

Siri | Glimstad



COVID-19 VACCINE MANDATES

The FDA is the governmental agency responsible for approving vaccines. It has not, as of June 1, 2021, approved any COVID-19 vaccine. It has only authorized the use of three COVID-19 vaccines under an emergency use authorization ("**EUA**"). An EUA requires a lower evidentiary standard than FDA approval requires. The clinical trials the FDA will rely upon to decide whether to approve these vaccines as safe and effective are ongoing.

The long-term safety and efficacy of the EUA vaccines are unknown. The FDA will rely upon the data collected from the clinical trials to ultimately decide whether to approve COVID-19 vaccines as safe and effective. At present, data on the long-term safety and efficacy of these products are unavailable.

An educational institution lacks the legal authority to mandate an EUA **product.** COVID-19 vaccine mandates are a direct violation of 21 U.S.C. § 360bbb-3(e) which requires that a person have the option to decline an EUA product. Elevated deference to meaningful choice is needed in the context of EUA products because they still unlicensed are are investigational. This elevated "choice" requirement does not exist in the presence of a mandate.

In anticipation that a COVID-19 vaccine will be approved by the FDA this summer, many colleges and universities across the country are mandating the COVID-19 vaccine for Fall 2021.

Federal law exclusively governs EUA products. The FDA has determined that the terms and conditions of an EUA product preempt state or local law imposing different or additional requirements on the medical product for which the EUA was issued.

VACCINE EXEMPTIONS

Most colleges and universities will accept a religious and/or medical exemption.

At least one COVID-19 vaccine will likely be granted full FDA approval soon. Once that occurs, avoiding this product will typically require obtaining an exemption.

In most states, depending on state law, a college student has two options to avoid a mandated vaccine:

- Medical Exemption
- Religious Exemption

MEDICAL EXEMPTION

The requirements of a medical exemption vary by state and are often fact-driven.

- Some states may only require a physician's attestation that a specific vaccine is or may be detrimental to the person's health.
- In most states, however, a medical exemption will not be accepted as valid based solely on a medical decision made by a doctor and patient, but rather will only be accepted if it meets certain legal and medical technical requirements, such as falling into a CDC-recognized contraindication or precaution.



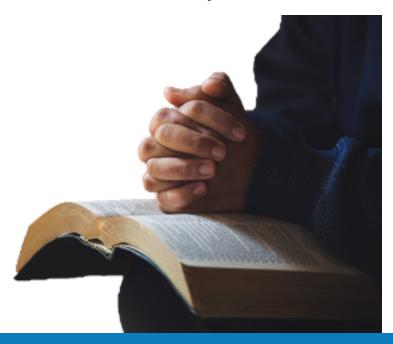
RELIGIOUS EXEMPTION

The Basics

Religious exemptions are complex and the rules are not logical or intuitive.

Generally Speaking

- Religion is defined broadly in the context of a religious exemption.
- You do not have to belong to any specific religion to qualify.
- Your religion as a whole does not have to be opposed to vaccination because it is your personal religious belief that is relevant.
- Your belief does not need to be factually true, however it does need to be a belief that is sincere to you.



RELIGIOUS EXEMPTION

The Pitfalls

Communicating any of the following prior to or in a religious exemption will often result in a **denial** of the request:

- · Vaccine science, safety, or efficacy;
- Listing philosophical or scientific arguments or reasoning;
- Stating that you are opposed to all medical intervention (unless your lifestyle evidences this belief as sincere);
- Citing the use of fetal cell lines in the production of vaccines as your only argument where vaccines not using fetal cell lines are available; or
- Stating a prior vaccine reaction.



RELIGIOUS EXEMPTION

The Inquiry

Even a perfectly-written religious exemption request can unravel during an inquiry, or interview, where the sincerity of the belief is questioned. You must prepare for this inquiry or risk **forfeiting** the religious exemption.

Example: Your religious exemption request states that you oppose vaccines because vaccines are a prophylactic (preventative) treatment and being vaccinated demonstrates a lack of faith in God. During the inquiry, you are asked if you get regular dental cleanings to prevent getting a cavity.



SEEK COUNSEL

Vaccine exemptions are an evolving area and can be complicated to navigate. For these reasons, you may want to seek the advice of a qualified professional to assist you throughout this process. You may only have one opportunity to correctly express your sincerely held belief.



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