INFORMED CONSENT ADDENDUM FOR: A PHASE 1, OPEN-LABEL DOSE-FINDING STUDY TO EVALUATE SAFETY, TOLERABILITY, AND IMMUNOGENICITY AND PHASE 2/3 PLACEBO CONTROLLED, OBSERVER-BLINDED SAFETY, TOLERABILITY, AND IMMUNOGENICITY STUDY OF A SARS-COV-2 RNA VACCINE CANDIDATE AGAINST COVID-19 IN HEALTHY CHILDREN AND YOUNG ADULTS

Protocol Number: C4591007

A change has been made to the research study you are currently taking part in. This informed consent addendum provides that additional information. All other information in the main consent form not addressed in this addendum still applies.

The following section describes the change(s). Please take as much time as you need to ask questions before agreeing to continue. If you want to drop out, you should tell your research study team who will make sure you end the research study in the safest way and inform you about follow-up care, if needed.

Change to the research study you are currently taking part in:

- If your child turns 12 years of age, before 6 months following the 2nd injection, and was given placebo at Visit 1 and Visit 2, he or she has the following 2 options: receive a BNT162b2 10-µg dose within the study (following provision of informed consent) or receive a BNT162b2 30-µg dose outside of the study.

- Please note, in May 2021 the U.S. Food and Drug Administration (FDA) that regulates vaccines issued an emergency use authorization (EUA) that allows **individuals 12 through 15 years of age to receive BNT162b2 at 30-µg**. An EUA is issued by the FDA to provide quick access to medical products, such as vaccines, that can be used when there are no other adequate, approved or available options during a public health emergency.

- As the EUA approval is age based as noted above but you opt for your 12-year-old child to receive the 10-µg within this study, please complete this informed consent.

You have the right to withdraw from this research study at any time. If after receiving this information you agree to continue taking part in this research study, please sign below.

SIGNATURES:

- I have read the information in this addendum to the informed consent document.

- I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.
- I have been given enough time to decide whether or not I want to continue in the study.
- I voluntarily agree to continue taking part in this study.
- I do not give up any of my legal rights by signing this consent document.
- I have been told that I will receive a signed and dated copy of this document.

OPTION 2: SIGNATURE LINES TO BE INCLUDED FOR A CHILD PARTICIPANT:

_____

Printed name of molecular prescreening participant

_____

Printed Name of Parent / Legally Acceptable Representative

_____ _____

Signature of Parent / Legally Acceptable Representative Date of signature§

As the consenting adult providing permission for this minor to participate in a research study I acknowledge that:

☐ I am a biological parent of this minor child and my spouse, the child's other biological parent, is aware of and in agreement with study participation or is deceased, unknown, incompetent, or not reasonably available

☐ I am the adoptive parent or legal guardian of this minor child and any other adult with whom I share legal responsibility for the care and custody of this child is aware of and in agreement with study participation or is incompetent or not reasonably available

☐ I have sole legal responsibility for the care and custody of this minor child (if legal custody is shared between divorced parents both parent signatures are required)

Signature lines if local regulations require signatures from both parents.

_____ _____

Printed Name of Parent / Legally Acceptable Representative Relationship to study participant

_____ _____

Signature of Parent / Legally Acceptable Representative Date of signature§

If local IRB permits assent of older children to be obtained by the co-signature, include appropriate signature line.

Signature of Child _____ Date of signature§ _____

Additional Signature Lines to be included:

PERSON OBTAINING CONSENT

Printed Name of the Person Conducting the Consent Discussion _____

Signature of the Person Conducting the Consent Discussion † _____ Date of signature _____

†The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same interview when the subject signs the consent document.

CONSENT FOR STUDY PARTICIPANT WHO CANNOT READ

The study participant has indicated that he/she is unable to read. One or more members of the study team read the consent document to the study participant, discussed it with the study participant, and gave the study participant an opportunity to ask questions.

Printed name of impartial witness ‡ _____

Signature of impartial witness _____ Date of signature§ _____

☐ Not applicable (*Check this box if the Signature of an impartial witness is not required. Signature of an impartial witness is required if the subject or subject's legal representative cannot read.*)

§Subject/legally acceptable representative/impartial witness must personally date their signature.

‡ Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the subject or the subject's legal representative cannot read, and who reads the informed consent and any other written information supplied to the subject. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance.