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Sample Informed Consent Form Template (Appendix C of Phase 3 study of Vaccine Candidate for COVID-19)

In 1 collection

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1 Works for me dx.doi.org/10.17504/protocols.io.bj6dkra6

Coronavirus Method Development Community PATH

Chris Ockenhouse

ABSTRACT

This is Appendix C of "Phase 3 randomized, double-blinded, placebo-controlled trial to evaluate the safety, immunogenicity, and efficacy of **Vaccine Candidate** against COVID-19 in adults > 18 years of age"

This generic Phase 3 protocol was developed by the PATH team with support of the Bill and Melinda Gates Foundation. The aim of the collection is to share recommended best practices in designing and implementing a Phase 3 study of a COVID-19 vaccine candidate. As Phase 3 trials of different Vaccine Candidates proceed around the world, following the same protocols will ensure consistency and comparability of the Phase 3 trial results.

Please note that this is an evolving document, to be versioned and updated, based on community feedback and new data.

ATTACHMENTS

Generic Phase 3 Protocol
COVID-19 Vaccine -
25AUG2020-version
1.docx

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COLLECTIONS ⓘ

PATH **Collection of Protocols and Guidelines for Phase 3 study of Vaccine Candidate for COVID-19**

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[Collection of Protocols and Guidelines for Phase 3 study of Vaccine Candidate for COVID-19](#)

GUIDELINES

APPENDIX C: SAMPLE INFORMED CONSENT FORM TEMPLATE

Phase 3 randomized, double-blinded, placebo-controlled trial to evaluate the safety, immunogenicity, and efficacy of *Vaccine Candidate* against COVID-19 in adults ≥ 18 years of age

Research Team

-
- <NAME, CREDENTIALS>
<PHONE NUMBER>
 - <NAME, CREDENTIALS>
<PHONE NUMBER>
-

1. We are asking you to be in a research study.

A research study is a way to learn new things. It is not the same as treatment or medical care. This is a study about an experimental vaccine for COVID-19 called **NAME OF VACCINE**. From now on, we will call it the “study vaccine.” We are asking you to be in the study because you are healthy and you live or work in an area that has high rates of COVID-19 infection. We plan to select about **XX** people to be in the study.

This form explains what will happen in this study. We will tell you the risks and benefits of being in the study. Take your time to decide if joining the study is right for you. If it helps, talk to people you trust. Ask questions about anything that is not clear. If you decide to join, you will sign this form. We will give you a copy to keep.

Researchers from **SPONSOR** and **<NAME OF RESEARCH PARTNERS/SITE>** are conducting this study. **[NAME]** is providing funding for the study.

2. Here is a summary of the study:

- We are testing a vaccine for COVID-19 in this study. We are comparing this study vaccine to **[ANOTHER VACCINE or PLACEBO]**. You will have an equal chance of getting the study vaccine or the **comparator vaccine/placebo**. *If a placebo is used: A placebo is a substance that looks like the vaccine, but does not have the vaccine in it.*
- You do not have to be in the study. You can say “yes” or “no” or leave after joining. If you say “no” or drop out, we will treat you the same. *If in health care setting: Any care you or your family receive here will not change.*
- If you join, you will be in the study for one year. You will have seven planned visits to the study clinic. We may ask you to come for more visits, if needed.
- The study involves these procedures:
 - Answering questions about yourself and your health.
 - Physical exams.

