

[Note to Sites: The community education slides can be used in part, or as an entire slide deck based on the audience and the time allotment for the planned engagement.]

Hello, my name is \_\_\_\_\_ and I work for \_\_\_\_\_.

I would like to tell you about an upcoming study we are doing called “CoVPN 3001”.

## Who we are

- [describe your organization and include a photo]
- [Feel free to also add your organization's website, FB page or Twitter handle and any other information about your organization].



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[Note to sites: Describe who you are and who you work for. You may want to give the name of the Principal Investigator, or Director of the clinic. You may also want to include photos of your office, your staff or your logo and any recruitment materials or advertisements that your site has posted in the office or around town. This will help make the connection between those images and your site.]



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**SARS-CoV-2**  
=

**Severe acute respiratory syndrome  
coronavirus 2**

Now let's talk about severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2.

## SARS-CoV-2

- SARS-CoV-2 is the name of the new coronavirus discovered in late 2019.
- It is the virus that causes the disease called COVID-19, short for “Coronavirus Disease of 2019.”
- In most people, the virus mainly affects the respiratory tract, but we are still learning about all of the ways it impacts the human body.
- People can carry this virus and transmit it to others, even when they do not have any symptoms themselves.
- Some people do not show any symptoms (“asymptomatic”). Some people have a mild to moderate infection and can recover at home. Other people may have a more severe illness and need to be treated in the hospital.



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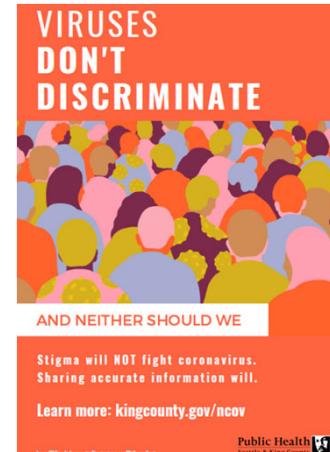
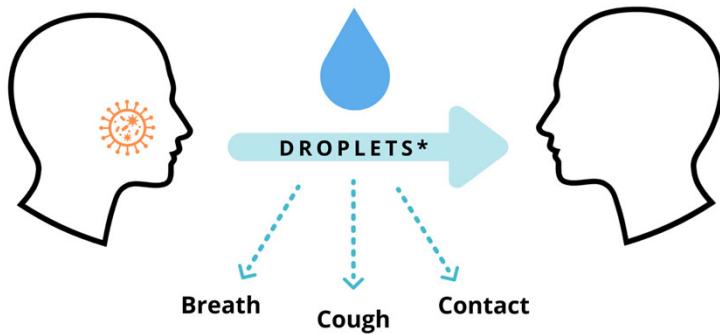


Image credit: Seattle & King County Dept.  
of Public Health

# How does SARS-CoV-2 spread?



- Droplets can land in the mouths or noses of people who are nearby, or can possibly be inhaled into the lungs.
- Droplets can also fall and remain on surfaces, where they are transmitted to people who touch that surface (examples include countertops, light switches, door knobs, etc.) and then touch their face.



Slide credit: Seattle & King County Dept. of Public Health

# Common symptoms of COVID-19 illness

Fever



100.4 F or higher

Cough



Difficulty breathing



**Symptoms may show up between 2 and 14 days after being around someone who has COVID-19.**



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Slide credit: Seattle & King County Dept. of Public Health

# Reducing the spread



Call your doctor and ask for instructions about how to stay home and be in quarantine.



Practice excellent hygiene habits



Clean frequently touched surfaces and objects



**Cloth face masks**



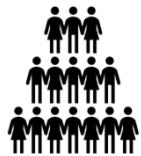
Wear cloth face coverings that cover your mouth and nose



