

**To:**

**From:**

**Date:**

**Re: Informed Consent**

**NOTICE OF POTENTIAL LIABILITY FOR LACK OF INFORMED CONSENT WHEN ADMINISTERING  
COVID-19 VACCINES (“GENE THERAPY”)**

**I. THE TEN POINTS OF THE NUREMBERG PRINCIPLES**

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made, and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

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

## II. Covid-19 Vaccines are Experimental and Require Informed Consent

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.<sup>1</sup> 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 ..."<sup>2</sup>

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:

1. that the Secretary has authorized the emergency use of the product;
2. 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
3. **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>

Vaccine administrators, such as yourself, Mr./Mrs. (doctor, nurse, pharmacist, misc. health care worker) have an obligation to inform participants of the adverse events and death which has occurred from these Covid-19 vaccines.

- "potential benefits and risks" of the Covid vaccines, AND
- Of "the extent to which such benefits and risks are unknown;" AND
- "**of the option to accept or refuse administration of the product**," AND
- "of the alternatives to the vaccine that are available and of their benefits and risks."<sup>1</sup>

### III. Vaccine Administrators have Duty to Inform Recipients of Known and Unknown Risks of the Covid-19 Vaccines

- Based on VAERS as of June 16, 2021, there have been 5,993 deaths reported,<sup>4</sup> and 358,379 adverse events related to the Covid-19 vaccines.<sup>5</sup>
- By comparison, from July 1, 1997, until December 31, 2013, VAERS received 666 adult death reports for all vaccines.<sup>6</sup>
- In 1976, the US government halted the rollout of the experimental swine flu vaccine for 25 deaths after 55 million people were inoculated.
- The FDA and these pharmaceutical companies allow children 12 years and older to receive this vaccine, however children were never studied in this trial. Never before in history have we given medications that were not FDA approved to people who were not initially studied in the trial. There were no trial patients under the age of 18! They're extrapolating the data from adults down to children and adolescents. This is not acceptable. Children are not little adults. Children have 99.997% survivability from the covid.
- The CDC's Advisory Committee is meeting in June to address the higher number of observed than expected myocarditis/pericarditis cases in 16–24-year-olds.”<sup>7</sup> This is inflammation of the heart. There is no such thing as a “mild case” of heart inflammation.
- Brain injuries after the COVID-19 vaccines are increasingly being reported. Search the federal government VAERS Database for any diagnostic term such as “dementia” or “Bell's Palsy” or “brain bleeding,” sadly the numbers are rising daily.<sup>8</sup>
- A study published by the renowned Cleveland Clinic in Ohio indicates that natural immunity acquired through prior infection with COVID-19 is stronger than any benefit conferred by a Vaccine. People that have had Covid in the past and are now recovered, have a much stronger (10-20x) antibody response to the vaccine. The response is much too strong and overwhelms the person's health system. Medical studies show severe side effects post vaccination in those persons with prior infection of Covid, including life-threatening harm to plaintiffs.<sup>9 10</sup> Health professionals have never blanket administered vaccines without checking for titers first (Hep B, MMR, Varicella, etc.). You must exclude vaccinating persons who already had the infection for which the inoculation is being considered.<sup>11</sup>
- Pregnant persons were not studied in the initial Covid-19 vaccine trials. As such, the risks/benefits are unknown. The mere fact that there are unknown risks needs to be communicated to each vaccine recipient.

Please consider this an official notice that you may be personally liable for injuries sustained by individuals from these vaccines should you refuse to inform your vaccine recipients of these risks. Any pressure, coercion, or threat of reprisal constitutes reckless endangerment and has a reasonable expectation of causing personal injury resulting in damages. Throughout world history, “I just did my job” has never been a defense to forced medical experimentation (or medicine intentionally lacking informed consent).

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<sup>1</sup> Title 21, Section 360bbb-3 of the Federal Food, Drug, and Cosmetic Act (the “FD&C Act”)

<sup>2</sup> <https://www.fda.gov/media/97321/download>

<sup>3</sup> 21 CFR § 50.24

<sup>4</sup> <https://vaers.hhs.gov/data.html>

<sup>5</sup> [https://www.openvaers.com/covid-data?fbclid=IwAR1LBbvL\\_banBKlvSBDZh7VJsvTYvKyZzzdcJFq5bqc\\_xAu0LOIOvVXNyZQ](https://www.openvaers.com/covid-data?fbclid=IwAR1LBbvL_banBKlvSBDZh7VJsvTYvKyZzzdcJFq5bqc_xAu0LOIOvVXNyZQ)

<sup>6</sup> Exhibit 5. Pedro L. Moro, Jorge Arana, Mria Cano, Paige Lewis, and Tom T. Shimabukuro, Deaths Reported to the Vaccine Adverse Event Reporting System, United States, 1997-2013, VACCINES, CID 2015:61 (September 2015).

<sup>7</sup> <https://childrenshealthdefense.org/defender/cdc-teens-vaccinated-pfizer-moderna-higher-risk-heart-inflammation/>

<sup>8</sup> <https://wonder.cdc.gov/vaers.html> June 2, 2021

<sup>9</sup> <https://www.news-medical.net/news/20210511/Severe-COVID-19-linked-to-genetic-clotting-predisposition.aspx>

<sup>10</sup> <https://www.medrxiv.org/content/10.1101/2021.05.04.21256617v1.full.pdf>

<sup>11</sup> <https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html>