- Nasal swabbing for COVID-19 testing.
 - Blood draws.
 - Getting two injections in your upper arm of either the study vaccine or **comparator vaccine/placebo**, about two weeks apart.
 - For some participants: recording if you have any side effects.
 - Phone calls or electronic messaging.
 - If you become infected with COVID-19: doing testing and medical procedures that help manage your health.
- All vaccines may have side effects. You may have headache, nausea, vomiting, abdominal pain, diarrhea, fever, chills, tiredness, and muscle and joint aches. You may have pain, redness, itchiness, and swelling where you got the injection. There can be very rare but serious risks, too. We will tell you more about these. The COVID-19 vaccine in this study has been tested in **XX** people before. These earlier studies showed that it is okay to test the study vaccine in many more people, like we will do in this research study.
 - We do not know if the study vaccine will protect you from COVID-19. The study vaccine may do nothing, it may protect you, or there is a very rare chance it could make COVID-19 disease worse for you or others who take it. (We tell you more about this later.) Also, you may not get the study vaccine. Because of all of these things, you must continue to practice safe distancing, proper handwashing, and mask-wearing throughout the study to protect yourself from COVID-19.
 - Being in this study may not help you personally, but it might. If we find that the study vaccine protects against COVID-19, then those who got the vaccine are likely to have protection. Those who got the **comparator vaccine/placebo** will be offered the study vaccine so they, too, can have a chance for protection from COVID-19. We do not know how long the protection will last.
 - There are no costs to you to be in the study.
 - If you join this study and receive the study vaccine, you probably will not be able to join other research studies of COVID-19 vaccines.
 - We are not sure how getting the study vaccine now will affect your body's reaction to a future, approved vaccine for COVID-19.
 - **<DESCRIBE ANY PAYMENTS TO PARTICIPANTS, e.g., "We will pay you \$10 for each study visit">**.
 - We will keep your study information confidential.
 - Those who are able to get pregnant must agree to use birth control to be in this study.
 - We will ask to keep your left-over blood samples for future research. You can say "no" to sample storage and still be in the study.

3. What do we want to learn in this study?

This study is about a vaccine for COVID-19. COVID-19 is a respiratory infection that has spread around the world. The infection is caused by a virus called SARS-CoV-2. From now on, we will call it "the COVID-19 virus." People can catch the virus by breathing the air near people who are infected. They may also get the virus by touching something that has the virus on it and then touching their eyes, nose, or mouth. Keeping distance from others, wearing a mask, and frequent hand washing are important ways to prevent infection.

COVID-19 infection causes a wide range of health issues. Some people show no symptoms, while others experience serious medical problems and need a ventilator to help them breathe. Many people have died from the virus.

In the end, the best protection against COVID-19 will be an effective vaccine. That is what this research study is about. Everyone's body has an immune system—special cells that act together to fight viruses and other invaders. The study vaccine is designed to help prepare the immune system to fight the real COVID-19 virus if it enters the body.

What is the vaccine in this study? The study vaccine is called **[NAME]**. It is made by **[COMPANY]**. The study vaccine was tested in **XX** people in earlier studies with no serious health concerns. Results of earlier studies show that we can test the study vaccine in larger groups of people. The study vaccine does not contain the live COVID-19 virus, so there is no way that you can get COVID-19 infection or give it to others from taking the study vaccine.

We would like to answer these questions in the study:

- Does the study vaccine prevent infection with the COVID-19 virus?
- Can people take the study vaccine safely and without too much discomfort?
- Does study vaccine work well to prepare someone's immune system to fight a COVID-19 infection?

4. Will this study help you?

Being in this research study may not help you personally, but there is a chance it might. Everyone in the study receives physical exams and follow-up of any health issues that arise during the study. You may find this helpful.

If we see that the study vaccine is safe and effective, we will offer it to everyone in the study. This will be a benefit to you and others in the study. But it is also possible that the study vaccine may not protect people from COVID-19 infection. It may even cause harm, although we do not think this is likely.

5. Protecting yourself from COVID-19 infection during the study

Because we do not know if the study vaccine will protect you or others against the COVID-19 virus and half of participants will not get the study vaccine, you must do these things to continue to protect yourself:

- **Keep your distance.** Stay at least 2-3 meters (6-9 feet) away from others who are not in your household.
- **Wear a mask** anytime you are near someone who is not in your household. This protects you and others from the COVID-19 virus. We will give you masks while you are in the study.
- **Wash your hands properly.**
 - Use soap and water.
 - If you lack soap, use water alone and rub your hands vigorously together; follow it up with hand sanitizer.
 - You should wash for at least 20 seconds and rub all parts of your hands.
- **Use hand sanitizer.** If you cannot wash your hands properly or at all, use alcohol-based hand sanitizer (gel or wipes) that has at least 60 percent alcohol. We will give this to you in the study. Wipe or gel your hands frequently when you are out in public and touching things.

6. How will you find out if you can be in the study?

We will need to see if you meet the study requirements. You will need to agree to participate and sign this form before we see if you are able to be in the study. We will:

- Do a physical exam.
- Look at your health records and ask you questions about your health.
- Take blood to confirm that you are in good general health. We will tell you the results of these tests. If the tests show you have a health concern, we will refer you for care.