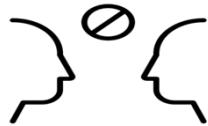
**Bandanas**



Stay home



Large gatherings are prohibited



Stay 6 feet apart from other people, and avoid contact with people who are sick

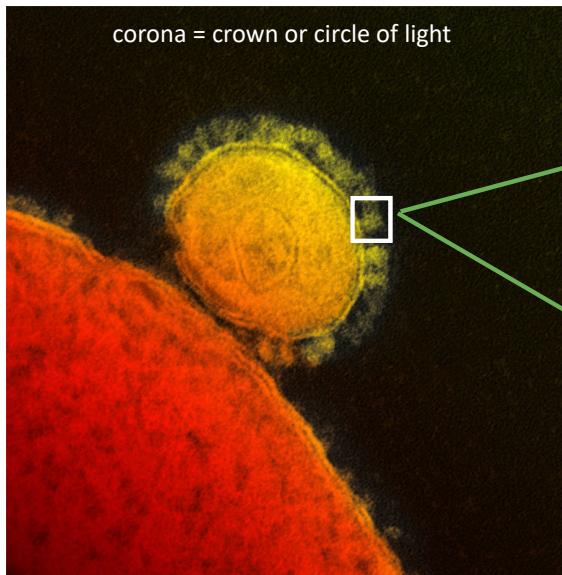


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Slide credit: Seattle & King County Dept. of Public Health

# SARS-CoV-2 and its spike protein (the vaccine target)

Slide credit: Vaccine Research Center, NIAID



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**Spike Protein**

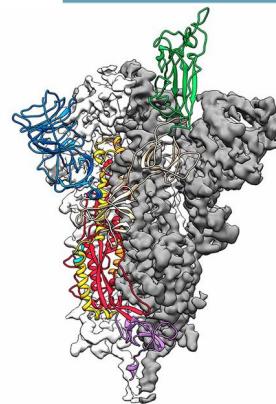


Image credit: Wrapp D, Wang N, Corbett KS, Goldsmith JA, Hsieh CL, Abiona O, Graham BS, McLellan JS. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. *Science*. 2020 Feb 19:eabb2507. doi: 10.1126/science.abb2507.

When we're talking about SARS-CoV-2 and coronaviruses, you might be wondering what they look like. Here is an image of the virus, and you can see the spike proteins that go all around it. In the box is one spike protein. Scientists have been able to map the structure of the spike protein, shown on the right.



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# Understanding Vaccines

# What could a SARS-CoV-2 vaccine do?

## Benefit the individual

- ➡ Reduce the severity of illness
- ➡ Prevent infection

## Benefit the community

- ➡ Reduce transmission
- ➡ Healthier communities



Right now, there is no effective vaccine against COVID-19, and we are testing many vaccines to try to find one. There are several reasons why a vaccine would be very helpful.

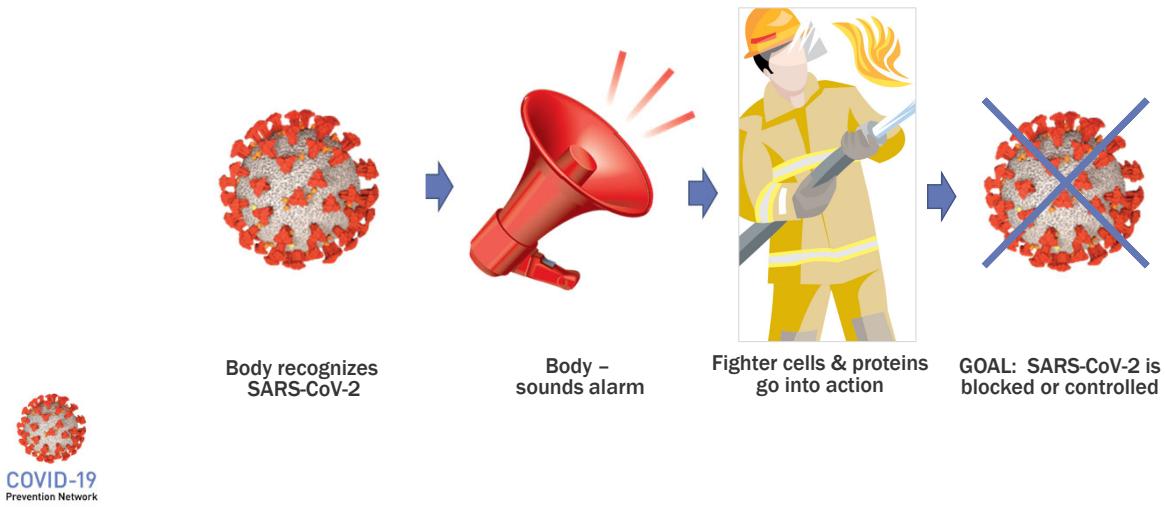
We hope that a vaccine will help to reduce the severity of COVID-19 illness, so that people don't get as sick and recover faster. We also hope that we could prevent new infections.

