

USM MANDATORY VACCINATION

Frequently Asked Questions (updated 5/18/2021)

This Q&A includes general responses to frequently asked questions. For more specific answers and details regarding procedures, please contact your university.

What does emergency use authorization by the Food and Drug Administration (FDA) mean?

Emergency use authorization (EUA) facilitates the use of medical countermeasures—including vaccines—during public health emergencies, such as the COVID-19 pandemic. An EUA requires a finding that it's "reasonable to believe" that the vaccine "may be effective" to prevent serious or life-threatening diseases, or to mitigate a disease or condition.

In the case of the COVID-19 vaccines under EUA, both the safety and efficacy have now been demonstrated well beyond the initial clinical trial data; millions of shots have been administered, and only one vaccine— Johnson & Johnson—has been linked to any serious issue following its EUA approval. That review led to the requirement that a warning be added to the Johnson & Johnson label regarding a very rare side effect, and the vaccine remains in use in the U.S.

Why have the COVID-19 vaccines not yet received full approval by the FDA?

Emergency use authorization by the FDA requires a determination of the <u>safety and efficacy</u> of a vaccine. In the case of the COVID-19 vaccines currently available in the U.S., that determination was based on the submission of data from carefully designed clinical trials on tens of thousands of patients.

For full approval, however, the FDA also requires <u>duration</u> data, meaning documentation of efficacy for an extended period of time. For the vaccines currently available, the six-month period of observation ends in April/May, and the nine-month period in July/August. It's anticipated that the FDA will reconvene the Advisory Committee on Immunization Practices at the end of those periods to determine whether full approval will be recommended to the FDA.

What about the VAERS (Vaccine Adverse Event Reporting System) data that shows reports of adverse reactions/incidents after vaccination?

The VAERS database is a compilation of voluntary reports from all sources. There are several significant limitations to the interpretation of the data, including:

- Reports may include incomplete, inaccurate, coincidental, and unverified information.
- The number of reports alone cannot be used to reach accurate conclusions about the existence, severity, or frequency of problems associated with vaccines.
- A report to VAERS does not—in itself—mean the vaccine caused the adverse reaction.



What documentation do I have to show to prove I've been vaccinated?

If you've been vaccinated in Maryland and have given your university permission to obtain your data (HIPAA authorization), additional documentation will not be necessary.

Otherwise, the vaccination card provided by the vaccination site or a note signed by a physician should be sufficient for documentation. If you have been given some sort of electronic passport, your university may be able to accept that as sufficient documentation.

What documentation do I have to provide for a medical exemption?

Your university will establish a process for you to submit documentation from a licensed health care provider certifying that you have been diagnosed with one of the conditions the CDC considers a contraindication for vaccination or that there are other special medical circumstances that support a vaccination exemption. Contraindications include a severe allergic reaction after a previous dose of the COVID-19 vaccine, an immediate allergic reaction to a previous dose of any component of the vaccine, or a known allergy to any component of the vaccine.

What documentation do I have to provide for a religious exemption?

Your university will advise you of the information you need to provide for a religious exemption and which office handles exemption requests.

If I've already had COVID-19 and recovered, do I still need to get vaccinated?

Getting vaccinated is a safer way of building protection against COVID than getting infected. So, yes, you must be vaccinated regardless of whether you've already had COVID. Experts don't yet know how long you're protected from getting sick again after recovery, and it's possible—though rare—that you could be infected again with the virus that causes COVID-19.

If you were treated for COVID-19 with monoclonal antibodies or convalescent plasma, you should wait 90 days before getting a COVID-19 vaccine. Talk to your doctor if you're unsure what treatments you received or if you have more questions about getting a COVID vaccine.

What COVID-19 prevention and containment strategies will universities continue?

Universities will define and maintain certain masking, physical distancing, and hygiene protocols (e.g., handwashing, cleaning, ventilation). These protocols will be communicated to students, faculty, and staff, and may be adjusted as the semester progresses.