You will not have a COVID-19 test at your screening visit.

If it is needed, you may have more than one screening visit. We will review the results of the screening with you. If you meet the requirements, then you can decide if you want to join. If you do not meet the requirements, you will not be able to join the study. If you decide to join, we will ask you a few questions about the most important parts of the study. We want to make sure we have explained these to you well enough for you to understand.

7. What will happen during the study?

Here is what will happen in this study.

Clinic visits: You will come to the clinic at least seven times during the study. We will give you money to cover your **<transportation, parking>**. At each visit, we will review what will happen at that visit. At the end of each visit, we will tell you what you need to do after the visit. This will help you know what to expect.

Phone calls or electronic messages: We will call or send an electronic message (text messages or email) to remind you of upcoming study visits, to record any side effects, or to check on your well-being. During the study, we will ask you to text or call us every two weeks to report on your health. If we do not hear from you, we will call or

text you.

Blood draw: We will take blood samples from a vein in your arm at different visits as described below. If the sample is lost or broken, we may need to take another sample to replace it. We use people trained to take a blood sample.

Asking you questions: We will ask you questions about these things during the study:

- Your health history.
- Any health problem you may be having.
- What medications you are taking.
- For those able to become pregnant: whether you are continuing to use effective contraception.

It should take about 15-30 minutes of your time to answer these.

Physical exams and testing:

For screening:

- We will measure your pulse, blood pressure, temperature, and breathing ("vital signs").
- We will listen to your heart, lungs, and feel your abdomen.
- We will feel your lymph nodes in your neck, armpits, and groin.
- We will test your muscle strength, coordination, nerves, and reflexes.
- We will measure your height and weight.
- We will take about 8 mL (1.5 teaspoons) of blood from a vein in your arm to check the numbers of your blood cells, and for any problems with your liver or kidneys.
- If you are able to become pregnant, we will do a urine or blood pregnancy test. You must agree to avoid pregnancy by using effective contraception for 30 days before you start the study until two months after the last vaccine you receive in the study. This is about three-and-a-half months total. We tell you more about this below.

We will go over your screening results with you. If we find a health problem, we will help you get medical attention.

During the study:

- We will do a physical exam only if you report a symptom or if you leave the study early.
- We will take a venous blood sample to check for antibodies to the COVID-19 virus four times during the study and any other time that you report symptoms of possible infection with COVID-19. This will be about XX mL (X teaspoons) of blood each time.
- We will do a nasal swab test for the COVID-19 virus at your first study visit, even if you do not show symptoms. If the test shows you have the COVID-19 virus, we will stop any remaining study vaccinations. We will continue to follow you in the study to evaluate you and direct you to care if you need it.
- After your first study visit, you will be tested for the COVID-19 virus only if you tell us you have symptoms. If you report symptoms, you will have two tests for COVID-19: (1) nasal swab test; and (2) a blood test. If your tests are negative but you still have symptoms, we will do the tests again the next day.
- To determine if you have a COVID-19 infection, we will follow standard medical practice for evaluating you for this infection. We will ask you to meet us at [Name of Facility]. We will do physical exams, take your vital signs, measure your oxygen level, evaluate your heart, take a chest x-ray or ultrasound of your lungs, and do laboratory testing to help us know more about what is happening in your body. Depending on your symptoms, we may do other testing. If you become very ill, we will make sure you have access to the proper care you need.
- If we determine you have a COVID-19 infection, we will tell you the results and counsel you about how to quarantine and how to inform others, so they can get tested. We will continue to follow you in the study to evaluate you and direct you to care if you need it.

Reporting your symptoms:

Since this study is about a vaccine for COVID-19 infection, it is important that we keep track of your symptoms and test you.

- For the first eight weeks of the study, we will see you routinely and will ask you about any symptoms you might be having.

- After the first eight weeks, we will not see you again for another six months. However, each week we want you to call or text us to tell us whether you had any illness that week. If we do not hear from you, we will reach out to you. Also, we will call or text you about every two weeks to see if you have had any COVID-19 symptoms.
- We will give you a phone number to call at any time of the day or night to talk to someone if you are feeling COVID-19 symptoms. The phone service can direct you to the nearest place to get a nasal swab and a blood test for COVID-19 infection.