Another way the vaccine could be helpful would be to reduce the amount of transmission in the entire community. If lots of people get vaccinated, it would mean that they would be protected from SARS-CoV-2. If they are protected, it means they would not be passing the virus to others. In this way, a vaccine would help the community by preventing new infections as well. Also with fewer people getting infected, it means fewer people have to miss work because they are sick or have to take care of their loved ones, so the community as a whole is healthier and stronger.

So what do vaccines do?

# How does a vaccine work?

- By teaching the body to recognize and fight invaders



Vaccines work by teaching the body to recognize an invader, such as SARS-CoV-2. This sounds an “alarm” in the body, calling the fighter cells and proteins that are part of our immune system into action. Ultimately this will help the body to prevent or control an infection and reduce the severity of disease. This is called the “Immune Response.”

# Can vaccines cause SARS-CoV-2 infection or cause COVID-19 illness?

**NO!** The vaccines being tested are made from synthetic (laboratory made) pieces copied from SARS-CoV-2, not the whole virus. Therefore, the vaccines CANNOT cause infection or cause you to get COVID-19 illness.



*Image Credit: Bridge HIV/SFDPH*

So let's think about this a little further. Many people wonder if these vaccines can give a person SARS-CoV-2 infection. **The answer is NO.**

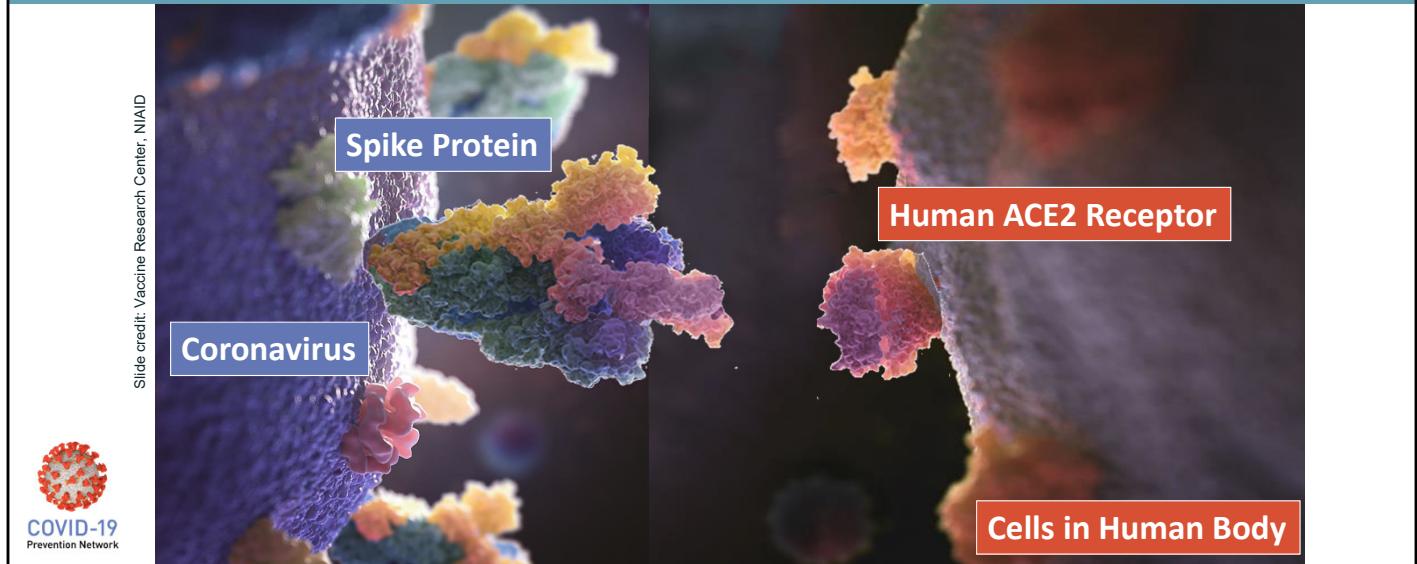
The vaccines only contain copies of pieces of the virus that are made in a laboratory. The pieces are used to teach your body to recognize the virus, without showing your body the virus itself.

For example, if you see a tire or a steering wheel you will probably think of a car. But you cannot drive with just those 2 parts! Or, if you took a mobile phone apart and just had the SIM card, you could not use that phone to make a call or send a text message. They wouldn't work, because they are only pieces.

In the same way, when you only have pieces copied from the virus, there is no way the pieces could come together to create real SARS-CoV-2. This is why we can say with confidence that the vaccines cannot give you an infection or cause COVID-19 illness.

