PATIENT CONSENT FORM FOR EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

I declare that I am 18 years of age or older. I further acknowledge that:

1. I understand that the Pfizer-BioNTech COVID-19 Vaccine is a vaccine that may prevent COVID-19. This vaccine is not currently FDA-approved to prevent COVID-19. This vaccine has been authorized by the FDA for emergency use to prevent COVID-19 in individuals 12 years of age and older under an Emergency Use Authorization (EUA). I understand that other vaccine products have also been authorized by the FDA for emergency use to prevent COVID-19 under an Emergency Use Authorization (EUA).

2. I understand that Pfizer-BioNTech COVID-19 Vaccine is not recommended to be administered to individuals with known history of a severe allergic reaction to any component of the Pfizer-BioNTech COVID-19 Vaccine. The active components are:

   - mRNA = BNT162b2 RNA
   - ALC-0159 = 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
   - potassium chloride
   - monobasic potassium phosphate
   - dibasic sodium phosphate dihydrate
   - ALC-0315 = (4-hydroxybutyl)azanediyl) bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
   - 1,2-Distearoyl-sn-glycero-3-phosphocholine
   - sodium chloride
   - sucrose

   I attest that I, or my child, have not had any severe allergic reactions to the components listed above.

3. I understand that it is not recommended that an individual get the Pfizer-BioNTech COVID-19 Vaccine if the individual has had a severe allergic reaction after a previous dose of this vaccine. **I, or my child, have not had a severe allergic reaction to a previous dose of the Pfizer-BioNTech COVID-19 Vaccine.**

4. I understand that signs of an allergic reaction may include rash, shortness of breath and swelling of the face, lips, tongue or throat. I understand that if I experience any of these symptoms, I should contact my healthcare provider or seek emergency medical help right away.

5. I understand that I/my child will be required to wait, as instructed, after the vaccination for observation.

6. I understand that the Pfizer-BioNTech COVID-19 Vaccine is a vaccine series comprising of two injections given 21 days apart. I understand and agree that I, or my child, will receive the first AND second part of the vaccine series.

7. I understand that immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a weakened immune response to the Pfizer-BioNTech COVID-19 Vaccine.

8. I understand that Pfizer-BioNTech COVID-19 Vaccine may not fully protect all those who receive it and no guarantees or promises have been made to me concerning the effectiveness of this vaccine.

9. I understand that side effects following the Pfizer-BioNTech COVID-19 Vaccine include:

   - injection site pain,
   - tiredness,
   - headache,
   - muscle pain,
   - chills,
   - joint pain,
   - fever,
   - injection site swelling,
   - injection site redness,
   - nausea,
   - general feeling unwell, and
   - enlarged lymph nodes.

10. I understand that severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine.

11. I understand that there may be other risks or complications that are not yet known and may only become known as more people obtain the Pfizer-BioNTech COVID-19 Vaccine.

12. I understand that there is currently limited data available on the use of this vaccine in pregnant or breast-feeding women. If I am, or my child is, pregnant, breast-feeding, or may become pregnant, I should ask my doctor, or my child's doctor, for advice before receiving this vaccine.

13. I understand that Texas Children's Hospital, as the vaccination provider, must include my, or my child's, vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system. I understand that Texas Children's Hospital, as the vaccination provider, must create a medical record in its designated Electronic Medical record in order to gather information for vaccination purposes. I understand that Texas Children's Hospital is responsible for sharing data related to the COVID19 vaccinations, including the FDA, Centers for Disease Control (CDC) and other state and federal agencies, and such data sharing may include all personal information I have provided about myself and/or my child to Texas Children's Hospital for purposes of receiving this vaccine, errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

RELEASE OF LIABILITY:

I have read and understand the acknowledgements above, and I hereby release Texas Children's Hospital and their affiliated entities, and all of their agents, employees, trustees, and representatives, from any and all liability which may arise from the vaccination and/or from sharing or otherwise using the information provided to me concerning such vaccination. I understand that the Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, I am aware that I need to visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

CONSENT TO THE VACCINATION:

I have been given and read or have had read to me the Pfizer-BioNTech COVID-19 Vaccine "FDA EUA Fact Sheet for Recipients and Caregivers." I understand all risks as outlined in that fact sheet. I have been given the opportunity to ask questions to a health care

professional about the Pfizer-BioNTech COVID-19 Vaccine and have had all questions answered to my satisfaction.

I have received a Notice of Privacy Practices ("Notice"). The Notice explains how Texas Children's Hospital may use and disclose the patient's Protected Health Information for treatment, payment and health care operations purpose. "Protected Health Information" means the patient's personal health information found in the patient's medical and billing records. If you have questions about the Notice, please contact the Privacy Office at (832) 824-2091.

I hereby CONSENT to the Pfizer-BioNTech COVID-19 Vaccine and authorize Texas Children's Hospital representatives to administer two doses of the Pfizer-BioNTech COVID-19 Vaccine to me, or my child.

Vaccine Recipient Name (Printed):______________________

Vaccine Recipient Signature (Only if not a minor): ___________________________

If signing on behalf of Vaccine Recipient, I attest that I am Patient's Parent/Conservator/Legal Guardian

Parent/Conservator/Legal Guardian Name (Printed): ___________________________

Parent/Conservator /Legal Guardian Signature:______________________________

Date:_______________________________