What symptoms do we want to know about?

Please notify us or call the 24-hour number if you have any of these symptoms:

- A dry cough that does not go away.
- Trouble breathing or catching your breath.
- Fever or feeling hot.
- Chills or rigors.
- Muscle aches.
- Tiredness.
- Nausea or vomiting.
- Headache.
- Sore throat.
- Loss of taste or smell.
- Congestion or runny nose.

Using effective contraception: We do not know the effects of the study vaccine on a pregnancy or a fetus. If you are able to become pregnant, you must agree to use effective contraception from 30 days before vaccination to two months after your last vaccination in the study. This is about three-and-a-half months in total. Effective contraception means one of these methods:

- Barrier contraception.
- Hormonal birth control.
- Intrauterine device (IUD).
- Surgical sterility.
- Abstinence from sexual activity that can lead to pregnancy.

We will review what method you are using and can tell you if it meets the requirements for the study.

Getting the vaccine(s) or placebo: Everyone will have two injections of either the study vaccine or **the comparator vaccine/placebo**. We will give you the injections in the upper arm. The first injection takes place at your enrollment visit and the next one takes place about 15 days after that. After each injection you will be asked to stay at the clinic for at least 30 minutes. Study staff will measure your vital signs and check for any redness or swelling where you got the injection.

Recording your side effects: Some people will be asked to record side effects after each study vaccination for that day and six more days. We will show you how to do it and give you the tools you need. You may have to measure redness or swelling on your arm and take your temperature. You will need to record it in a memory aid we give you. You will get text messages or emails to remind you. Everyone has two study vaccinations in this study, so you will record in your memory aid for 14 days total. We will collect your memory aid and together we will review the side effects you recorded.

8. What are the study products and how are they being studied?

The products in this study are:

- The study vaccine: **[write clearly about it.]** This vaccine is experimental. It can only be used in research. The vaccine is used with an **adjuvant**. That is something that helps strengthen the body's response to the vaccine. The adjuvant is called **[NAME]**. It **is/is not licensed** to be used with vaccines.
- **[if applicable]** The comparator vaccine: **[write clearly about it]**. This vaccine is **[licensed for use...]**. It **does/does not** have an adjuvant. **If it does:** The adjuvant is **[NAME]**. Adjuvants help to strengthen the body's response to a vaccine.
- **[if applicable]** The placebo: A placebo is a substance that looks like the study vaccine but does not have the vaccine in it. In this study, the placebo is **[describe: salt water, etc.]**

There are two groups in the study: half of the people in the study will get the study vaccine. The other half will get the **[comparator vaccine/placebo]**. You have an equal chance of getting the study vaccine or the **[comparator vaccine/placebo]**.

You are assigned to a study group by chance. A computer program will put you into a group. Neither you nor the study team who sees participants will know whether you are receiving the study vaccine or the **[comparator vaccine/placebo]**. Some people involved in the study will know this information and can reveal it, if needed. However, we do our best to keep you and the study team from knowing what you are getting. This allows a fair comparison of the study vaccine. At the end of the study we will tell you what product you received.

9. What are the risks of this study?

All research studies have some risks. Here are the risks we know about and how we manage them.

Risks of the study vaccine

Your safety and well-being are important to us. We carefully review safety of the study as we go along. A group of safety experts will be able to see the side effects of people getting the study vaccines. This group can recommend we stop the study if they determine there are serious safety concerns.

[NAME of Study vaccine]

This vaccine has been given to **XX** people before. The vaccine did not cause any serious health concerns in earlier studies. The side effects from the study vaccine can be felt in your whole body or just in your arm where you get the injection. There are side effects that are common. This means that most people who had the study vaccine felt these side effects. There are also side effects that are not likely to happen, but would be very serious if they did occur. We tell you about the common side effects and the rare, but serious, side effects below.