## The pieces involved - 1

- The coronavirus spike protein is on the surface of the virus. It directs how the virus attaches to cells to start the infection process.
- An ideal vaccine targets the coronavirus spikes in order to block infection.



The spike is the protein on the surface of coronaviruses that directs how the virus attaches to cells in people. In this picture, you see the coronavirus spike sitting on the outer surface of the virus, as it approaches a human cell. The ACE2 receptor on human cells acts like a lock, and the spike protein is like the key that will fit into that lock, allowing the virus to enter into the cell.

When we talk about the pieces of the virus that have been copied to make the vaccine, we are talking about this spike protein.

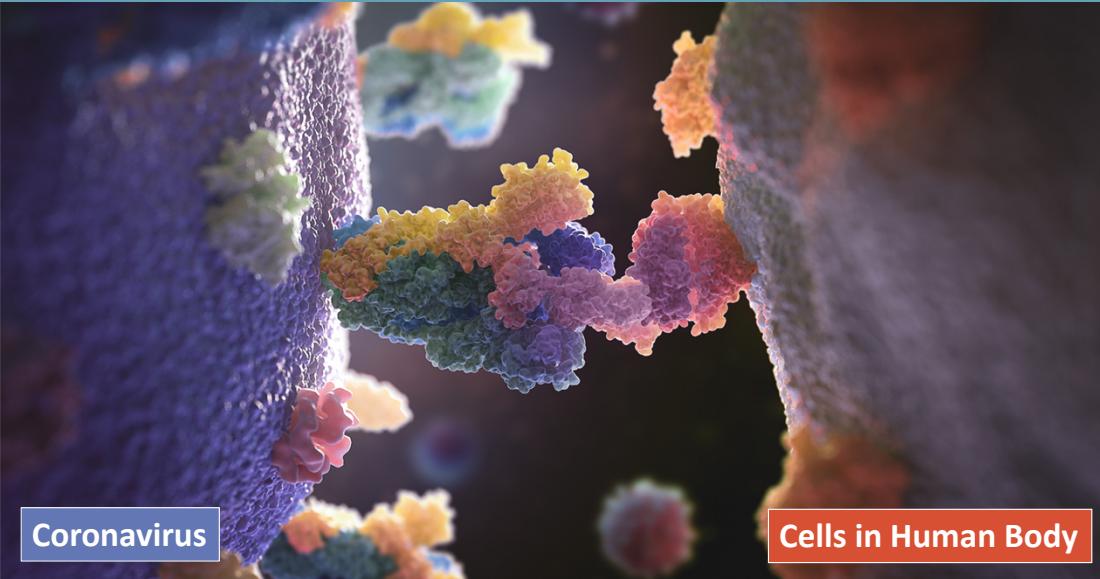
## The pieces involved - 2

- The coronavirus spike protein attaches to the ACE2 receptor to start an infection.

Slide credit: Vaccine Research Center, NIAID



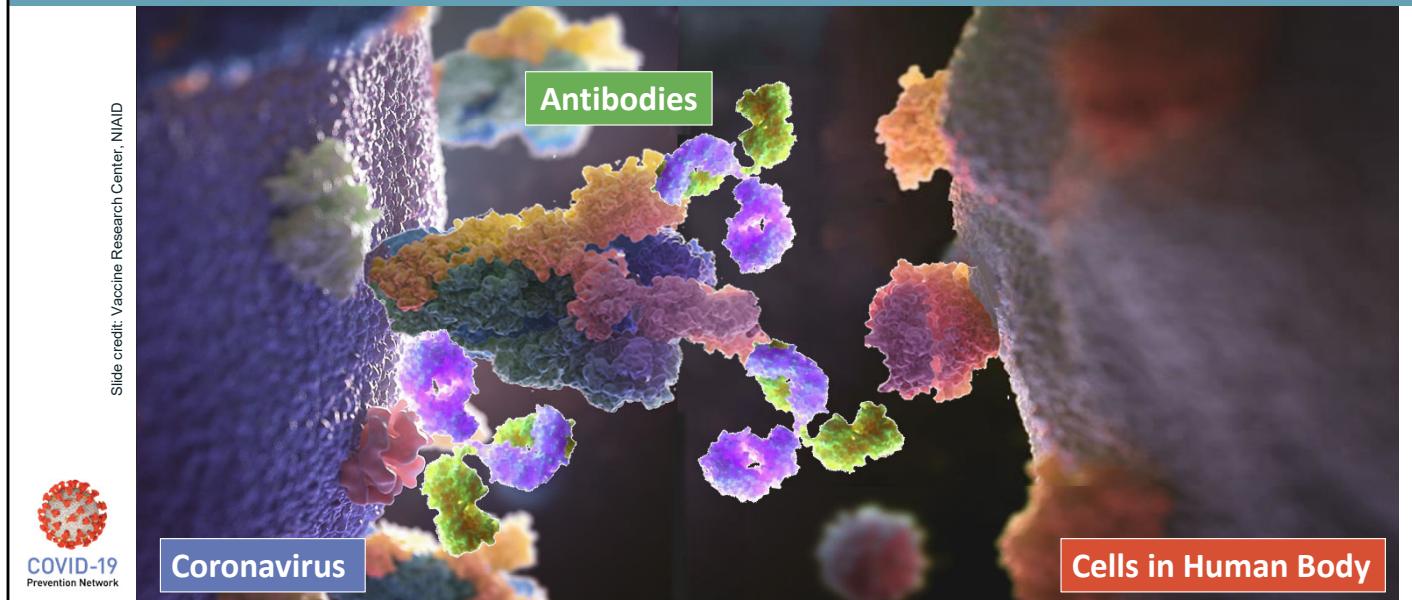
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In this picture, you can see the coronavirus spike protein successfully attached to the receptor on the human cell, starting an infection. This is what we hope to avoid!

