COVID-19 Citizen Science Booster Study

Study Title: The BOOSTED (Booster Options Or Switching Tested for Effectiveness and Downsides) Study

This research study, led by Drs. Gregory Marcus, Alexis Beatty, Jeffrey Olgin, and Mark Pletcher at UCSF will help us learn more about the different FDA-approved COVID-19 boosters, and more specifically, may help clarify the effects of mixing or matching these boosters.

This study is completely voluntary. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team.

Why is this important?

While the FDA has approved of mixing and matching COVID-19 booster shots, the long-term effects and symptoms have not been thoroughly studied. There is currently no clear guidance on which booster may be best. There are currently no strong recommendations about which booster might be best, particularly among individuals like you that have equal access to either booster and no clear medical need for one or the other. In this study, we aim to provide more conclusive evidence to guide booster recommendations in the future. We need people like you to help us monitor post-booster symptoms and compare the effectiveness of mixing or matching boosters.

The BOOSTED Study is a part of the COVID-19 Citizen Science Study, which is funded by the National Institutes of Health (NIH), Patient-Centered Outcomes Research Institute (PCORI), and the Bill and Melinda Gates Foundation.

What's involved?

If you decide to participate, we will send you a notification through email, text, or push notification with your study-based assignment: encouragement to pursue the Moderna booster or encouragement to receive the Pfizer booster. You will have a 50% chance of assignment to the Moderna booster, and a 50% chance of assignment to the Pfizer booster. Of note, these are not mandates, but rather recommendations for one or the other that are open to you regardless of the study. If adhering to your assigned vaccine results in difficulty or delay, you should get whichever vaccine is available to you, regardless of your assigned booster. After getting your booster, we recommend you continue completing COVID-19 Citizen Science (CCS) surveys. We will only know what you actually received, what side effects you may experience, and what ultimately happens in the long-run through the surveys you fill out as part of your normal participation in the COVID-19 Citizen Science study. Importantly, the nature of this participation in CCS and the surveys delivered to you will not change as a result of your participation in this study.

How much time will it take?

Once you enroll, you will be asked a few more questions and receive your assignment, which should take a total 1-2 minutes.

Getting the booster shot can take 20-60 minutes, depending on your location, however that time is not expected to be meaningfully different than it would be if you decide against participating in this study. There are no additional follow up surveys after this beyond the regular weekly CCS surveys, which take 5-10 minutes per week.

Are there any risks to participate in this study?

Risks associated with getting the Covid-19 booster vaccine dose are not specifically related to this study since you indicated you were planning on getting the booster vaccine even if you were not in a study. There is a small risk that you might be delayed in getting your booster vaccine if the type you are trying to get because of the randomization is not available as quickly as other types. Though the study has asked you through the randomization to get a particular type of booster vaccine, ultimately the choice is yours and filling out the study survey after your vaccine will help investigators take into account which booster vaccine you actually got.

Unknown risks:

- Given the current scientific evidence, the Moderna and Pfizer COVID-19 boosters are equally safe and protective when using either the mix or match booster strategies. However, it may be possible that getting one or the other may result in different symptoms, or that mixing or matching the booster to previous COVID-19 vaccines is more or less effective in immunity.

The risk of loss of privacy is the same as if you choose to only participate in the CCS study without randomization to a booster:

Some participants may find answering personal questions about sensitive topics (behavior, medical conditions, or lifestyle) to be a bit uncomfortable. As with any mode of electronic participation, there is always a small risk of loss of privacy. We'll always do everything we can to protect your data, but no app or study can ever be perfectly safe from hacking. Your information will be transmitted and stored using state-of-the-art security systems similar to those that protect websites used by banks and electronic health record systems. Specifically, our platform is hosted on Amazon Web Services (AWS), a cloud-based server system and computing services. These systems and services are compliant with the U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA). All research data are stored behind a secure firewall, guarded by intrusion detection software, and encrypted at rest and in transit in our Amazon Virtual Private Cloud.

Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Representatives of the National Institutes of Health (NIH)

- Representatives of the University of California
- Other agencies that might inspect research records

See our Privacy Policy and Data Security Measures, available in the app and on the web, for more information.

Will I get advice about my health from the study?

No, we won't provide any information about your health or clinical interpretation of your data from the study. Participation does not in any way substitute for professional medical advice, diagnosis, or treatment that your doctor or other healthcare provider may give you. Always ask the advice of your healthcare provider if you have any questions about a medical condition. Do not disregard professional medical advice or delay in seeking care because of something you have read as part of this study. If you think you may have a medical emergency, call your doctor or dial 911 immediately.

Are there benefits to participating?

There are no direct benefits to participating in this study relative to receiving a booster without participating, but we hope you will find it rewarding to contribute to scientific discoveries about COVID-19 and vaccines!

What if I want to stop? What if I have questions?

You can stop participating at any time, and you can always email Drs. Gregory Marcus, Alexis Beatty, Jeffrey Olgin, or Mark Pletcher, or our study staff at: covid19@eurekaplatform.org. If you have any questions or concerns about this project or your rights as a research participant, you may contact the UCSF Institutional Review Board at 415-476-1814.

What are my other choices?

Of course, this study is entirely voluntary. Your other choices may include:

- Getting a COVID-19 booster of your choice
- Taking part in another study.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctors, Gregory Marcus, Alexis Beatty, Jeffrey Olgin, or Mark Pletcher, if you feel that you have been injured because of taking part in this study. You can tell the doctors in person or call them at (415) 353-2554.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment

may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor, depending on a number of factors. The University and the study do not normally provide any other form of compensation for injury.
For further information about this, you may call the office of the Institutional Review Board at (415) 476-1814.

Due to the coronavirus public health crisis, the federal government issued a Declaration under the Public Readiness and Emergency Preparedness (PREP) Act. If the Declaration applies, it limits your right to sue and recover for losses from the researchers, healthcare providers, any study sponsor or manufacturer or distributor involved with the study, including the University of California, while participating in this COVID-19 clinical study. However, the federal government has a program that may provide compensation to you or your family for certain claims if you experience serious physical injuries or death and these costs are not covered by other payors. To find out more about this "Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Your study doctors, Gregory Marcus, Alexis Beatty, Jeffrey Olgin, Mark Pletcher, can be reached at (415) 353-2554. The study coordinators are Michelle Yang (415) 580-1768, Kathleen Chang (415) 547-0356, and Gracie Wall (415) 562-5906. Study personnel can also be reached at covid19@eurekaplatform.org.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Institutional Review Board at (415) 476-1814.

If you wish to participate in this study, you should sign below.

Participant	Signature of Participant.	Date and Time
Person Obtaining Consent.	Signature	Date and Time

[Electronic signature will be obtained via DocuSign]