The common side effects from the study vaccine are usually mild and do not last long. These include:

Whole body side effects:

- Fever
- Chills
- Tiredness
- Headache
- Muscle aches
- Joint pain
- Nausea
- Vomiting
- Abdominal pain

Side effects on your arm where you got the injection:

- Redness
- Hardness
- Swelling
- Itching
- Pain
- Tenderness

Extremely rare, serious side effects:

Severe allergic reaction. In some people a vaccine might cause an allergic reaction. This allergic reaction can rarely be very severe and lead to anaphylaxis, a condition where the throat swells and a person cannot breathe. The beginning signs of anaphylaxis can be itching, hives, and a swelling of the throat or mouth. Without treatment, people can die from this serious allergic reaction. We manage this risk by not allowing people in the study who have had allergic reactions to past vaccines. Anaphylaxis tends to happen early after getting a vaccine. This is why we have people stay in the study clinic for at least 30 minutes after vaccination. We are trained to provide the right

treatment for any allergic reaction to the study vaccines.

Vaccine enhanced disease. A vaccine might make the disease worse if someone is exposed to the germ that causes the disease. This is extremely rare. It has happened in some animal studies of vaccines for other coronaviruses (the COVID-19 virus is a type of coronavirus). It has also happened in humans with a vaccine against a respiratory virus called RSV. Animal studies of this study vaccine did not show any sign of this problem when the animals were given the COVID-19 virus after vaccination. We will keep track of each person in the study who gets a COVID-19 infection after receiving a study vaccine. We will closely monitor what happens with their illness. A group of experts is watching over the safety of the study participants. They could see who is getting the study vaccine and who is not. Because COVID-19 is so widespread, people in both the study vaccine group and the **comparator vaccine/placebo** group may become infected with COVID-19 as the study goes on. This expert group will compare the severity of illness between the study groups. They can advise that we stop the study if it seems that the study vaccine is causing COVID-19 to be more severe in people who got the study vaccine than those who did not.

Risks to pregnancy and to the fetus: We do not know the risks of the study vaccine on a pregnancy or a developing fetus. We manage this risk by asking anyone who can become pregnant to use effective birth control from 30 days before first vaccination to two months after their last vaccination in the study. We do a pregnancy test before vaccination for anyone who can become pregnant. We will not vaccinate anyone who has a positive pregnancy test.

If you become pregnant during the study: We will not give you any more vaccinations. We may continue to take blood if it would not harm your pregnancy and you agree. We will continue to test you for COVID-19 anytime you show symptoms. We will keep in touch with you and collect information about your pregnancy and the outcome of the pregnancy, even if it is after the study ends.

Harm from taking blood

- Taking blood can cause pain and bruising. This should not last long.
- It is very rare, but sometimes taking blood can cause an infection. This is not likely to happen because we clean the skin and use trained people to take the blood.
- Sometimes people faint when blood is taken. We will make sure you are seated or lying down when we take the blood. We are trained to provide care if fainting occurs.
- Your body will make more blood to replace the blood that we take out.

Discomfort from nasal swabbing

The nasal swab test for the COVID-19 virus can be very uncomfortable. For the test, we will ask you to tip your head back slightly. We will insert a cotton swab far up your nostril, the breathing hole in your nose. We will do this in each nostril. The test causes many people to cough, sneeze, gag, or have watery eyes.

Loss of confidentiality

We keep your personal information secure. However, there is always a small chance that someone who is not allowed could see your personal information by mistake. If this happens and we find out about it, we will tell you.

Loss of opportunity

If you take part in this study and you receive the study vaccine, it is likely that you cannot be in another COVID-19 vaccine trial.

Unknown risks

- We do not know what affect this study vaccine will have on an approved vaccine for COVID-19, when one becomes available.
- There may be other risks that we do not know about yet. If we learn new information during the study that might affect your decision to stay in the study, we will tell you about it.

10. What will happen if you are hurt because of being in the study?

If you have a medical problem or illness that you think may be related to this study, tell us right away by contacting **<NAME, PHONE NUMBER>**. **<NAME>** can help you get care. If you cannot reach us and you need treatment, do not delay seeking care. You can tell us what happened later.

[Modify wording to fit the study plans for treatment of injuries and payment.] There are limited funds available to the study for care of study-related injury. Also, the study has modest no-fault insurance for study-related injury. Although the Investigators and **SPONSOR** will make every effort to cover the costs of any study-related injury, we cannot guarantee full coverage. The uncovered costs may fall on you and/or your health insurance. We will reimburse you to the extent we can for costs of medical care needed for any study-related injury. However, because of the limitations for coverage of study-related care costs, there is the chance that you may be responsible for at least some of the cost of care.

