<h1 style="text-align:center">Vaccine EUA and Distribution</h1>

For more information, visit www.ochsner.org/vaccine or call the COVID-19 hotline at 1-844-888-2772 or 504-842-0201.

How are vaccines approved? What is the process?
- Vaccines are approved by the Food and Drug Administration (FDA) after rigorous and extensive development in laboratories, as well as pre-clinical animal studies and testing on human volunteers, to ensure they are safe and effective.
- Monitoring of the vaccine and how it's produced, including regular facility inspections, must continue for as long as the manufacturer holds a license for the vaccine.
- Additionally, the drug sponsor follows a multi-layered approval process, which includes an investigational new drug application, clinical trials and presentation of data to a special FDA advisory committee.

What is an Emergency Use Authorization (EUA)?
- During a public health emergency, an EUA authorizes the Food and Drug Administration (FDA) to make a product available to diagnose, treat or prevent serious or life-threatening diseases.
- The FDA and the U.S. Department of Health and Human Services have assured the public that no safety or efficacy evaluation steps would be skipped in approving the vaccine.

How long does emergency use last?
- An emergency authorization functions like a temporary approval for the duration of the emergency or until the FDA grants approval. To win full FDA approval for a New Drug Application, the pharmaceutical sponsor will have to submit additional research to fully define the drug's safety and benefit for patients.

When will Ochsner receive the vaccine/be ready to give shots?
- Some Ochsner campuses received COVID-19 vaccines on Monday, December 14, 2020. Others will receive them in the days following. We will be ready to deploy to our frontline workers, essential personnel and members of our highest-risk community as soon as vaccines are made available.

How many vaccines will Ochsner get?
- The state of Louisiana is in charge of allocating the vaccines. Ochsner is expecting to receive 9,375 doses of the Pfizer vaccine in its first shipment. Of that, Ochsner Lafayette General is slated to receive 2,925. We are operationally prepared to support as many doses as we receive.

What locations are available for the vaccine?
- Ochsner Health will offer vaccinations at regional hubs and hospital sites across the state. The goal is to make it as convenient as possible for our employees and our patients to receive the vaccine.

Should I take a COVID test before or do I need to be COVID-free before receiving the vaccine?
- You do not need to take a COVID-19 test prior to receiving the vaccine. If you are COVID-19 positive, then it is recommended that you follow the CDC guidelines and isolate for 10 days to limit exposure to others. Once you are out of isolation, you are able to receive the vaccine.

How much will the vaccine cost?
- There will be no direct cost to employees or patients at this time.

Vaccine Safety, Effectiveness and Side Effects

What is the difference between each vaccine?
- The Pfizer and Moderna vaccine are two shots – one shot followed by a booster either 21 or 28 days depending on the vaccine. Both use mRNA, or messenger RNA, which gives cells instructions to create a protein like the SAR-CoV2 protein. Once the protein is created, it triggers the immune response leading to the production of antibodies.
- The Janssen and AstraZeneca/University of Oxford vaccines use one shot. Both utilize the adenoviruses which is the same viruses that can cause the common cold. These inactivated/non-infective adenoviruses can be used to deliver DNA, which are instructions for proteins. For the COVID-19 vaccine, researchers swap in a gene from SARS-CoV-2 (COVID-19) so that the modified cold virus makes the SARS-CoV2 protein, stimulating production of antibodies and additional immune responses to fight off the virus. The process creates an immune memory, which ultimately teaches the body to both recognize and attack the virus.

Is the vaccine safe?
- Current data from COVID-19 vaccine trials that have been released supports the safety and efficacy of the vaccines. There have been no significant safety concerns for either the Pfizer vaccine or Moderna vaccine which are the two vaccines we anticipate will get EUA by end of the year. Over 37,0000 people have received the COVID-19 vaccine during the Pfizer and Moderna vaccine trials with no significant side effects. The benefits of vaccination greatly outweigh the risks of not being immunized.

What does vaccine efficacy mean?
- Most commonly used in clinical trials, vaccine efficacy is a percentage measured by calculating the risk of disease among vaccinated and unvaccinated persons.
- For example, vaccine efficacy of 90% means a 90% reduction from the number of cases you would expect if they have not been vaccinated.
- Vaccine effectiveness is different and shows the ability of vaccine to prevent outcomes of interest in the "real world."

If I participated in a vaccine trial, can I still get the vaccine?
- Each trial sponsor needs to review to see if any such potential process and amendment to the original protocol (where participants stay blinded for the 24-month duration of the study) would be subject to the input of the regulatory authorities.
- If you are currently a participant in one of the Ochsner vaccine trials, please contact your study staff for more information.

Now that a vaccine is in emergency use, does that mean that vaccine trials have stopped?
- No, the current vaccine trials will continue for the intended duration which for most trials is 24 months.
- Additionally, we will see more trials for new vaccines and new targeted populations and these new potential trials will need research participants.
- With more than 7 billion people in the world, more trials are needed to help vaccinate the entire world.

I heard some of the vaccine trials were canceled – does that mean they're not safe?
- No COVID-19 vaccine trial has been canceled. Two trials were paused which is normal for all clinical trials to take a closer look at symptoms participants develop to see if there are possible side effects. Sometimes the symptoms have nothing to do with the actual product. This process is in place to ensure that any product brought to the public is as safe as possible. Both trials that were paused were resumed once an independent safety monitoring board deemed the side effects not related to the vaccine.

