Pfizer-BioNTech COVID-19 Vaccine COMIRNATY (COVID-19 VACCINE, mRNA) Consent and Screening Form

SECTION 1: INFORMATION ABOUT PATIENT TO RECEIVE VACCINE (PLEASE PRINT)

PATIENT'S NAME (Last)	(First), (M.I.)	PATIENT'S DATE OF BIRTH:	PT'S AGE:

PARENT/LEGAL GUARDIAN'S NAME (Last): IF PT IS MINOR	(First), (M.I.)	PATIENT'S GENDER: M / F

ADDRESS	City/State/Zip

PARENT/GUARDIAN DAYTIME PHONE NUMBER AND MOBILE NUMBER: IF PT IS MINOR	PARENT/GUARDIAN EMAIL ADDRESS: IF PT IS MINOR

RACE: **Required per State of Texas Immunization Registry**

American Indian or Alaska Native | Asian | Native Hawaiian or Other Pacific

Black or African American | White | Other Race

ETHNICITY:

Required per State of Texas Immunization Registry

Hispanic | Non Hispanic

FOR VACCINE RECIPIENTS:

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. **If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated.** It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

	YES	NO	DON'T KNOW
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine?			
--> if yes, which vaccine product did you receive? __Pfizer-BioNTech __Moderna __ Jassen (J&J) __Other			
-->Have you received a complete COVID-19 vaccine series (i.e., 1 dose Janssen or 2 doses of an mRNA vaccine [Pfizer-BioNTech, Moderna])?			
-->Did you bring your vaccination record card or other documentation?			

3. Have you ever had an allergic reaction to:

(This would be a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)

◆ **A component of a COVID-19 vaccine, including either of the following:**	YES	NO	DON'T KNOW
○Polyethylene glycol (PEG), which is found in some medications, such as laxatives & prepartions for colonoscopy procedures			
○Polysorbate, which is found in some vaccines, film coated tablets & intravenous steroids			
○A previous dose of COVID-19 vaccine			

4. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication?			

(This would be a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)

5. Check all that apply to patient receiving vaccine:

__ Am a female between ages 18 and 49 years old
__ Am currently pregnant or breastfeeding
__ Am a male between ages 12 and 29 years old
__ Have a history of myocarditis or pericarditis
__ Have a bleeding disorder
__ Take a blood thinner
__ Had a severe allergic reaction to something other than a vaccine or injectable therapy such as food, pet, venom, environmental or oral medication allergies

5. (cont) Check all that apply to PATIENT receiving vaccine:

__ Diagnosed with Multisystem Inflammatory Syndrome (MIS-C or MIS-A) after a COVID-19 infection

__ Have a weakened immune system (i.e., HIV infection, cancer) or take immunosuppressive drugs or therapies	
__ Had COVID-19 & was treated with monoclonal antibodies/convalescent serum	
__ Have a history of heparin-induced thrombocytopenia (HIT)	
__ Have received dermal fillers	__ None of the above

SECTION 3: INFORMATION ON THE RISKS AND BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE AND COMIRNATY (COVID-19 VACCINE, MRNA)

The Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY (COVID-19 VACCINE, mRNA) may not protect everyone. Side effects that have been reported with both include injection site pain, tiredness, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, feeling unwell, and swollen lymph nodes. There is a remote chance that either the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 VACCINE, mRNA) could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 VACCINE, mRNA). For this reason, a vaccination provider will ask the person receiving the vaccine to stay at the place where they received their vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include difficulty breathing, swelling of the face and throat, a fast heartbeat, and/or a severe rash all over the body.

SECTION 4: CONSENT I have reviewed the information on risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY (COVID-19 VACCINE, mRNA) in Section 3 above and understand the risks and benefits. In providing my consent below, **I agree that:**

- I have reviewed this consent and screening form.
- **I certify that I am: (a) the patient and at least 18 years of age; (b) the parent or legal guardian of the patient and confirm that the patient is at least 5 years of age; or (c) authorized to consent for vaccination for the patient named above. Further, I hereby give my consent to Clinical Pediatric Associates of North Texas or their agents to administer the COVID-19 vaccine, Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 VACCINE, mRNA), which consists of two (2) doses administered 21 days apart.**
- I understand that I am not required to accompany the child named above if they are over 16 years old to their vaccination appointments and that, by giving my consent below, the child may receive the applicable Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 VACCINE, mRNA) whether or not I am present at the vaccination appointments.
- **I understand that this product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 5 years of age and older; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.**
- I understand that it is not possible to predict all possible side effects or complications associated with receiving vaccine(s). I understand the risks and benefits associated with the above vaccine and have received, read and/or had explained to me the Emergency Use Authorization Fact Sheet on the COVID-19 vaccine, available at https://www.fda.gov/media/144414/download. I also acknowledge that I have had a chance to ask questions and that such questions were answered to my satisfaction. I also understand the need for continued masking/social distancing after
- **I acknowledge that I have been advised to remain near the vaccination location for approximately 15 minutes after administration for observation and possibly up to 30 minutes if medical provider deems necessary. If I experience a severe reaction, I will call 9-1-1 or go to the nearest hospital.**

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• I acknowledge that: (a) I understand the purposes/benefits of ImmTrac2, Texas immunization registry and (b) TxDSHS will include my personal immunization information in ImmTrac2 registry and my personal immunization information will be shared with the Centers for Disease Control (CDC) or other federal agencies as required by the local, state & federal government.

• If I have health insurance that covers the child named above, I give permission for my insurance company to be billed for the costs of administering the Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 VACCINE, mRNA). The government is paying for the actual Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 VACCINE, mRNA), and I will not be billed for that portion of the cost of my immunization.

I GIVE CONSENT to Clinical Pediatric Associates of North Texas to vaccinate the patient named at the top of this form with the applicable Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY (COVID-19 VACCINE, mRNA) and have reviewed and agree to the information included in Section 4 of this form.

_____ _____

Signature of the Patient if 18 years old & over Date signed

_____ _____

Signature of the Parent/Legal Guardian named above Date signed

Manufacturer / EUA Date	Lot #	Expiration Date	Route	Dose	Injection site
Pfizer-BioNTech (5-11 years) / 10/29/2021			Intramuscular (IM)	0.2mL	
Pfizer-BioNTech (12-15 years) / 10/29/2021			Intramuscular (IM)	0.3mL	
Comirnaty (16 – 17 years) / 8/23/2021			Intramuscular (IM)	0.3mL	

Entered into IMMTRAC (initial and date) _____ Notes/Comments: _____ rev. 11/2/21

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