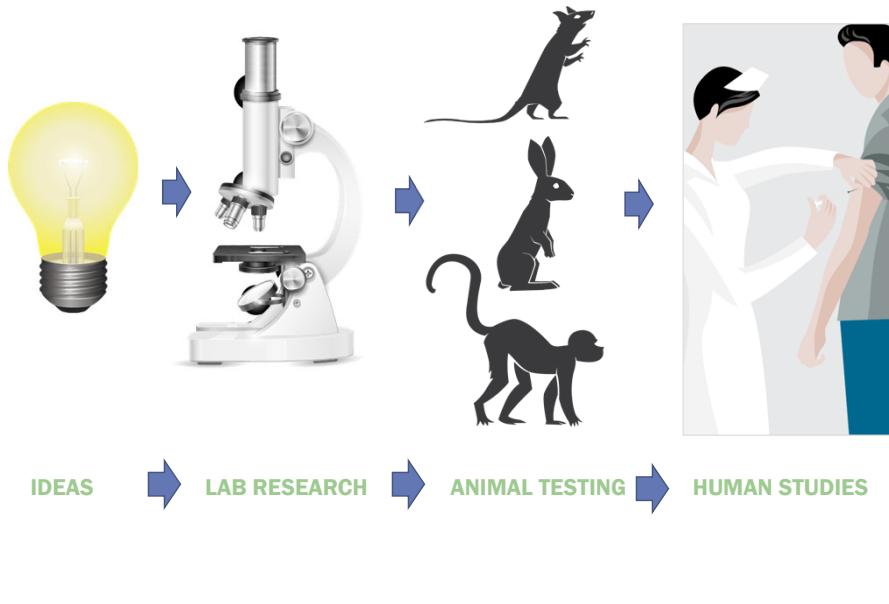
# The goal: antibodies!

- Vaccine-induced antibodies can block the spike protein from attaching to human cells.



In this image, you can see antibodies that have attached to the spike protein, shown in purple and green. They are shaped like the letter Y, and they use their top “arms” to attach to the spike protein, blocking it from being able to access the receptor on the human cells. Antibodies can also use their “foot” at the bottom to pull the virus into other cells that act like a garbage disposal, breaking the virus down and clearing it out of the body.

# How do you test a vaccine?



Before study vaccines are tested in people, they go through a long development process. Many researchers have ideas for vaccine products, but only the best ideas move forward.

First these ideas get explored in a laboratory under a microscope and using other lab tools. If an idea seems promising in the lab, it goes into studies in animals. It's important to do this step in animals first to see how their bodies respond before moving ahead with testing in people. However, what happens in animals is not always the same as what happens in people.

We only move ahead with studies in people when we have a strong sense that they will not do harm, after we have promising data from the animals and the labs that shows that the products appear safe and lead to the right kinds of responses by the body's immune system. In some cases, researchers are able to take a vaccine technology that has been used for another disease and swap out pieces of the virus to try it against a new disease. In this way, we can build on what has already been learned from past research.

