Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: An international, Bayesian platform adaptive, randomized, placebo-controlled trial assessing the effectiveness candidate interventions in preventing COVID-19 disease in healthcare workers

Principal Investigator: Michael Avidan, MBBCh

Research Team Contact: Linda Yun, 314-273-2240 or 636-751-1089

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. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are a health care or essential worker who is at risk of exposure to the SARS-CoV-2 virus that causes COVID-19. Essential workers are the personnel needed to maintain essential services. Examples of essential services include but are not limited to: Health Care / Public Health / Human Services; Teachers; Law Enforcement, Public Safety, First Responders; Food Services and Accommodations; and Transportation

The purpose of this research study is to determine if the MMR vaccine reduces incidence or severity of COVID-19 infection in exposed health care and essential workers.

The MMR vaccine is approved by the U.S. Food and Drug Administration for the prevention of measles, mumps, and rubella**.** However, the use of the MMR vaccine is considered investigational in this study. In this study, the MMR vaccine will be used as a prophylaxis and will be compared to a placebo (an inactive substance).

WHAT WILL HAPPEN DURING THIS STUDY?

You will be randomly assigned to one of two (2) study groups. This means that the study group you are assigned to will be determined purely by chance, like flipping a coin. You will have a 1 out of 2 chance of being in the study treatment group. Neither you nor the research team will know which study group you are in, but we will be able to get this information quickly if we need it to ensure your safety.

Study groups:
- Education and surveillance plus placebo
- Education and surveillance plus MMR vaccine

The study groups above may be removed and new ones added depending on the efficacy of the treatment. The study team will notify you if the study groups are changed.

The study drug will be administered one time at Washington University School of Medicine within 7 days of being randomly assigned to a study group. You will need to come to the medical center to receive the study injection. You will need to bring your Healthcare worker ID to this visit. This visit should last about 45 minutes.
You will be provided educational materials about social and clinical practice that could prevent or delay infection.

You will be asked to complete a self-finger stick approximately at 3 times points; at study entry, and approximately day 60 and day 150. We will provide you with kits and shipping materials to return the self-collected samples.

You will be asked to enter information on how you are feeling physically and emotionally through a secure online system or through short message service (SMS) on a mobile smart phone. Through SMS you will be reminded to answer a simple question about your health daily or at minimum, once per week. These questions will take about 10 seconds to answer. You will be able to skip any questions you would prefer not to answer.

If you are tested for COVID-19 you will be asked to enter additional information about how you are feeling physically and emotionally through an online system or through short message service (SMS). You may also be asked to self-collect a nose swab and/or a throat swab, or come to the medical center to be swabbed to confirm the COVID-19 diagnosis, if this has not been done as part of your care. If you self-collect your swab, your results will be uploaded to your medical record. If testing has been completed as part of your routine care or from you place of work, we will collect your test results from your medical record or ask for documentation of the confirmed diagnosis. We may ask you to upload the results to a secured folder. We will try to collect any residual specimen available that was submitted for COVID testing after the test is done.

We will follow-up with you for approximately 150 days after you begin the study to check on your health status. If resources are available, the follow-up may be extended to 2 years. We might also check your medical and laboratory results in your health record.

We will ask you to provide the contact information of a family member or friend who we can contact if you become sick.

If you are a woman of childbearing potential and become pregnant during the study we would like to ask additional questions about your pregnancy. You will be asked to sign a separate consent form so that we can collect this information.

You may not be in any other interventional COVID-19 prevention or treatment research studies while you are on this study.

Will you collect my social security number?
You will be asked to provide your social security number on an electronic form that is used to enter you into the medical record system so that we can provide study drug to you.

Will you save my research information and/or biospecimens to use in future research studies?
We would like to use the data and specimens we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding COVID-19, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. 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 should this occur. By allowing us to use your data and specimens, you give up any property rights you may have in the data and blood.

We will share your data and specimens with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

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

Please place your initials in the blank next to Yes or No for each of the questions below:

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

_____ Yes _____ No

My data and specimens may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes _____ No

- Identifiers may be removed from your private information including data and specimens and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 5,000 people will take part in this study conducted by investigators at Washington University. Approximately 30,000 people will take part study wide.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 5 months. Study participation is approximately 2 months and we will follow you for 3 additional months using surveys, phone calls, SMS and medical record review.

