16.1.3 List of IECs or IRBs (plus the name of the Committee Chair if required by the Regulatory Authority) and representative written information for subject and sample consent forms

For the List of IECs or IRBs, please refer to the Appendix 16.1.3 of the mRNA-1273-P301 Part A study.

The sample informed consent forms are provided on the following pages.

Informed Consent Form Addendum to Master ICF, dated 22 Dec 2020

Informed Consent Form Addendum to Master ICF, dated 04 Jan 2021

Informed Consent Form Addendum Version 2.0 dated 25 Mar 2021

INFORMED CONSENT FORM ADDENDUM to MASTER ICF

Sponsor / Study Title:	**ModernaTX, Inc. / "A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older"**
Protocol Number:	**mRNA-1273-P301**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

In the Informed Consent Form you signed when you agreed to take part in this study, you were told you would be informed if there was new or updated information about the study. The purpose of this additional form, called an "Informed Consent Form Addendum," is to provide you with new information since the last Informed Consent Form you signed.

In December 2020, the United States Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) to multiple vaccines for the coronavirus disease (COVID-19), including Moderna's mRNA-1273 vaccine. This means that the mRNA-1273 vaccine has a special authorization by the FDA to be used outside of clinical trials in a health emergency like the current pandemic. This authorization was granted after the FDA's review of the safety and efficacy (how well the vaccine protects against COVID-19) data that has been observed to date.

Although the study has had initial success, it is not completed, and we continue to gain valuable information from your participation. In this document, we want to provide you with additional information about the safety and efficacy data of the study and the changes to the study visits and procedures.

This Addendum includes updates to the following sections from your original Informed Consent Form:

What are the potential risks and discomforts?

This section is being updated because since you agreed to take part in the study more than 15,600 participants in this study, and other ongoing studies have received at least one dose of the mRNA-1273 vaccine, with most participants in all studies combined receiving two doses. Data gathered from these participants to date have been analyzed.

The most frequent common side effects that we have seen so far typically occur in the week after receiving a dose of mRNA-1273 and are the following:

- Fever
- Pain at the injection site
- Redness and hardness of the skin at the injection site
- Headache
- Muscle aches or pain
- Joint aches or pain
- Fatigue (tiredness)
- Nausea/vomiting
- Chills
- Under arm gland swelling on the side of study vaccination

Not every study participant experienced all of these side effects, which have been generally mild to moderate in severity. These side effects have been reported more often after the second dose of the mRNA-1273 vaccine and as typically lasting 2 to 3 days in duration anytime they occurred.

While we have not seen this in the studies so far, there is a very small chance that the mRNA-1273 could cause a severe reaction shortly after vaccination (within minutes to about one hour after receiving a dose). Symptoms of a severe reaction might include difficulty breathing, a fast heartbeat, a bad rash all over your body, dizziness, weakness, or swelling of your face and throat.

Are there risks if you become infected with the coronavirus after receiving the study vaccine?

To date, we have observed that there have been fewer cases of severe COVID-19 in participants who received the mRNA-1273 vaccine compared to those who received placebo. This continues to reassure us currently that the vaccine does not increase your risk for severe illness. We will continue to monitor this closely and let you know if that changes.

What are the advantages and disadvantages of participation in the study?

In this study, we followed all participants closely after two doses of either placebo or mRNA-1273 to see if they became sick with COVID-19. In November 2020, the data were analyzed by Moderna and reviewed by an independent group of safety experts. It was determined that the vaccine was approximately 94% effective at preventing COVID-19 (this also called “vaccine efficacy”). This means that for every 100 people exposed to the virus, the vaccine should prevent about 94 of them from getting sick with COVID-19. This result

means that the study achieved its main goal to show if the mRNA-1273 vaccine can protect people from getting sick with COVID-19.

