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INFORMED CONSENT J&J (Janssen)
COVID-19 Vaccine

Introduction
The following is an informed consent document. Please read it carefully. It does not take the place of a conversation with the doctor regarding this proposed treatment. This document is intended to provide information that a patient should have in order to make an informed decision about a particular medical procedure, in this case whether or not to have the COVID-19 vaccine.

Purpose
The purpose of a COVID-19 vaccination is to try and prevent acquiring a COVID-19 infection by immunization with an inactivated coronavirus vaccine.

Despite extensive research and safety data, vaccines are not 100% guaranteed to be safe or effective. Agreeing to have a vaccine means that you accept the very small risk of vaccine related consequences as well as the risk of acquiring COVID-19 despite having been vaccinated.

The purpose of this form is to explain what those risks are so that you understand them. A patient should not agree to undergo any medical treatment unless and until they understand the possible risks, benefits, alternatives, and the reason for having the treatment done.

The Vaccine
This consent is for the Johnson and Johnson (J&J) Janssen COVID-19 vaccine. All of the relevant information about this vaccine, its mechanism of action, risks, and side effects is in the document entitled "FACT SHEET FOR RECIPIENTS AND CAREGIVERS. EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER" which is provided as a separate handout. Please review this information.

Pregnant and Lactating Patients
Our providers support receiving the vaccine even if you are pregnant, trying to become pregnant or are lactating. We feel that the risks from a COVID infection exceed the possible risks of the vaccine. Please see our website for more information. Many national women's health organizations, such as ACOG, agree with this recommendation.

CDC Statement on Guillain-Barré syndrome
"COVID-19 vaccine safety is a top priority for the federal government, and we take all reports of health problems following COVID-19 vaccination very seriously. CDC and FDA are monitoring reports of Guillain-Barré syndrome (GBS) after receiving Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine. GBS is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness or in the most severe cases paralysis. Each year in the United States, an estimated 3,000 to 6,000 people develop GBS; it is typically triggered by a respiratory or gastrointestinal infection. Most people fully recover from GBS.

"Reports of GBS after receipt of the J&J/Janssen COVID-19 Vaccine in the Vaccine Adverse Event Reporting System (VAERS) are rare, but do likely indicate a small possible risk of this side effect following this vaccine. Around 100 preliminary reports of GBS have been detected in VAERS after 12.8 million doses of J&J/Janssen COVID-19 Vaccine administered. These cases have largely been reported about two weeks after vaccination and mostly in males, many aged 50 years and older. Available data do not show a similar pattern with mRNA vaccines (Pfizer-BioNTech and Moderna), after over 321 million doses administered in the United States. This issue will be discussed as part of an upcoming ACIP meeting.

"In the United States, nearly all COVID-19 hospitalizations and deaths are now occurring in unvaccinated people. The risk of severe adverse events after COVID-19 vaccination remains rare. Everyone age 12 years and older is recommended to receive a COVID-19 vaccine."

Blood Clot Warning – rare cases of blood clots and low platelets
According to the CDC: "After reviewing all available safety data, CDC and FDA recommend use of this vaccine resume in the United States given that the known and potential benefits outweigh the known and potential risks. This adverse event is rare, occurring at a rate of about 7 per 1 million vaccinated women between 18 and 49 years old. For women 50 years and older and men of all ages, this adverse event is even more rare.

For three weeks after receiving the vaccine, you should be on the lookout for possible symptoms of a blood clot with low platelets. These include:

- Severe or persistent headaches or blurred vision
- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Easy bruising or tiny blood spots under the skin beyond the injection site

Seek medical care right away if you develop one or more of these symptoms."

Alternatives
The current COVID-19 vaccine alternatives include the Pfizer version and the J&J Janssen version.

Agreement and Consent
To make sure that you fully understand the information contained in this Informed Consent, your physician is available to discuss the information with you after you have had a chance to read it, and before you decide whether to have the above vaccine administered. If you have questions, you are encouraged and expected to ask them, and your physician and her/his staff will be available to discuss these with you.

Your signature on this informed consent indicates:

A. That you have read and understood the information provided in this form.
B. That you have read and understood the information provided in the J&J (Janssen) COVID-19 Vaccine EUA Fact Sheet – July 8, 2021 version.
C. That you have read and understood the information provided in the CDC Statement on Guillain-Barré syndrome.
D. That you have been verbally informed about the COVID-19 vaccine.
E. That you have had a chance to ask questions.
F. That you have received all the information you want concerning this treatment.
G. That you authorize and consent to receiving a J&J (Janssen) COVID-19 Vaccine

DATE:_____ TIME: _____

NAME: _____SIGNATURE:_____

If signed by other than patient, indicate relationship: _____

PHYSICIAN'S STATEMENT:

The undersigned physician hereby certifies that s/he discussed the following procedure(s) with the patient and provided a full explanation of the indications for the vaccine, the benefits of getting the vaccine, the risks of the vaccine (common and remote, minor and serious), and the alternatives.

The undersigned physician further certified the patient was encouraged to ask questions, and that all of her questions were answered. The patient has agreed to receive the COVID-19 vaccine.

DATE:_____ TIME: _____

DR NAME: _____SIGNATURE:_____