WHAT ARE THE RISKS OF THIS STUDY?

You could 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.

Some risks described in this consent document, if severe, could cause death.

MMR Vaccine

Likely:

- Pain at the injection site

Less Likely:

- Rash
- Fever
- Malaise (feeling of discomfort, illness, or uneasiness whose exact cause is difficult to identify)
- Loss of appetite

Rare:

- Trouble breathing
- Panniculitis (painful bumps under the skin)
- Atypical measles (altered expression of measles, AMS begins suddenly with high fever, headache, cough, and abdominal pain)
- Syncope (fainting)
- Headache
- Dizziness
- Irritability
- Vasculitis (inflammation of blood vessels)
- Pancreatitis (swelling of parotid glands)
- Diarrhea
- Vomiting
- Parotitis (swollen parotid glands)
- Nausea
- Thrombocytopenia (low platelet count)

- Purpura (purple colored spots noticeable on the skin)
- Regional lymphadenopathy (lymph nodes of abnormal size or consistency)
- Leukocytosis (increased white blood cell count)
- Anaphylaxis (potentially life-threatening allergic reaction)
- Anaphylactoid reactions (reactions similar to anaphylaxis)
- Angioedema (rapid swelling beneath the skin)
- Bronchial spasm (muscle contractions in the airway that cause difficulty breathing in patients suffering from serious respiratory diseases.)
- Arthritis (the swelling and tenderness of one or more of your joints)
- Arthralgia (joint pain)
- Myalgia (muscle pain)
- Encephalitis (inflammation of the brain)
- Encephalopathy (any brain disease that alters brain function or structure)
- Measles inclusion body encephalitis (MIBE) a disease of the immunocompromised host and typically occurs within 1 year of acute measles infection or vaccination
- Subacute sclerosis pan encephalitis (SSPE) viral infection caused by defective measles virus
- Guillain-Barre Syndrome (GBS) is a rare neurological disorder in which the body's immune system mistakenly attacks part of its peripheral nervous system
- Acute disseminated encephalomyelitis (ADEM)
- Transverse myelitis (inflammation of the spinal cord)
- Convulsions or seizures (a medical condition where body muscles contract and relax rapidly and repeatedly, resulting in uncontrolled actions of the body)
- Ataxia (degenerative disease of the nervous system)
- Polyneuritis (disorders that affects peripheral nerves)
- Polyneuropathy (damage to peripheral nerves)
- Ocular palsies (damage to ocular nerves)
- Pareshtesia (burning or prickling sensation)
- Pneumonia (infection that inflames the air sacs in one or both lungs)
- Pnumonitis (inflammation of lung tissue)
- Sore throat
- Cough
- Rhinitis (irritation or inflammation of membranes inside the nose)
- Stevens-Johnson syndrome a rare, serious disorder of the skin and mucous membranes. It's usually a reaction to medication that starts with flu-like symptoms, followed by a painful rash that spreads and blisters. Then the top layer of affected skin dies, sheds and begins to heal after several days.
- Henoch-Schönlein purpura a disorder that causes the small blood vessels in your skin, joints, intestines, and kidneys to become inflamed and bleed.
- Erythema multiforme (skin reaction)
- Urticaria (hives)
- Measles-like-rash
- Pruritis (itchy skin)
- Nerve deafness (a type of hearing loss from damage to the inner ear)
- Otitis media (inflammation of middle ear)
- Retinitis (inflammation of the retina of the eye)
- Optic neuritis (inflammation of the optic nerve)

- Papillitis (specific type of optic neuritis)
- Conjunctivitis (commonly known as "pink eye")
- Epididymitis (inflammation of the tube at the back of the testicles)
- Orchitis (inflammation of one or both testicles)

You could receive a placebo (an inactive substance) during this study. This means that you would receive no active study treatment while participating and your symptoms could get worse.

Finger Stick

The finger stick may cause bleeding, bruising, or pain. Some people become dizzy or feel faint. There is also a rare risk of infection.