If you received two doses of the mRNA-1273 vaccine as part of the study, we believe that you now have the benefit of protection against getting sick with COVID-19. However, it is important for you to understand there are some limitations and aspects of the vaccine that we are still trying to learn more about which are listed below:

- The vaccine is not 100% effective and a few people who have received the vaccine have still gotten sick with COVID-19.
- We do not know yet if people who received the vaccine and became infected can still carry the virus and pass it to other people around them.
- If you only received one dose of mRNA-1273 vaccine during the study, you might have some level of protection but likely not as much as those who received two doses. We have not fully studied how well the vaccine works with just one dose, and we think the best protection against becoming sick with COVID-19 starts about two weeks after receiving your second dose.
- Lastly, we do not know for how long our vaccine protects you from getting sick, which means your protection could wear off at any time, and we do not know when this might happen.

Therefore, even if you think you received the vaccine, we strongly encourage you to still follow all instructions from your study doctor and local guidance around limiting your exposure to the virus (e.g., social distancing, mask wearing, and hand-washing).

The study team is very thankful for your dedication to this study. Although we have learned a lot about this vaccine based on your contributions so far, your continued participation in the study will help provide additional scientific information that will benefit the general population in the future.

Are there any alternative treatments?

While there are no COVID-19 vaccines that are yet approved with a full license and broadly available in the United States, the FDA has granted EUA to multiple COVID-19 vaccines in December 2020, including the mRNA-1273 vaccine. COVID-19 vaccines are initially limited in supply under EUA. Therefore, they are available only to some people in the general public that are considered to be at high risk of exposure to the virus or at risk of poor outcomes if they get sick. We expect that COVID-19 vaccines will be extended to more people on a rolling basis through the first half of 2021 when more vaccine doses become available.

As an alternative to continued participation, you may be able to receive a COVID-19 vaccine outside the study based on the current recommendations by the government on populations that are prioritized to receive the vaccine. This will vary based on your status (e.g., age, occupation, and health status), as well as availability of any COVID-19 vaccines in your region. If you receive a COVID-19 vaccine outside of the study, you will not be able to continue your participation.

Your study doctor will be able to tell you specifically about the availability of COVID-19 vaccines under EUA in your local area. Your study doctor will also talk to you about options for receiving the mRNA-1273 vaccine (if you received placebo or only 1 dose of mRNA-1273) through your continued participation in this study.

Study Procedures

All participants were originally selected for this study because they were at high risk for exposure to the severe acute respiratory syndrome coronavirus 2 (SARs-CoV-2; the virus that causes the disease called COVID-19) and, in some cases, also at high risk for worse outcomes if they became sick with COVID-19. As we have shown the vaccine to be effective protecting people from getting sick with COVID-19, we are changing the design to offer participants options for continuing in the study based on this new information:

1. You can remain “blinded” (not know what treatment you received) and continue participation as originally planned.

2. You can request to be “unblinded,” which means learning if you received the mRNA-1273 vaccine or placebo and continue study participation.

If you choose option #1, we would like to collect an additional blood sample and nasopharyngeal swab at the time of this visit. The blood sample will be approximately 20mL (or about 4 teaspoons). You will then continue with your study visits as originally planned.

If you choose option #2, we would like to invite you to continue participation following the original study schedule with the potential for up to 3 extra clinic visits and 2 additional safety calls based on whether you received mRNA-1273 or placebo. We call this new set of study activities “Study Part B - Open Label,” and it is completed in addition to your original plan of study procedures and visits. Details for each of the visits and what will occur at each visit are provided in the table below:

STUDY PART B – OPEN LABEL

Visit	When	What Will Be Done
Open Label Visit – Day 1	Completed for all participants	• Review updated study information as part of informed consent • Medication review and discussion of any changes in your health since your last study contact • Blood sample collection • 1 nasopharyngeal swab for SARS-CoV-2 testing • Unblinding (if you choose): You are told whether you received placebo or mRNA-1273. **Two-Dose mRNA-1273 Participants ONLY**: • Receive documented confirmation of vaccine receipt **Placebo or Single-Dose mRNA-1273 Participants ONLY**: • mRNA-1273 offered • Confirmation that you may receive vaccine after review of inclusion /exclusion criteria • Symptom-directed physical examination (including vital signs) • Pregnancy test • Study vaccination with mRNA-1273 • 30-minute observation after study vaccination
Open Label – Day 8 Safety Call	Safety call is performed approximately 8 days after the 1st study vaccination. **(ONLY if mRNA-1273 Received at OPEN LABEL DAY 1)**	• Medication review and discussion of any changes in your health since the last visit, including presence of any COVID-19 symptoms

