Date: April 12, 2021

To: Whom It May Concern:

Re: Covid-19 Experimental Vaccine Candidates

Any compulsory Covid-19 vaccination requirement is a violation of federal law. I urge you to advise all students that they have the right to refuse or to take any COVID-19 vaccine. Any other action is contrary to federal law.

## Covid-19 Vaccines are Experimental.

Covid-19 vaccines are not approved by the FDA. The Covid-19 vaccines are only approved under an Emergency Use Authorization, for investigational use only.¹ Covid-19 vaccines lack requisite studies and are not approved medical treatment. The FDA's guidance on emergency use authorization of medical products requires the FDA to "ensure that recipients are informed to the extent practicable given the applicable circumstances ... That they have the option to accept or refuse the EUA product ..."2

Title 21, Section 360bbb-3 of the Federal Food, Drug, and Cosmetic Act (the "FD&C Act") vests the Secretary of Health and Human Services with the permissive authority to grant Emergency Use Authorizations ("EUAs") providing that appropriate conditions designed to ensure that individuals to whom the product is administered are informed:

- that the Secretary has authorized the emergency use of the product;
- of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
- of the option to accept or refuse administration of the product, of the
  consequences, if any, of refusing administration of the product, and of the
  alternatives to the product that are available and of their benefits and risks.<sup>1</sup>

The right to avoid the imposition of human experimentation is fundamental, rooted in the Nuremberg Code of 1947, has been ratified by the 1964 Declaration of Helsinki, and further codified in the United States Code of Federal Regulations. In addition to the United States regarding itself as bound by these provisions, these principles were adopted by the FDA in its regulations requiring the informed consent of human subjects for medical research. It is unlawful to conduct medical research, even in the case of an emergency, unless steps are taken to secure **informed consent** of all participants.<sup>3</sup>

The following Emergency Use Authorizations have been issued for Covid-19 vaccinations: