COVID Vaccines and Research in the St. Louis Area

Coronavirus disease 2019 (COVID-19) is caused by the new virus called severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2). Anyone can be infected, but older people and people with health conditions like diabetes and hypertension are more likely to get severe illness or die from COVID-19.

In the St. Louis region (as well as nationwide), people of African American race and LatinX ethnicity are more than twice as likely to be infected or to die from COVID-19 (see https://stlcorona.com/resources/covid-19-statistics1/ and https://www.stlouis-mo.gov/covid-19/data/demographics.cfm). We don't understand all the reasons why, but we suspect that this is revealing underlying healthcare disparities in these communities that have evolved over years of fragmented healthcare in the region. Washington University and St. Louis University (as well as other local, national and international sites) will be conducting phase 3 vaccine studies designed to determine whether they are able to protect people from being infected or developing severe disease from COVID-19. We would like to partner with the entire community in testing these vaccines – especially minority communities that are being disproportionately affected. We are asking for your assistance and support in getting the word out about this as an opportunity to participate.

We acknowledge that there has been longstanding poor treatment for certain populations (especially Black/African American, LatinX, and indigenous populations) in both clinical care and research. This has led to significant health disparities and remarkably high rates of infection and death from COVID-19 in these populations. Under these circumstances, the African American community is justifiably exhausted and reeling from the cumulative, toxic stress of the COVID-19 pandemic. That is why we stand with others who advocate for trauma-informed approaches that promote equity within communities of color. We have been doing research to try to understand and develop treatments and preventions, including vaccines, against COVID-19. We want to address some common questions and misconceptions about COVID-19 vaccines and provide an opportunity for further discussion.

Our intention is to be able to give all people a fair and equitable opportunity to participate in vaccine trials as we try to find vaccines that protect everyone from COVID-19. The best way to prevent disease and, in this case, to stop a pandemic is through vaccination.

1. What are we doing?

We are doing phase 3 studies of potential vaccines against COVID-19. Phase 3 means that the vaccines have already been tested in people in Phase 1 and II studies to evaluate if they are safe and whether they generate an immune response that is

directed against SARS-CoV-2. The studies are large – 30,000 people total, with ~250-500 to be enrolled at each local university for each study. Participants will be consented and screened for eligibility. They will be randomized (like flipping a coin) to either get the investigational vaccine or placebo (a saltwater injection). They will then be closely followed to make sure that they don't have side effects from the vaccine. They will also be monitored weekly to see if they develop symptoms that might be due to COVID-19. If they develop symptoms, we will bring them in to test for COVID-19 and evaluate them to see if they need additional medical care. If participants need medical treatment, we will refer them to appropriate medical care. Participants will be closely monitored if they get sick with COVID-19.

2. How do we know the vaccines are safe?

One of the first and most important things that is followed when developing and testing vaccines is to ensure that they are safe and have limited side effects. To make sure of this, all participants in studies are asked to report any new symptom or problem that they have after they receive injection of a vaccine or a placebo (inactive substance such as salt water) in the study. The reports are all collected and reported to the investigators, an independent safety board, and numerous independent human subjects protection review boards that are set up for each research site. Researchers do not have any reason to not report problems, and can get into a lot of trouble if adverse events in participants are not documented and taken care of.

3. Will I get COVID-19 from the vaccine studies?

The vaccines do not contain SARS-CoV-2, just a fragment of it, and so you cannot get COVID-19 from the vaccine. We will NOT be exposing anyone to COVID-19 as part of the vaccine studies.

4. Why are you just asking for African Americans to do research now? Are we guinea pigs for studies that won't benefit us?

Research studies have been conducted using samples from people who've been infected with COVID-19 since the epidemic was first recognized. As soon as the virus was sequenced in January 2020, researchers began designing vaccines and conducting early trials. The initial trials (phase I and phase II) were done in hundreds of mainly young, healthy people and showed that in these populations the vaccines were safe and they resulted in an immune response that we think should have a good chance of protecting against infection and disease. The problem is that very few African Americans enrolled in those studies, and we need to know how the vaccines work in every population, but especially in the populations hit the hardest. The vaccine efficacy studies (Phase III) we are doing now are looking to see if these vaccines will work to prevent infection and disease in people who are at the highest risk of developing infection and disease.