Visit	When	What Will Be Done
Open Label Visit – Day 29	Approximately 1 month after the first study vaccination (second study vaccination) **(ONLY if mRNA-1273 Received at OPEN LABEL DAY 1)**	• Medication review and discussion of any changes in your health since your vaccination • Symptom-directed physical examination (including vital signs) • Pregnancy test • Blood sample collection (*only for participants who get 1 dose of mRNA-1273 in Study Part B*) • Second study vaccination with mRNA-1273 (if previously received 2 placebo vaccinations) • 30-minute observation after study vaccination
Open Label – Day 36 Safety Call	Safety call is performed approximately 8 days after the 2nd study vaccination. **(ONLY if mRNA-1273 Received at OPEN LABEL DAY 29)**	• Medication review and discussion of any changes in your health since the last visit, including presence of any COVID-19 symptoms
Open Label Visit – Day 57	Approximately 2 months after the first study vaccination **(ONLY if mRNA-1273 Received at OPEN LABEL DAY 29)**	• Medication review and discussion of any changes in your health since your study vaccination • Symptom-directed physical examination (including vital signs) • Blood sample collection

If you find out you received two doses of mRNA-1273 vaccine, you only need to complete the Open-Label Day 1 activities as described in the above table. You will then continue to be followed in the study according to your original schedule. Your study doctor can also provide you documentation that you received the vaccine.

If you find out you have received placebo and your study doctor determines that you still meet the criteria for participation in the study, you will have the option to receive two doses of the mRNA-1273 vaccine, with each dose given approximately one month apart. When you receive your first dose you will be given a vaccination card to bring back when you return for your second dose. We ask that you then come back to the clinic for an extra visit about 1 month after the second dose to evaluate your health and collect a follow-up blood sample of approximately 20mL (or about 4 teaspoons). After that visit, you will continue with the original study schedule for weekly eDiary prompts and monthly safety calls to monitor your health, including the presence of potential COVID-19 symptoms. If you have COVID-19 symptoms, you will have an illness visit for evaluation and a nasopharyngeal swab to test for the virus.

If you only received one dose of mRNA-1273 during the study for any reason your study doctor will offer you an opportunity to receive an additional dose if you meet criteria to receive mRNA-1273. You will follow the visit schedule above except you will not receive a second dose at the Day 29 visit and you do not need to complete the Day 36 phone call and Day 57 visit. You will still need to come to the clinic at Day 29 to be evaluated and have a blood sample drawn of approximately 20mL (or about 4 teaspoons).

If the additional visits (clinic visit or phone call) for the Study Part B overlap with already planned visits for the study, they may be combined and you will only have study procedures done once. Your study doctor can tell you if this will happen.

If you received placebo or only one dose of mRNA-1273 and you became sick with COVID-19 during the study, you are still eligible to receive mRNA-1273 in this new part of the study based on your study doctor's evaluation of your health. We do not know for sure, but we think there is the potential that the vaccine can provide you added protection, so this option is offered to you. The types and rates of side effects are similar between those participants who received the vaccine after being infected with the SARs-CoV-2 virus and those who had never been infected before they receive the mRNA-1273 vaccine.

You do not need to commit to receiving the vaccine to know what you originally received in the study. You may unblind and discover that you received placebo, but then decide not to receive the nRNA-1273 vaccine for any reason. This is okay and does not impact your ability to continue in the study. However, if you receive a COVID-19 vaccine outside of this study, you will not be able to continue in the study.

You will continue to be followed to your original end-of-study visit approximately 25 months after you originally entered the study and received either mRNA-1273 vaccine or placebo.

Is there a payment if you decide to participate in the Study Part B - Open Label period of the study?