Once human studies begin, there is very careful monitoring of study volunteers to keep track of any side effects or symptoms they have, and to make sure they get any care or treatment that is needed. There are several SARS-CoV-2 vaccines being studied in people, because we don't know yet what will be effective to protect against this new virus. This is the heart of what research is, to explore new ideas and come up with new answers.

When research studies are done in people they are called "clinical trials." (The earlier stages in the lab and animals are called "pre-clinical" trials.) We often like to say "study" instead of trial, because it's a good reminder that we are still trying to study and learn about the products.

# Stages of clinical trials

## PHASE 1

12 to 18 months

Trials to test safety and whether the body can tolerate the product. Often involves comparing against a placebo with no active ingredients. Usually less than 100 people.

## PHASE 2

Up to 2 years

Identifying the maximum tolerated dose, the best dosing schedule, and if the immune system is having the desired responses. Usually a few hundred to a few thousand people.

## PHASE 3

2+ years

"Does this product prevent infections, or help to reduce the severity of disease?" Involves thousands of people, including some at risk of infection.

With SARS-CoV-2, we are working as quickly as possible. No phases are skipped. Instead, we overlap the phases, starting the next phase as quickly as we have the necessary safety data collected and analyzed from the earlier phase. The new phase can start while the long-term follow-up of people in the earlier phase continues. Other steps can be done in parallel, instead of one after the other.



Once you get to trials in people, there are three main steps:

- Phase 1 — involves a small number of healthy volunteers to test for safety and immune responses; usually lasts 12–18 months
- Phase 2 — involves hundreds of volunteers to identify the best dose and vaccine administration schedule; can last up to 2 years
- Phase 3 — involves many thousands of volunteers to test the safety and efficacy of the vaccine; can last 2+ years

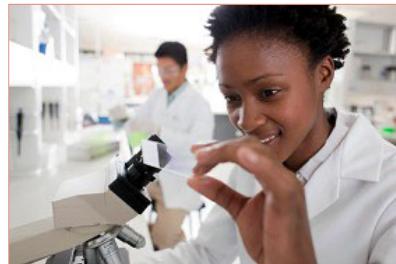
The study that I'd like to tell you about is a Phase 3 study. It is the first time where we will try to answer the question, "Does this vaccine work to protect people against getting severe COVID-19 illness, or from getting SARS-CoV-2 infection?" The Phase 1 and 2 studies are still doing the long-term follow up with the volunteers who enrolled in those trials, but we do have the safety data about how people reacted to the vaccines that tells us it is safe to move ahead with Phase 3 now. I'll describe more of that information in a moment.

You've probably heard in the news that these studies for a COVID-19 vaccine are being done faster than usual. What we want you to know is that none of the steps are being skipped. We are just changing the structure of how the work is done, such as doing some steps in parallel instead of one after the other. We're also overlapping the phases, starting the next phase just as soon as we have the safety data collected and analyzed from the previous phase.

It is also important to know that throughout these studies, there are several groups that oversee the studies to make sure that participants are protected. There are independent safety monitoring groups that oversee each study while it is in progress. In addition, the US Food and Drug Administration (FDA), the US National Institute of Allergy and Infectious Diseases (NIAID), and the US Biomedical Advanced Research and Development Authority (BARDA) have all been involved in reviewing the study data and making sure it is safe to move from one phase to the next.

## Study vaccines

- The **study vaccine** is experimental. That means we do not know if it will be effective to use in people (if it will prevent SARS-CoV-2 infection or reduce the severity of COVID-19 illness).
- The **study vaccine** can only be used in research.



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It is very important to remember these 2 things if you are thinking about joining a vaccine study.

1. The study vaccine is experimental. This means we are still researching the product and we do not know if it is effective to use in people. We do *not* know if it will prevent SARS-CoV-2 or reduce the severity of COVID-19 illness.
2. This vaccine is only used for research. It is not available to the general public or available for sale.