Universities will likely continue COVID-19 testing for some time and will communicate the details of their testing protocols for vaccinated and unvaccinated individuals. In addition, universities will communicate quarantine protocols for those exposed to COVID-19 and isolation protocols for those testing positive for the disease.

Violation of university protocols may result in student conduct or employee disciplinary proceedings.



If I'm vaccinated, do I still have to wear a mask?

We expect that mask wearing will continue as long as there is sufficient risk of COVID-19 presence and spread in the community. Universities will consult CDC, state, and local health guidelines on masking. As masking requirements change over time, universities will communicate those changes.

While vaccination protects an individual from getting seriously ill with COVID-19, it doesn't always prevent an individual from carrying the virus or transmitting it. Therefore, conditions on campus and in the surrounding communities will influence campus masking rules.

If I'm vaccinated, do I still have to physically distance?

The conditions on campus will determine the degree to which physical distancing will be required, especially in indoor spaces. Your university will determine the amount of space required between desks, chairs in a conference room, lounge chairs, etc.

What if I can prove that everyone in my group (e.g., class, chess club) is vaccinated? Does that change the answer?

You must comply with your university's masking and distancing rules whether or not the individuals in your group are vaccinated. Only in situations where university officials allow unmasking will the removal of face coverings be permitted.

If I've been vaccinated, do I still need to be tested?

All individuals will need to show a negative COVID-19 test result upon arriving on campus for the fall semester.

Additional testing protocols will be determined by your university. Students who can document vaccination will be tested less frequently than those not vaccinated. Testing frequency will be influenced by the positivity rate on campus and in the surrounding communities, and/or the introduction of new COVID-19 variants into these communities.

Campus testing protocols will be defined and disseminated by your university.

I'm an international student and received a vaccine other than Pfizer, Moderna or Johnson & Johnson. What do I need to do?

Universities will accept any vaccine authorized by the FDA or the World Health Organization (WHO). International students who have been vaccinated with a vaccine not authorized by either of these organizations may be tested and quarantined for a period of time upon arrival on campus, and may be revaccinated with an FDA-authorized vaccine.

For international students coming from areas where vaccines are not widely available, vaccination will be offered upon arrival on campus.



What if I try to get vaccinated but there are no available doses for me?

Students planning to be on campus in the fall should make arrangements in ample time to be fully vaccinated prior to arrival. With eligibility opened nationwide to those 16 and older, expanded vaccine availability, and a rising number of vaccination sites across the country, this should not be an issue.

If you cannot make such arrangements, contact your university over the summer so that appropriate arrangements can be made for your vaccination and quarantine upon arrival on campus.

If I've had my first vax appointment but not my second by the time I arrive on campus, will you let me in?

Every effort should be made to get fully vaccinated prior to arriving on campus. Given that states maintain control over which vaccines are available at any site, it's important that you complete the full series of doses at one vaccination site.

Those who do arrive on campus having had only the first shot in a two-dose series may be required to quarantine until fully vaccinated.

I don't want to room with someone who hasn't been vaccinated.

Health and safety considerations will guide university decisions regarding residence hall assignments of non-vaccinated students. Exceptions to the vaccination mandate will be very limited, meaning residence hall populations should be considered safe.

What if it turns out we need an additional booster?

Your university will work with the Maryland Department of Health and its local health department to obtain the booster vaccine as it becomes available, following federal and state guidelines.

It's expected that students living on or near campus should be eligible for any new vaccine—as in a booster shot—when it becomes available to the community.

If you're testing only non-vaccinated people for COVID-19 (or allowing only vaccinated people at certain events), aren't you de facto revealing private medical information about me?

Testing protocols will differ for vaccinated and non-vaccinated individuals, but all individuals on campus will be tested periodically. The testing site personnel will not divulge information as to vaccination status, but the frequency of testing required may imply that status. Even if someone assumes you're not vaccinated because of your testing schedule, they will not know why unless you tell them.

Documentation—either of vaccination or of an approved exception—will be sufficient for an individual's presence on campus and, therefore, for participation in all on-campus events or activities.