<*Compensation*>

Conclusion

This Addendum does not replace the most recent version of the Informed Consent that you already signed. It simply adds updated information to it.

By signing this Addendum, you confirm that you received updated information about study mRNA-1273-P301, and you agree to continue taking part in the study.

As you have been told, taking part in this study is voluntary. This means that you can choose whether you want to continue in the study after receiving this updated information.

You can choose to stop being in the study at any time and for any reason. If you decide to stop taking part in the study, there will be no penalty and you will not lose any benefits you are supposed to receive. Choosing to no longer take part in the study will not affect the quality of the health care you are given.

Statement of Consent

- I have read and understand the statements in this Informed Consent Form Addendum.
- I have had the chance to ask questions, and I am satisfied with the answers given to me.
- I agree to continue taking part in this study of my own free will.
- I understand that I and/or my legal representative will receive a copy of this signed and dated Addendum.
- Based on the new information shared in this Informed Consent Addendum, I would like to continue in the study in the following manner (check the appropriate boxes):

☐ I wish to continue participation in the study and know my treatment assignment. (check one box below)

☐ If I find out that I received placebo, I wish to receive the mRNA-1273 vaccine.

☐ If I find out that I received placebo, I do not want to receive the mRNA-1273 vaccine.

☐ I wish to continue participation in the study without unblinding my treatment assignment.

☐ I do not wish to continue participation in the study and I wish to know my treatment assignment.

_____

Printed Name of Participant, in full

_____

Signature of Participant **Date (DD-Mmm-YYYY)**

- I have presented the study updates and answered the participant's questions.
- I will give the participant/legal representative a copy of this signed and dated Informed Consent Form Addendum.

_____

Printed Name of Person Obtaining Consent (Study Doctor/Delegate), in full

_____

Signature of Person Obtaining Consent **Date (DD-Mmm-YYYY)**

If required,

_____

Printed Name of Legally Authorized Representative or Legal Guardian (if participant is a minor), in full

_____

Signature of Legally Authorized Representative or Legal Guardian (if participant is a minor) ***Date (DD-Mmm-YYYY)***

If required,

_____

Printed Name of Impartial Witness, in full

_____

Signature of Witness **Date (DD-Mmm-YYYY)**

INFORMED CONSENT FORM ADDENDUM to MASTER ICF

Sponsor / Study Title:	**ModernaTX, Inc. / "A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older"**
Protocol Number:	**mRNA-1273-P301**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

In the Informed Consent Form you signed when you agreed to take part in this study, you were told you would be informed if there was new or updated information about the study. The purpose of this additional form, called an "Informed Consent Form Addendum," is to provide you with new information since the last Informed Consent Form you signed.

In December 2020, the United States Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) to multiple vaccines for the coronavirus disease (COVID-19), including Moderna's mRNA-1273 vaccine. This means that the mRNA-1273 vaccine has a special authorization by the FDA to be used outside of clinical trials in a health emergency like the current pandemic. This authorization was granted after the FDA's review of the safety and efficacy (how well the vaccine protects against COVID-19) data that has been observed to date.

Although the study has had initial success, it is not completed, and we continue to gain valuable information from your participation. In this document, we want to provide you with additional information about the safety and efficacy data of the study and the changes to the study visits and procedures.

This Addendum includes updates to the following sections from your original Informed Consent Form:

What are the potential risks and discomforts?

This section is being updated because since you agreed to take part in the study more than 15,600 participants in this study, and other ongoing studies have received at least one dose

of the mRNA-1273 vaccine, with most participants in all studies combined receiving two doses. Data gathered from these participants to date have been analyzed.

The most frequent common side effects that we have seen so far typically occur in the week after receiving a dose of mRNA-1273 and are the following:

- Fever
- Pain at the injection site
- Redness and hardness of the skin at the injection site
- Headache
- Muscle aches or pain
- Joint aches or pain
- Fatigue (tiredness)
- Nausea/vomiting
- Chills
- Under arm gland swelling on the side of study vaccination

Not every study participant experienced all of these side effects, which have been generally mild to moderate in severity. These side effects have been reported more often after the second dose of the mRNA-1273 vaccine and as typically lasting 2 to 3 days in duration anytime they occurred.