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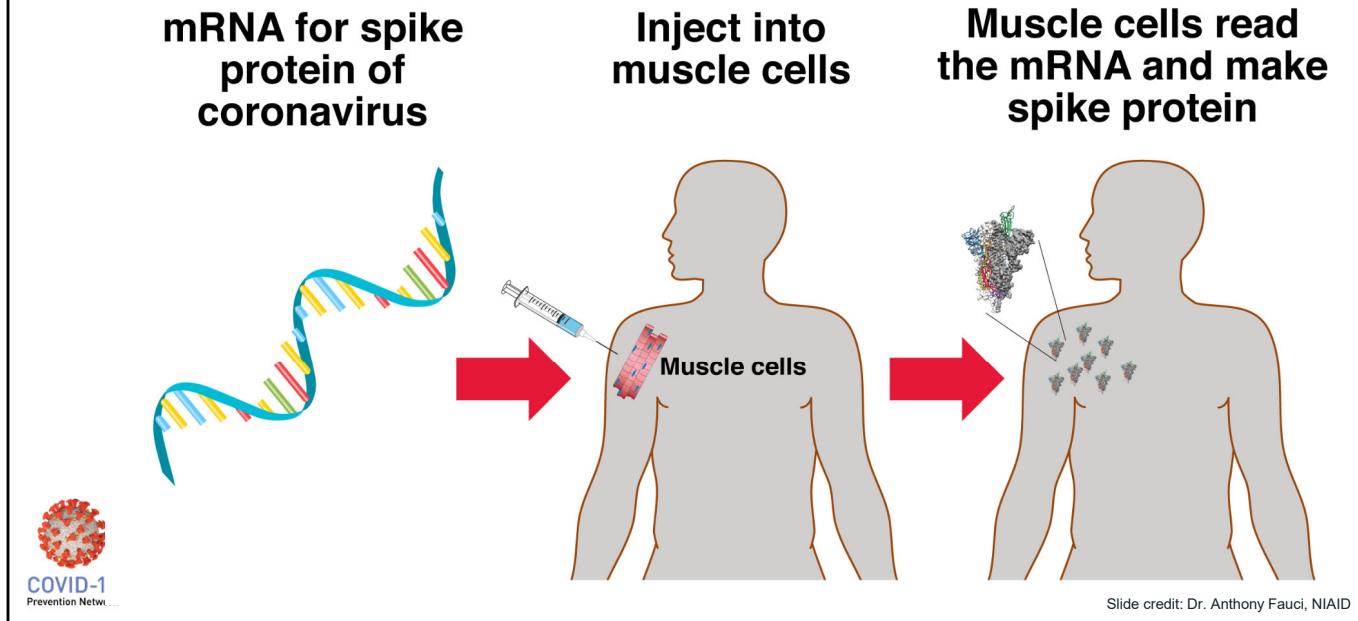
# Understanding the Cove Study

## What is CoVPN 3001?

- **Cove Study** is a Phase 3 study of an experimental vaccine against SARS-CoV-2 called mRNA-1273.
- This study is also known as “mRNA-1273-P301” or “CoVPN 3001.”
- The study vaccine was developed by ModernaTX, Inc. They are located in Cambridge, Massachusetts. Moderna specializes in developing the use of mRNA technology for vaccines and treatments for a number of diseases.
- The study vaccine is known as a mRNA vaccine.
- The study will enroll about 30,000 people in the US.