11. Will you be told any of your test results?

We will tell you the results of any standard health testing we do in this study. If your results show that you may have a health concern, we will treat you or refer you to proper treatment.

We do not plan to give results back to you that are for research. The tests are experimental and will not be used to manage your health.

12. Will you learn the results of the study?

We intend to share the overall results of the study with other scientists and the public by publishing the results in a scientific journal.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

We may call you, send you a letter, or invite you to a meeting to learn the results and tell you what study product you received. It may take up to one year after the entire study has finished for us to know the results. If you do not hear about the study results from us and you want to know, please contact us using the phone numbers on this form.

13. What other choices do you have besides taking part in the study?

You can choose not to join the study. You will not have any penalties or lose any benefits if you say “no.”

14. What happens to your study information?

In this study, we will record some personal information about you. We need some of this information to show that you consented to research and to know how to reach you during the study. If you seek medical care during the study, we may need to look at your medical records.

We will keep your personal information confidential. Here is how we protect it:

- Your name and contact information are kept in a locked cabinet or password protected computer files. Only the study team can unlock it.
- On study forms, we will use a number in place of your name.
- The information using your study number in place of your name is put into computers. These are password protected.
- The study team keeps a link between your name and your study number. After **<# years>** we will destroy the link and any documents that identify you.

Groups who oversee our research can see study records. These are people from the ethics committee(s)/institutional review board (IRBs), the sponsor and organizations who may work for them, and government agencies, such as the **[insert national regulatory authorities]**.

- They may see your name and other personal information.
- They may see your medical records if these are used for study purposes.
- They are not allowed to share any personal information about you.

We will keep your personal information for **<DESCRIBE HOW LONG DATA WILL BE MAINTAINED.>** After that time, we will destroy it.

We will share what we learn in this study with others. We will remove your name and other identifying information when we share the study information with others.

Here are the ways we may share your study information:

- We may write an article or share the study results at meetings or on websites.
- We will post the results on <http://www.ClinicalTrials.gov>, as we mentioned earlier.
- We may share the study responses of each person with other researchers. This lets other researchers see and use the results.
- We may share the study data with the group that paid for this study.

No one will be able to identify you from sharing the information in the ways we have described here.

15. Using your information and samples for future research

We are asking to store the blood samples and study information that you provide for use in future research. Future research on leftover samples and study information can help us better understand COVID-19 and vaccines for it. If you agree to this storage and future use of your samples, your samples may be stored and used indefinitely.

You can say “yes” now and change your mind later. If you say “yes” now and change your mind later, we will destroy any extra samples and information that are in our storage. We cannot destroy samples and information that are already used or that have your code number removed.

If you say “yes,” we will store your samples in a secure area at **[institution/biorepository]** that is certified to store the samples. Your study information will be securely stored electronically. The samples and information are labeled with a study number, not with your name. When we share your data or specimens for future research, we will do this in a way that other researchers will not be able to identify you.

Someone using your samples or information may make a new discovery that makes money. There are no plans to share the money with you or others.

You can say “no” to sample storage and still stay in this study. There are no penalties or loss of benefits if you say “no.”

Here is what you should know to make your decision:

- Allowing us or others to use your extra samples and study information will not help you. It may help other people in the future.
- Research on your samples would be used to study COVID-19 and COVID-19 vaccines.
- We do not plan to give test results back to you or your doctor. They are for research and not helpful to manage your health.
- We may share your samples and information with others. We will not provide information that can identify you when we share your samples.
- The risk of allowing future use of your samples or information is that someone who is not authorized could see your test results or information by mistake. This risk is extremely low because no one using your samples will know who you are.

ADD IF GENETIC TESTING MAY BE DONE ON THE SAMPLES

There may be genetic testing done on your samples. Your genes are passed to you from your birth parents. They affect how you look and how your body works. The differences in people's genes can help explain why some

people get a disease while others do not. Here is what you should know about the genetic testing:

- **Delete if not applicable:** The genetic testing will only involve genes related to COVID-19.
- **Delete if not applicable:** The genetic testing could involve all of your genes (your genome).
- **Delete if not applicable:** Researchers may continue to grow your cells for future research. This is called making a cell line.
- The results of the genetic testing will not be given back to you or your doctor.