While we have not seen this in the studies so far, there is a very small chance that the mRNA-1273 could cause a severe reaction, also called “anaphylaxis”, shortly after vaccination (within minutes to about one hour after receiving a dose). Symptoms of a severe reaction might include difficulty breathing, a fast heartbeat, a bad rash all over your body, dizziness, weakness, or swelling of your face and throat.

Anaphylaxis has been reported following administration of mRNA-1273 vaccine in the general public after emergency use authorization. It is important that you tell your study doctor if you have a known allergy or have had previous episodes of severe reactions.

Are there risks if you become infected with the coronavirus after receiving the study vaccine?

To date, we have observed that there have been fewer cases of severe COVID-19 in participants who received the mRNA-1273 vaccine compared to those who received placebo. This continues to reassure us currently that the vaccine does not increase your risk for severe illness. We will continue to monitor this closely and let you know if that changes.

What are the advantages and disadvantages of participation in the study?

In this study, we followed all participants closely after two doses of either placebo or mRNA-1273 to see if they became sick with COVID-19. In November 2020, the data were analyzed by Moderna and reviewed by an independent group of safety experts. It was determined that the vaccine was approximately 94% effective at preventing COVID-19 (this also called “vaccine efficacy”). This means that for every 100 people exposed to the virus, the vaccine should prevent about 94 of them from getting sick with COVID-19. This result means that the study achieved its main goal to show if the mRNA-1273 vaccine can protect people from getting sick with COVID-19.

If you received two doses of the mRNA-1273 vaccine as part of the study, we believe that you now have the benefit of protection against getting sick with COVID-19. However, it is important for you to understand there are some limitations and aspects of the vaccine that we are still trying to learn more about which are listed below:

- The vaccine is not 100% effective and a few people who have received the vaccine have still gotten sick with COVID-19.
- We do not know yet if people who received the vaccine and became infected can still carry the virus and pass it to other people around them.
- If you only received one dose of mRNA-1273 vaccine during the study, you might have some level of protection but likely not as much as those who received two doses. We have not fully studied how well the vaccine works with just one dose, and we think the best protection against becoming sick with COVID-19 starts about two weeks after receiving your second dose.
- Lastly, we do not know for how long our vaccine protects you from getting sick, which means your protection could wear off at any time, and we do not know when this might happen.

Therefore, even if you think you received the vaccine, we strongly encourage you to still follow all instructions from your study doctor and local guidance around limiting your exposure to the virus (e.g., social distancing, mask wearing, and hand-washing).

The study team is very thankful for your dedication to this study. Although we have learned a lot about this vaccine based on your contributions so far, your continued participation in the study will help provide additional scientific information that will benefit the general population in the future.

Are there any alternative treatments?

While there are no COVID-19 vaccines that are yet approved with a full license and broadly available in the United States, the FDA has granted EUA to multiple COVID-19 vaccines in December 2020, including the mRNA-1273 vaccine. COVID-19 vaccines are initially limited in supply under EUA. Therefore, they are available only to some people in the general public that are considered to be at high risk of exposure to the virus or at risk of poor outcomes if they get sick. We expect that COVID-19 vaccines will be extended to more people on a rolling basis through the first half of 2021 when more vaccine doses become available.

As an alternative to continued participation, you may be able to receive a COVID-19 vaccine outside the study based on the current recommendations by the government on populations that are prioritized to receive the vaccine. This will vary based on your status (e.g., age, occupation, and health status), as well as availability of any COVID-19 vaccines in your region. If you receive a COVID-19 vaccine outside of the study, you will not be able to continue your participation.

Your study doctor will be able to tell you specifically about the availability of COVID-19 vaccines under EUA in your local area. Your study doctor will also talk to you about options for receiving the mRNA-1273 vaccine (if you received placebo or only 1 dose of mRNA-1273) through your continued participation in this study.

