**How Does COVID Infect Humans?**

The COVID-19 virus has a unique “spike protein” on its surface that bind to cells expressing ACE2 receptors, and facilitates the virus entering the cell. The spike protein does not cause illness; it only helps the virus enter other cells. Once inside the cell, the virus hijacks the cell’s machinery to replicate itself. When it has made enough copies, the virus bursts the cell and the copies are released to invade other nearby cells in the body, spreading the infection.

**How does the vaccine work?**

The COVID-19 vaccines contain viral mRNA that “write” the spike protein without replicating the rest of the virus. The spike protein on its own is harmless; it is also unique to the COVID-19 virus. When this mRNA is taken up by human cells, the cells use their own ribosomes to make copies of the spike protein. These spike proteins are released into the body, triggering the body to create antibodies and immune cells against them. The resulting immune cells and antibodies can then destroy viral particles (or infected cells with spike proteins attached) if the body is exposed to COVID-19 infection. This stops the spread of the infection to nearby cells.

**Is the COVID-19 vaccine effective at preventing disease and transmission?**

Yes. In the Moderna vaccine trial, over 30,000 volunteers ages 12 or older were vaccinated with two doses, 28 days apart, of either the vaccine or a placebo. 7000 of the volunteers were over age 65, 42% were in medically high-risk populations (co-infection with HIV, HepB, or HepC, or diagnosis of diabetes), and 28% were from communities of color. Published results in the New England Journal of Medicine showed excellent antibody titres in the vaccinated group 90 days after the second injection.

In the currently available data, only 11 of >14,000 vaccinated people from the Moderna trial developed symptoms of COVID-19 and tested positive by PCR during the 90 days after administration, compared with 185 of the equally sized placebo group. In addition, none of the patients in the vaccination group developed serious disease or disease long-term sequelae, as compared with 30 severe cases and one death in the placebo group. However, the investigators only tested patients who developed COVID-19 *symptoms*; “silent infections” were not investigated. Therefore, we cannot say that the COVID-19 vaccine will stop you from contracting the virus. This is similar to influenza vaccination.

Page 1

**How did this vaccine development differ from typical vaccine development & approval?**

Development of the COVID-19 vaccines was done under a program established in 2001 specifically to deal with public health emergencies. This Emergency Use Authorization (EUA) process is closely monitored for safety by the FDA. No steps were skipped as compared to typical vaccine development. However, the federal government and private investors provided capital funds to the vaccine companies so that they could hire more scientists and recruiters to perform the steps faster – increasing the speed of recruitment, data analysis, etc. In addition, the companies were allowed to combine their Phase II trial (which measure antibody levels after vaccination without measuring clinical disease) and Phase III trials (to study development of disease in the vaccinated patients). The safety monitoring was the same as in the typical vaccine development process.

One additional difference is that the EUA process allowed approval of the vaccine after only 3 months follow-up, instead of the typical 6 months. However, both Moderna & Pfizer started enrolling candidates in late July (the injection of capital from Operation Warp Speed allowed these two companies to recruit >70,000 subjects in just 3 months, rather than the usual 1-3 years that it may take to recruit enough subjects). Thus, they will be able to apply for full approval this spring.

Remember that vaccine approval does not end the monitoring of vaccine safety. The FDA and CDC have operated the Vaccine Adverse Event Reporting System (VAERS) since 1990, soliciting reports from the public and from healthcare providers of any possible adverse events related to vaccine administration. Of the tens of millions of vaccine doses administered each year, approximately 30,000 events are reported to the VAERS and are investigated by the CDC. The vast majority (nearly 90%) of these events are minor reactions.

**If I get vaccinated, do I still need to wear PPE?**

PLEASE continue to follow PPE guidance using eye protection, face masks, gloves, frequent hand sanitizing, cleaning procedures for equipment, and follow department specific and local policies. We will need time to understand the reality of how long the vaccine will continue to provide protection. PROTECT YOURSELF and PROTECT OTHERS!

Page 2

**What vaccine will I receive?**

First responders and personnel have been designated as 1st priority to receive vaccine in Phase 1 of the vaccination process. There are 2 similar vaccines that have received EUA by the FDA – Pfizer and Moderna. Fire departments in Orange County will be receiving vaccination using the Moderna vaccine. This involves 2 injections, 28 days apart.

Moderna & Pfizer have shown similar effectiveness in their trials. But they have *VERY* *different* storage needs, with Pfizer requiring storage at -70°C, and only remaining potent for 5 days after removal from this ultra-low storage temperature. On the other hand, the Moderna vaccine can be stored for up to 28 days in a normal refrigerator, making it more appropriate for Fire Department logistics.

**Is the COVID-19 vaccine safe?**

Reported side effects from the Moderna vaccine included arm redness at injection site, 1-2 days of mild fever (after 2nd dose), mild headache, or fatigue. If you experience these or any other side effects, let your supervisor know so you can be directed on whom to contact. As the vaccinator, we will also report all side effects that you share with us to the CDC’s VAERS system. In the Moderna trial, there were NO serious adverse events amongst the nearly 15,000 patients who received the vaccine.

Despite misinformation that has been circulating claiming various dangers of the vaccine, and of vaccines in general, 70 years of vaccine experience refute this. We will try to address some of the most popular myths related to vaccine safety:

1. mRNA vaccines CANNOT implant material into the human genome (DNA) or fundamentally change a human’s genetic structure. The mRNA does not enter the cell nucleus or contact DNA. The vaccine utilizes the cell’s normal processes to produce *inert* proteins that mimic the virus in order to trigger the body’s immune response. The cell that does this is then destroyed by the body’s immune system.
2. The vaccine doesn’t use any live virus or live virus components. Thus there is no chance for it to cause infection.
3. While the COVID-19 vaccines are the first vaccines against infectious diseases that have used mRNA technology, similar technology using mRNA has been used to treat other conditions, including gastric cancer and hATTR, a rare debilitating human peripheral nerve disease.
4. As described above, the incidence of side effects from any approved vaccines is *extremely* low. For COVID-19, 75000 people received both doses in the 2 trials >90 days ago and few significant side effects have occurred.

Page 3

**What if I develop COVID-19 symptoms after vaccination?**

Since there is still a chance that you could get (and transmit) COVID-19 after vaccination, we will continue to follow our current protocol of monitoring, testing, and quarantine. This may change over time as we (and the country) get more data. Since COVID vaccination will not affect PCR or Antigen tests results, you will be asked to get testing. If you become symptomatic and test positive, it means that you have contracted the disease.

**If there are so many new and unharnessed treatments for COVID-19, why do we need a vaccine?**

Unfortunately, none of the “prophylactic” treatments have shown efficacy in preventing or treating COVID-19. Even the HHS-supplied treatments Remdesivir and the monoclonal antibodies have shown questionable results and have only decreased mortality by *at most* < 50%. Only steroids have shown statistically significant survival benefit, and this benefit is only about a 50% decrease in mortality.

On the other hand, while most young and healthy people will recover from COVID-19, research indicates that as many as 1 in 3 people who contract COVID experience prolonged illness lasting more than 2 weeks, and/or a post-COVID syndrome which effects their quality of life for several months or more. In addition, there is some evidence that even minor illness from COVID-19 can increase risk of cardiac arrhythmias and sudden cardiac death in athletes and other healthy people.

Page 4