Mandated Reporting of Disease Status

If you decide to participate in this study, we may test you for COVID-19. The results of these tests could indicate that you have this condition. If that happens, we will refer you to a doctor who specializes in treating your condition. We will make every effort to keep your personal information confidential. However, we are required by law to report certain positive tests to the State of Missouri and/or local and agencies. The test results could also be reported to the Centers for Disease Control (CDC). You may be contacted by these agencies for more information. Becoming aware of a new diagnosis could have serious health, personal and/or social consequences. For more information about the risks of this testing, please talk to your study doctor.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

We hope that, in the future, other people might benefit from this study if the MMR vaccine is found to reduce the prevalence or severity of COVID-19.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.
You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study. However, the research team will provide you a parking voucher if you have to pay for parking at your vaccine administration visit.

WHO IS FUNDING THIS STUDY?

The COVID-19 Therapeutics Accelerator, and the University are funding this study. The University and the research team are not receiving payment from any other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator Dr. Erik Dubberke at 314-454-8296 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

The federal government has issued a declaration under a law known as the Public Readiness and Emergency Preparedness (PREP) Act to address the coronavirus (COVID-19) public health emergency. If you are injured or harmed as a result of participating in this study, that federal government declaration may limit your ability to obtain damages by filing a lawsuit against the study's researchers, health care providers, study site, study sponsor, and/or manufacturer or distributer of the drug. However, if you are injured or harmed as a result of participating in this study, the federal government has established a program that may provide compensation to you or your family. To find out more about this program, known as the "Countermeasures Injury Compensation Program" (CICP), go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427. The CICP is the payer of last resort, meaning that the CICP would generally only reimburse or pay for items or services to the extent such items or services are not covered by other third-party payers, such as your health insurance or workers' compensation you receive.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those indicated 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. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- COVID-19 Therapeutics Accelerator
- PRA Health Sciences, the contract research organization
- 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

- Off-site laboratories to analyze samples
- 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.
- Mobile phone number with Telerivet.com and Messagebird.com for data collection.
- Sealed Envelope Ltd the online platform for data collection
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- 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.
- Protected health information (PHI) may be shared with the data safety monitoring committee to make sure the study is safe and with University College London the 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 only collect information pertinent to the research. This information with be de-identified when possible. All study records will be stored and transmitted securely with access limited to the research team.

Research monitors, auditors, the study sponsor, the Institutional Review Board, and other regulatory authorities will be granted directed access to your original health care record to verify the conduct of the clinical trial procedures and/or data. This access will be permitted to the extent permitted by the applicable laws and regulations without violating the confidentiality of your information. By signing this form you are authorizing such access.

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.

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?

We need to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- To collect information about how you are feeling
- Remind you to answer electronic surveys
- Remind you to take the drug
- Confirm receipt of the drug

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions 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. There is always a risk that the message could be intercepted or sent to the wrong email address. 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 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 email communications sent or received on any electronic devices used for work or through a work server.

Can we contact you by short message service (SMS)?
We will contact you by SMS for the purposes listed below. Some of these messages may contain health information that identifies you.

- To collect information about how you are feeling
- Remind you to answer electronic surveys
- Remind you to take the drug
- Confirm receipt of the drug

Only the research team will have access to your SMS communications. We will only communicate by SMS to send you the information listed above. If you have any questions 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 SMS.

- There is always a risk that the message could be intercepted or sent to the wrong phone number. To avoid sending messages to the wrong person, the first message we send you will be a test message to ensure we have the correct phone number.
- When using any phone, you should be careful to protect your username and password or pin code.
- Your employer will have access to any messages sent or received on any electronic devices used for work.

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 or the study sponsor might decide to end your participation in this research study earlier than planned. This might happen for no reason, because you do not complete study requirements, or because the investigator feels it is no longer safe for you to participate due to one or more of the following reasons: you develop confirmed symptomatic COVID-19 or another illness which prevents you from completing further study requirements, your condition worsens, or you choose to enroll in a treatment trial.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Linda Yun, 314-273-2240 or 636-751-1089. If you experience a research-related injury, please contact: Dr. Erik Dubberke, 314-454-8296.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office 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.

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 EXPIRATION DATE: 05/06/21.

_____ _____
(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)