Study Procedures

All participants were originally selected for this study because they were at high risk for exposure to the severe acute respiratory syndrome coronavirus 2 (SARs-CoV-2; the virus that causes the disease called COVID-19) and, in some cases, also at high risk for worse outcomes if they became sick with COVID-19. As we have shown the vaccine to be effective protecting people from getting sick with COVID-19, we are changing the design to offer participants options for continuing in the study based on this new information:

1. You can remain “blinded” (not know what treatment you received) and continue participation as originally planned.

2. You can request to be “unblinded,” which means learning if you received the mRNA-1273 vaccine or placebo and continue study participation.

If you choose option #1, we would like to collect an additional blood sample and nasopharyngeal swab at the time of this visit. The blood sample will be approximately 20mL (or about 4 teaspoons). You will then continue with your study visits as originally planned.

If you choose option #2, we would like to invite you to continue participation following the original study schedule with the potential for up to 3 extra clinic visits and 2 additional safety calls based on whether you received mRNA-1273 or placebo. We call this new set of study activities "Study Part B - Open Label," and it is completed in addition to your original plan of study procedures and visits. Details for each of the visits and what will occur at each visit are provided in the table below:

STUDY PART B – OPEN LABEL

Visit	When	What Will Be Done
Open Label Visit – Day 1	Completed for all participants	• Review updated study information as part of informed consent • Medication review and discussion of any changes in your health since your last study contact • Blood sample collection • 1 nasopharyngeal swab for SARS-CoV-2 testing • Unblinding (if you choose): You are told whether you received placebo or mRNA-1273. **Two-Dose mRNA-1273 Participants ONLY**: • Receive documented confirmation of vaccine receipt **Placebo or Single-Dose mRNA-1273 Participants ONLY**: • mRNA-1273 offered • Confirmation that you may receive vaccine after review of inclusion /exclusion criteria • Symptom-directed physical examination (including vital signs) • Pregnancy test • Study vaccination with mRNA-1273 • 30-minute observation after study vaccination
Open Label – Day 8 Safety Call	Safety call is performed approximately 8 days after the 1st study vaccination.	• Medication review and discussion of any changes in your health since the last visit, including presence of any COVID-19 symptoms

Visit	When	What Will Be Done
	(ONLY if mRNA-1273 Received at OPEN LABEL DAY 1)	
Open Label Visit – Day 29	Approximately 1 month after the first study vaccination (second study vaccination) **(ONLY if mRNA-1273 Received at OPEN LABEL DAY 1)**	• Medication review and discussion of any changes in your health since your vaccination • Symptom-directed physical examination (including vital signs) • Pregnancy test • Blood sample collection (*only for participants who get 1 dose of mRNA-1273 in Study Part B*) • Second study vaccination with mRNA-1273 (if previously received 2 placebo vaccinations) • 30-minute observation after study vaccination
Open Label – Day 36 Safety Call	Safety call is performed approximately 8 days after the 2nd study vaccination. **(ONLY if mRNA-1273 Received at OPEN LABEL DAY 29)**	• Medication review and discussion of any changes in your health since the last visit, including presence of any COVID-19 symptoms
Open Label Visit – Day 57	Approximately 2 months after the first study vaccination **(ONLY if mRNA-1273 Received at OPEN LABEL DAY 29)**	• Medication review and discussion of any changes in your health since your study vaccination • Symptom-directed physical examination (including vital signs) • Blood sample collection

If you find out you received two doses of mRNA-1273 vaccine, you only need to complete the Open-Label Day 1 activities as described in the above table. You will then continue to be followed in the study according to your original schedule. Your study doctor can also provide you documentation that you received the vaccine.