Does Ochsner endorse the COVID-19 vaccine and suggest all employees and patients receive the vaccine?
- Ochsner Health fully supports and highly encourages widespread vaccination under the Emergency Use Authorization (EUA) for all employees and our patients. Ochsner will only recommend and administer vaccines that the Food and Drug Administration (FDA) has certified as safe and effective for all patients and employees, including our most vulnerable populations. Ochsner's contributions to the vaccine trials have helped illustrate their safety to the FDA. Large scale vaccination of our community is the best way to keep everyone safe and to end the COVID-19 pandemic.

How long will the vaccine last?
- Since this is a novel virus, we are still unsure how long the vaccine antibodies will last. We are closely monitoring the research as more data becomes available.

What are the possible side effects of the vaccine?
- Similar to the flu shot, the vaccine is administered into a large muscle in the upper arm or thigh. Like with any vaccine, allergic reactions may occur. Some may experience mild fever, soreness, muscle aches, redness and/or swelling at the site of administration. These are signs of an immune response to the vaccine and expected in some patients.

What happens if I feel ill after receiving the vaccine?
- Contact your Health Care provider should you feel ill or experience an adverse effect discussed prior to your COVID-19 vaccination. If you are experiencing an emergency, call 911.

Can I have my flu shot around the same time as the COVID-19 vaccine?
- Yes, there are no restrictions in receiving your flu shot around the same time as the COVID-19 vaccine. In fact, Ochsner recommends that everyone aged 6 months and older get a flu shot.

Can I still become infected after receiving the vaccine?
- The vaccine cannot cause you to test positive via nasal swab or saliva test. This is not a live vaccine and will not cause you to shed virus.
- Some patients may still become infected or develop symptoms following vaccination against COVID-19. However, the current vaccines under consideration all have greater than 90% efficacy of preventing you from getting infected. They also have demonstrated that your risk of a severe infection that requires you to be hospitalized is greatly reduced following immunization.

Does the vaccine prevent me from getting it or spreading it?

- That is the intent. Instead of traditional vaccines, which may use the virus itself, the SARS-CoV-2 vaccine will use a protein on the outside of the virus. This means the vaccine can't cause COVID-19 in a person, because it's not using the virus that causes the disease.

- This stimulates your body's immune system to mount a response as if it were a true infection, minimizing your risk of infection or disease burden should you encounter the same virus later. The current vaccine candidates have been demonstrated to be over 90% effective in preventing you from developing symptomatic infection from COVID-19.
- However, in order to stop this pandemic, we need to use every tool available which includes the immunization, social distancing, hand washing and wearing masks.

Are there any restrictions, such as quarantining in place, after receiving the vaccine?
- No, there are no restrictions after receiving a COVID-19 vaccine, but you should continue to wear your mask, social distance and practice good hand hygiene.

Will I still have to mask and social distance after I get the shot?
- Yes. Until we reach herd immunity and the majority of the United States has been vaccinated, we will need to continue to practice social distancing, hand washing and wearing masks. These are the best ways to reduce your chance of being exposed to or spreading the virus until we end this pandemic.

If I've already had COVID-19 and recovered, should I still get vaccinated?
- Yes. There is not enough information currently available to say how long after infection someone is protected from getting COVID-19 again. In order to stop this pandemic, we need to use every tool available which includes the immunization, social distancing, hand washing and wearing masks.

<u>**Different Types of Vaccines**</u>

Is it uncommon to have multiple drug manufacturers produce and distribute a vaccine?
- It is not uncommon to have multiple pharmaceutical manufacturers produce and distribute a vaccine against the same preventable disease. In fact, numerous vaccines, such as those for influenza and DTaP (diphtheria, tetanus and pertussis) are well-known and common vaccines who use several different manufacturers for vaccine development and distribution.

Why are some of the COVID-19 vaccines two shots versus one shot?
- The series and dosing for each vaccine is based on the initial results from the clinical trial data. Just because some vaccines may have one shot vs two, doesn't mean that one is less effective than the other.

What happens if I don't get the booster/2nd shot within the allotted timeframe? Will I still be considered vaccinated?
- To best maximize the efficacy of the vaccine and to ensure an optimal effectiveness, it is highly recommended that you receive the second dose within the specified timeframe as directed by the manufacturer. If you don't receive the second shot, you will greatly decrease the chance of the vaccine working.

When do I receive my second dose for the Pfizer or Moderna vaccine? Is it at the same location as my first shot?
- The amount of time between your first and second dose will be anywhere between 21 and 28 days depending on the manufacturer's vaccine schedule. Once you receive your first dose, you will be able to schedule your second appointment before you leave and Ochsner will send message updates to ensure you receive your second dose.

Vulnerable Populations

Are there any health restrictions that would prevent me from receiving the vaccine?
- COVID-19 vaccination may not be for everyone. If you are unsure if you should receive the COVID-19 vaccine, please call your healthcare provider to discuss the possible benefits and risks.

Can I get the vaccine while pregnant or breastfeeding?
- Following guidelines from the FDA, no one is excluded from receiving the vaccine, even patients who are pregnant or breastfeeding, as there are no medical contraindications to receiving this vaccine.

Should children get vaccine? What ages is the vaccine for?
- Currently, there are a few trials that are enrolling various age groups including children ages 12 or greater.
- Just like the adult COVID-19 vaccine trials, data from children and adolescent COVID-19 vaccine trials will need to support the safety and efficacy of the vaccines before approval for the population.
- Ochsner will only recommend and administer vaccines that the Food and Drug Administration (FDA) has certified as safe and effective for all patients and employees, including our most vulnerable populations. The benefits of vaccination outweigh the risks of forgoing immunization.