Risks of Genetic Testing

We do not know all of the risks of genetic testing. The risks are related to loss of confidentiality. Here is what we know now:

- Sometimes genetic test results show that you are not genetically related to your parent or your child. Both you and your family member would need to be tested to find this out.
- Your results could show you had an increased chance of getting a disease or disorder. You could pass this increased risk to your children. This may cause problems with health or life insurance. This risk is low because researchers will not give the results back to you.
- There is a risk that someone could identify you by combining your test results with other genetic information about you that is linked to your name.

These risks are not likely to happen. This is because your name will not be with your genetic test result and we are not giving the results back to you.

16. Will you be paid for being in this study?

[SITES TO INSERT THEIR SPECIFIC LANGUAGE FOR PAYMENT] We will give you <INSERT AMOUNT> for each study visit you complete. This is for your time, inconvenience, and transportation.

17. Are there any costs to you if you join the study?

There are no costs to you if you join the study. If you have an injury that is not related to the study, you or your insurance will be responsible for bearing the cost of the treatment for that injury.

18. What to do you if you want to leave the study

You are free to leave the study any time. If you want to leave the study, please tell us. We may do the following if you agree:

- Ask why you are leaving the study because it is helpful for us to know. You do not have to tell us.
- Review the memory aid recordings if we have not done it yet.
- Ask you about any side effects or health issues and any medications you may be taking.
- Do a physical exam or do any laboratory testing needed for safety and your immune system. This helps us know you left the study in good health.
- Ask you to contact us if you have been diagnosed with COVID-19 infection. If you allow it, we would like to collect information about your illness.
- Update contact information in case we need to reach you for any reason

19. Can you be taken off the study?

The researchers may remove you from the study if these things happen:

- The study doctors think that staying in the study is not good for your health.
- You are not able to follow the directions of the study staff or keep study appointments.
- The study ends early.

20. Your rights

You have rights in this study:

- **You do not have to be in this study.** You can say “yes” or “no” to joining. You can leave the study at any time. If you do not join or you leave early, you will not have any penalties. You should not feel pressure to join or stay in the study.

- **By signing this consent form, you do not lose any rights you normally have.**
- **If we learn new information about the study, we will tell you.** You can decide if you want to stay in the study after you learn this new information.

21. Who to contact if you have questions?

- If you have questions about this study, please call **<NAME AND TELEPHONE NUMBER OF RESEARCH TEAM CONTACT>**.
- If you believe you **<OR INDICATE OTHERS IF RELEVANT>** have been hurt as a result of the research study, please call **<NAME AND TELEPHONE NUMBER OF RESEARCH TEAM CONTACT>**.
- **[Insert specific language required by your Ethics Committee/IRB here:]** If you have questions about your rights in this research study, please call **<NAME AND TELEPHONE NUMBER>**. This person is a member of the Ethics Committee at **<INSERT>**.

How do I know if this study is right for me?

Volunteering for a study can be a hard decision. These questions may help you decide:

- Think about how long the study will last. Do you have the time to be involved?
- Think about what the study is asking you to do. Is this okay with you?
- Think about the risks and benefits. Do you feel okay with these?
- If it helps, talk to friends, family, or others you can trust.

Confirmation of written consent

Use of your samples for future research

Do you agree to give us your extra samples from this study for future research related to COVID-19 or a COVID-19 vaccine? **Add, if applicable:** This may include genetic testing. (initials in the box)

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Yes

Study participant

Signing your name below means you voluntarily choose to be in this research study. It also means you have asked any questions you want to ask. You will get a copy of this form to keep.

Printed name

Date

Signature of Participant

Witness (Include if enrolling participants who are illiterate and using written consent)

Signing below means that the study participant whose thumbprint is above chose to be in this research study. It also means I was present the whole time the study was being explained. I confirm that the participant had a chance to ask questions. The participant will get a copy of this form to keep.

Printed name

Signature of Witness

Date

Member of research team

Signing my name below means I have explained this research study to you and answered your questions to the best of my ability. I will give you a copy of this form to keep.

Signature of Person Obtaining Consent

Date