If you find out you have received placebo and your study doctor determines that you still meet the criteria for participation in the study, you will have the option to receive two doses of the mRNA-1273 vaccine, with each dose given approximately one month apart. When you receive your first dose you will be given a vaccination card to bring back when you return for your second dose. We ask that you then come back to the clinic for an extra visit about 1 month after the second dose to evaluate your health and collect a follow-up blood sample of

approximately 20mL (or about 4 teaspoons). After that visit, you will continue with the original study schedule for weekly eDiary prompts and monthly safety calls to monitor your health, including the presence of potential COVID-19 symptoms. If you have COVID-19 symptoms, you will have an illness visit for evaluation and a nasopharyngeal swab to test for the virus.

If you only received one dose of mRNA-1273 during the study for any reason your study doctor will offer you an opportunity to receive an additional dose if you meet criteria to receive mRNA-1273. You will follow the visit schedule above except you will not receive a second dose at the Day 29 visit and you do not need to complete the Day 36 phone call and Day 57 visit. You will still need to come to the clinic at Day 29 to be evaluated and have a blood sample drawn of approximately 20mL (or about 4 teaspoons).

If the additional visits (clinic visit or phone call) for the Study Part B overlap with already planned visits for the study, they may be combined and you will only have study procedures done once. Your study doctor can tell you if this will happen.

If you received placebo or only one dose of mRNA-1273 and you became sick with COVID-19 during the study, you are still eligible to receive mRNA-1273 in this new part of the study based on your study doctor's evaluation of your health. We do not know for sure, but we think there is the potential that the vaccine can provide you added protection, so this option is offered to you. The types and rates of side effects are similar between those participants who received the vaccine after being infected with the SARs-CoV-2 virus and those who had never been infected before they receive the mRNA-1273 vaccine.

You do not need to commit to receiving the vaccine to know what you originally received in the study. You may unblind and discover that you received placebo, but then decide not to receive the mRNA-1273 vaccine for any reason. This is okay and does not impact your ability to continue in the study. However, if you receive a COVID-19 vaccine outside of this study, you will not be able to continue in the study.

You will continue to be followed to your original end-of-study visit approximately 25 months after you originally entered the study and received either mRNA-1273 vaccine or placebo.

Is there a payment if you decide to participate in the Study Part B - Open Label period of the study?

You may be compensated for your time and effort in accordance with the visits and amounts listed in the consent you previously signed. Please discuss this with the study staff for more information.

Whom to Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:

  Study Subject Adviser

  Advarra IRB

  6940 Columbia Gateway Drive, Suite 110

  Columbia, MD 21046

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00044270.

Conclusion

This Addendum does not replace the most recent version of the Informed Consent that you already signed. It simply adds updated information to it.

By signing this Addendum, you confirm that you received updated information about study mRNA-1273-P301, and you agree to continue taking part in the study.

As you have been told, taking part in this study is voluntary. This means that you can choose whether you want to continue in the study after receiving this updated information.

You can choose to stop being in the study at any time and for any reason. If you decide to stop taking part in the study, there will be no penalty and you will not lose any benefits you are supposed to receive. Choosing to no longer take part in the study will not affect the quality of the health care you are given.

Statement of Consent

- I have read and understand the statements in this Informed Consent Form Addendum.
- I have had the chance to ask questions, and I am satisfied with the answers given to me.
- I agree to continue taking part in this study of my own free will.
- I understand that I and/or my legal representative will receive a copy of this signed and dated Addendum.
- Based on the new information shared in this Informed Consent Addendum, I would like to continue in the study in the following manner (check the appropriate boxes):

☐ I wish to continue participation in the study and know my treatment assignment. (check one box below)

☐ If I find out that I received placebo, I wish to receive the mRNA-1273 vaccine.

☐ If I find out that I received placebo, I do not want to receive the mRNA-1273 vaccine.

☐ I wish to continue participation in the study without unblinding my treatment assignment.

☐ I do not wish to continue participation in the study and I wish to know my treatment assignment.

_____

Printed Name of Participant, in full

_____

Signature of Participant **Date (DD-Mmm-YYYY)**

- I have presented the study updates and answered the participant's questions.
- I will give the participant/legal representative a copy of this signed and dated Informed Consent Form Addendum.

