involvement in this study may last up to 10 weeks.

You will be compensated up to $100 in electronic gift cards for consenting to this study. This compensation will be provided in allotments of $50 after completing the consent document and then $25 after each follow-up call with the study team.

This study does utilize Twilio, a text messaging service, as a part of the intervention. Because of this, the ability and consent of you allowing to receive text messages by our study team is mandatory for enrollment.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because of the following:

- You are an employee, a student or household member of a participating school district, or a resident of St. Louis City or St. Louis County
- You are not completely up to date with your COVID-19 vaccinations per CDC guidelines AND
- You are considered eligible by the CDC at the time of enrollment to receive a COVID-19 vaccine

The primary goal of this study aims to do two things:

1. Understand COVID 19 and its impact on St Louis school districts over the course of the 2022-2023 academic year.
2. Assess two different strategies on their ability to increase vaccine uptake in these school districts.

WHAT WILL HAPPEN DURING THIS STUDY?

At the start of the study, you will be asked to fill out a survey regarding your beliefs on vaccination. After this, you will receive information through one of two sources, either (1) text message with an associated website link or (2) phone call with a study team member. Two weeks after receiving an intervention, a research team members will follow-up with you to see if there are any changes to your vaccination status. Depending on those answers, you might receive another round of information through one of two sources, either (1) text message with an associated website link or (2) phone call with a study team member. After two weeks of your 2nd randomization, a study team member will follow-up a second time to determine vaccination status.

During each follow-up session, a study team will provide the same vaccine-uptake survey to you and offer to provide vaccine resources on where to obtain a vaccine for the participants. If you receive a vaccine, an additional phone call will be performed 4 weeks after your vaccine dose to assess if you have completed that vaccination (whether series or booster). You can skip any question you prefer not to answer.

We will also ask demographic survey about your family such as your age, gender; race/ethnicity; insurance status and type; medical conditions; number of people in your home; income and educational level of your parents/guardians, and type of work. This survey is optional, and you will have an option later in this consent to opt out of sharing data for this survey.

Will you save my research information to use in future research studies?

As part of this study, we are obtaining data from you. We would like to use these data for studies going on right now as well as studies that may be conducted in the future. Your data may also be used for broad sharing throughout the research community. This means your data may be used for any sort of research and not just research related to your current condition including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. These researchers may be at Washington University, at other research centers and institutions, or commercial sponsors of research. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you for use of your

data. By allowing us to use your data you give up any property rights you may have in the data.

One way in which we may share your data with others is by putting it into a large database of information, called a data repository. If your data is placed in one of these repositories it will be placed in the "controlled-access" portion of the repository. This means that only qualified researchers, who have received permission from individuals that monitor the access to and use of the data, will be able to look at and use your information. Before we put it in this repository, we will remove any information, such as your name and birthdate, that might easily identify you. Even though these data will not have your name or other identifying information associated with it, it is still possible that someone may be able to trace these data back to you because genetic information is unique. Although your individual data will only be in the controlled access database certain summary information may be available to the general public.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for the question below:

My data may be stored and used for future research as described above.

_____ Yes **_____ No**
Initials **Initials**

Unless you agree to future use as described above, your private information data collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 1,000 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for up to 10 weeks. You will need to answer a one-time questionnaire. You will then receive one of two interventions: (1) Text message + Video or (2) Phone call with a study team member and then receive a follow-up survey by the team after two weeks. The phone call with a peer will take about 15 minutes during each call.

If you receive a vaccine an additional phone call will be performed 4 weeks afterthat vaccination (whether series or booster)..

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to

these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You may experience emotional discomfort when answering some questions or in your intervention. If any particular question makes you uncomfortable, you may discuss its importance and the need to answer it with a member of the study team. You may choose not to answer any question with which you still feel uncomfortable.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study. You might have a benefit from getting information through this study.

We hope that, in the future, other people might benefit from this study because understanding beliefs around vaccination will help with vaccination uptake and keeping children and their teachers safely in school.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will be asked to provide your social security number (SSN). You will be compensated up to $100 in electronic gift cards for consenting to this study. This compensation will be provided in allotments of $50 after completing the consent document and then $25 after each follow-up call with the study team.

WHO IS FUNDING THIS STUDY?

The National Institutes of Health is funding this research study. This means that Washington University in St. Louis is receiving payments from the National Institutes of Health to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the National Institutes of Health for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- The National Institutes of Health
- Your school district
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Public health agencies to complete public health reporting requirements.

- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- The data safety monitoring board or data coordinating center
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will store paper records behind locked doors and electronic data will be password protected. Your study data will be labeled with a unique ID number or bar code and no identifiers. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

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

We will disclose to the proper authorities information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?"

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email/text?
We would like to contact you by email/text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Appointment reminders
- Verification of study information
- Possible administration of an intervention
- Sending compensation

Only the research team will have access to your email/text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email or phone number. To avoid this, we will send a test message to ensure we have the correct email or telephone number on file.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.
- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ **Yes** _____ **No**
Initials **Initials**

Do you agree to allow us to send your health information via text?

_____ **Yes** _____ **No**
Initials **Initials**

If you have selected no, then you will be unable to participate in this study as communication via text messaging is mandatory for participation.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason, because you cannot complete study produces or because funding for the research study has ended.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Jason Newland, MD at 314-747-5128. If you experience a research-related injury, please contact: Jason Newland, MD at 314-747-5128.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Washington University in St. Louis

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after $STAMP_EXP_DT.

_____ _____

(Signature of Participant) (Date)

_____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____

(Signature of Person who Obtained Consent) (Date)

_____

(Name of Person who Obtained Consent - printed)