5. What are the risks of African Americans not participating?

If the vaccines aren't tested in the populations that are being hit the hardest, we might not know how well they work, and we might not identify problems until many people are vaccinated. Since all vaccines do not work the same way, we may find that one vaccine may work better in one situation while another vaccine may work better for other situations. For example, some flu vaccines work better in the elderly than others.

6. Why are we being encouraged to get a flu vaccine? Will it protect against COVID-19?

There is no reason to expect that the flu vaccines would protect against COVID-19. Flu vaccines were designed before COVID was widespread and have not been changed to address COVID-19. The reason we are encouraging people to get the flu vaccine is that influenza kills 35,000 people on average every year in the US. If we had a bad influenza season in addition to a surge in COVID cases in the winter, we would overrun the hospitals and run out of ICU beds and ventilators to take care of people. Additionally, there have reports of person infected with flu virus and COVID virus at the same time. We also know that some people infected with flu virus can be co-infected with other respiratory viruses or another flu virus at the same time. People can also be infected with one virus then the other in the same season but at different times. Getting infected by multiple respiratory viruses can result in worse outcomes.

7. What measures are in place to protect my health during the study?"

Participants are followed closely to track all adverse events (Side effects and complications) during the course of the trial regardless if the event is thought to be related to vaccine or not related to vaccine. Diaries are kept by the participant to help track any adverse event or side effects. Diaries are kept for 7-14 days after each vaccination. Phone calls, texts or electronic messages are typically made periodically throughout a study to check on the health of the participant. If participants get sick or have adverse events, the study doctors would help evaluate them and refer them for appropriate medical care. If the participant has an event that is not related to the vaccine they would see their own health care provider or we can help find a health care provider for them.

8. If someone has an adverse event, will he/she be responsible for all associated medical costs?

The studies are covered by the PREP Act, which is a federal legislation that limits a subject's ability to sue the researcher and the manufacturer of the vaccine. There is a fund of federal money set aside in case a subject should be injured by their participation in the study; if this happened the subject would have to contact the federal agency

within one year of vaccination to be considered for compensation under this legislation. This information is covered in the consent form.

9. Why would someone want to participate in this study?

A vaccine that protected people against COVID-19 would be one of the most effective ways to end the pandemic and allow people to return to social gatherings, work, and school. Participating in the study is one way to contribute to your community to help find a vaccine that works for everyone.

10. Can I stop wearing a mask if I participate in the vaccine study?

Since we do not know whether the vaccines work, people should continue to keep themselves safe as much as they are able. There are simple things you can do to help keep yourself and others healthy. Wash your hands often with soap and water for at least 20 seconds, especially after blowing your nose, coughing, sneezing, going to the bathroom, and before eating or preparing food. When in public, wear a cloth face mask that covers your mouth and nose. Avoid touching your eyes, nose, and mouth with unwashed hands. Stay home when you are sick. Cover your cough or sneeze with a tissue, then throw the tissue in the trash. Stay 6 feet apart from other people, particularly those who do not live in your household, when you are out in public.

11. How do I learn more information about the study so I can decide if I want to participate?

You can visit the websites listed below to find out more information about the studies and study participation. If you are interested in possible participation, we will send you a consent form which explains all aspects of the study including the purpose of the study, what you will be asked to do, the length of the study, what the potential risks and benefits for participating, privacy procedures, payments, what happens if you are injured due to participation, who to call should you have questions, subjects' rights, and the PREP Act.

For more information about local and national efforts to prevent COVID-19, please see the following websites:

- CoVPN – https://www.coronaviruspreventionnetwork.org/
- Washington University – http://idcru.wustl.edu/
- Saint Louis University – http://vaccine.slu.edu/