_____

Printed Name of Person Obtaining Consent (Study Doctor/Delegate), in full

_____

Signature of Person Obtaining Consent **Date (DD-Mmm-YYYY)**

If required,

_____

Printed Name of Legally Authorized Representative or Legal Guardian (if participant is a minor), in full

_____

Signature of Legally Authorized Representative or Legal Guardian (if participant is a minor) ***Date (DD-Mmm-YYYY)***

If required,

_____

Printed Name of Impartial Witness, in full

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Signature of Witness **Date (DD-Mmm-YYYY)**

Informed Consent Form Addendum

INFORMED CONSENT FORM ADDENDUM V.2 25Mar2021

Note: Addendum V.2 25Mar2021 is for Participants that have not returned for their Participant Decision Visit or have previously had their Participant Decision Visit and chose not to be unblinded.

STUDY TITLE:	ModernaTX, Inc. / "A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older"
PROTOCOL NUMBER:	mRNA-1273-P301
CLIENT:	Moderna
STUDY DOCTOR:	[Investigator Name] [Site Address] [Office Hours Tel] [Out of Hours Tel]
ETHICS COMMITTEE or INSTITUTIONAL REVIEW BOARD:	[EC/IRB Name] [EC/IRB Address] [Office Hours Tel]

In the Informed Consent Form you signed and dated when you agreed to take part in this study, you were told that you would be informed if there was new or updated information about the study.

The purpose of this additional form called an addendum is to provide you with new information that has become known since the last Addendum that you signed.

This addendum includes the following updates:

In the Study Procedures section of the informed consent form (ICF), the Participant Decision visit in Part B of this study is still a key visit for Part B and is now important to complete as it is mandatory that you become unblinded during this visit to understand what you received in Part A (mRNA-173 or placebo). Therefore, at the Participant Decision Visit, you will be told if you received mRNA-1273 or placebo. However, the choice to receive mRNA-1273 (if you received placebo) is no longer an option because study vaccine is no longer available. At the Participant Decision visit you will have a nasopharyngeal swab and blood test, be unblinded, and then you will remain in the study and continue participation as originally planned.

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We would also like to inform you that at the time of the first database lock, we will unblind any remaining participants that have not been unblinded to confirm what they received in Part A of the study (mRNA-1273 or placebo). This information will be provided to your study site and your site will share the information with you if you have not previously received it.

Once you know your Part A treatment assignment, if you choose to receive a vaccine outside the study, you will need to be discontinued from the study.

This addendum does not replace the most recent version of the Informed Consent that you already signed. It simply adds updated information to it.

By signing this addendum, you confirm that you received updated information about study mRNA-1273-P301 and you agree to continue taking part in the study.

As you have been told, taking part in this study is voluntary. This means that you can choose whether or not you want to continue in the study after receiving this updated information.

You can choose to stop being in the study at any time and for any reason. If you decide to stop taking part in the study, there will be no penalty and you will not lose any benefits you are supposed to receive. Choosing to no longer take part in the study will not affect the quality of the health care you are given.

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Whom to Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns, or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:

  Study Subject Adviser

  Advarra IRB

  6100 Merriweather Drive, Suite 600

  Columbia, MD 21044

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00044270.

Informed Consent Form Addendum

Statement of Consent

- I have read and understand the statements in this Informed Consent Form Addendum.
- I have had the chance to ask questions, and I am satisfied with the answers given to me.
- I agree to continue taking part in this study of my own free will.
- I understand that I and/or my legal representative will receive a copy of this signed and dated Addendum.

_____

Printed Name of Patient, in full

_____

Signature of Patient **Date (DD-Mmm-YYYY)**

<PIFullName>

Informed Consent Form Addendum

- I have presented the study updates and answered the participants's questions.
- I will give the participant/legal representative a copy of this signed and dated Informed Consent Form Addendum.

Printed Name of Person Obtaining Consent (Investigator/Delegate), in full

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Signature of Person Obtaining Consent **Date (DD-Mmm-YYYY)**

If required,

Printed Name of Impartial Witness, in full

Signature of Witness **Date (DD-Mmm-YYYY)**

<PIFullName>