# The mRNA vaccine approach

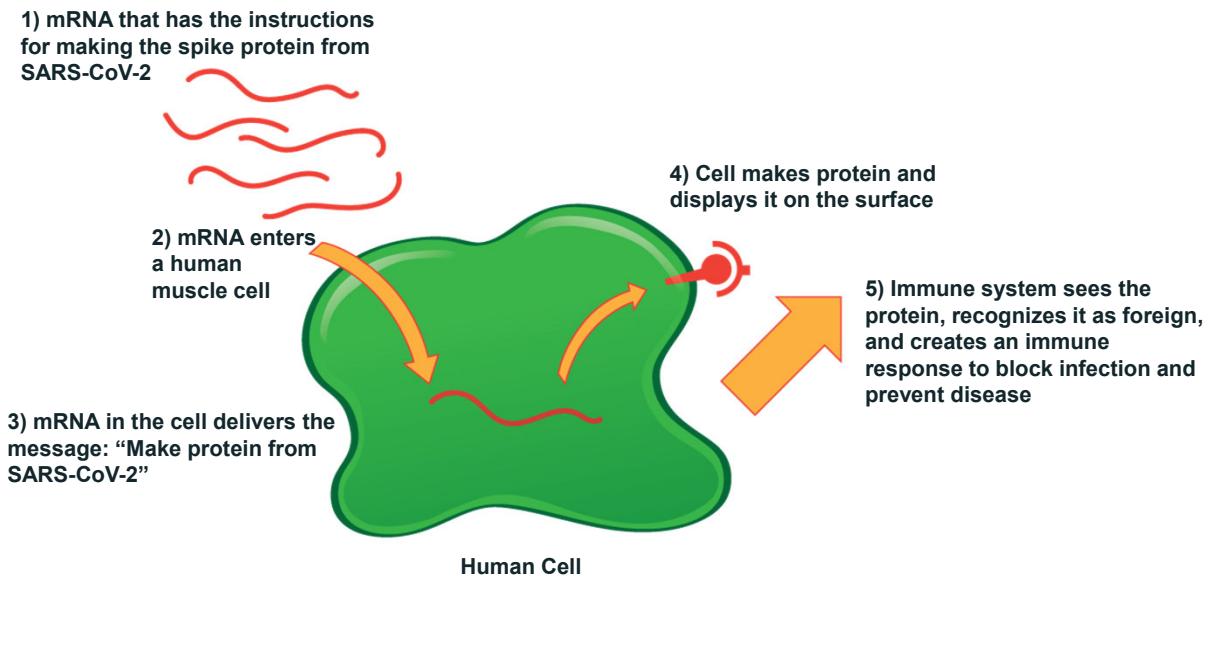


RNA is the instruction manual for how the SARS-CoV-2 virus makes copies of itself. The Messenger RNA, or mRNA, carries the instructions into human cells.

- Messenger RNA (mRNA) in the vaccine carries instructions into human cells for making the spike protein found on the surface of SARS-CoV-2, teaching the cells how to make the spike protein.
- The vaccine is injected into a person's deltoid muscle cells in their upper arm. Once inside the cells, the mRNA in the vaccine delivers its message and teaches cells to make part of the spike protein.
- The cells then display that bit of the SARS-CoV-2 spike protein on their surface.
- Once on the cells' surface, the immune system can see that protein and recognize it as a foreign "invader." The immune system starts to make an immune response to SARS-CoV-2, including making those important antibodies to help block infection, and making T-cells that help to clear the virus out of the body so that it does not develop into severe disease.

If a person is ever exposed to the real SARS-CoV-2 virus, the immune system will already recognize it because of the vaccine, and will be able to respond quickly to fight back. This study will tell us if the vaccine is successful at working in this manner.

# What happens in cells



[\*\*Note to sites: this information is another way of explaining how the mRNA works. You may want to choose the previous slide or this one, depending on what is appropriate for your audience. You don't need both.]

RNA is the instruction manual for how the SARS-CoV-2 virus makes copies of itself. The Messenger RNA, or mRNA, carries the instructions into human cells.

(1 & 2) Messenger RNA (mRNA) carries instructions into human cells for making the spike protein found on the surface of SARS-CoV-2, teaching the cell how to make the spike protein.

(3) Once inside the cell, the mRNA in the vaccine delivers its message and teaches cells to make part of the spike protein.

(4) The cell then displays that bit of the SARS-CoV-2 spike protein on its surface.

(5) Then the immune system can see that protein and recognize it as a foreign "invader," and it starts to make an immune response to SARS-CoV-2. This immune response can include making antibodies to help block infection, and making T-cells that help to clear the virus out of the body so that it does not develop into severe disease.

If a person is ever exposed to the real SARS-CoV-2 virus, the immune system will already recognize it because of the vaccine, and will be able to respond quickly to fight back. This study will tell us if the vaccine is successful at working in this manner.

## Who will be enrolled?

The study will enroll adults **aged 18 and older** who are **at risk of infection with SARS-CoV-2**. This can include, but is not limited to:

- Adults over age 65
- People with underlying health conditions, such as heart disease, high blood pressure, and diabetes
- People with a greater chance of exposure at their job
- People who live or work in elder-care facilities
- People who work in jails or prisons
- People from racial and ethnic groups that have been impacted in greater numbers by the epidemic, such as African Americans, Latinx, and Native Americans



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# The main research questions

- **The researchers want to learn:**

- Is the study vaccine safe to give to people?
- Can the study vaccine reduce the severity of COVID-19 illness?



# The general risks of vaccines

## Common:

- Fever, chills, rash, aches and pains, nausea, headache, brief dizziness (but most people can still do their planned activities)
- Pain, redness, swelling, or itching where you got the injection

## Rare:

- Allergic reactions such as hives or difficulty breathing



*Always tell us if you are having a reaction to any of the injections!*



All vaccines have some risks, and this is true for this study vaccine too.

**Common risks** are things like fever, chills, rash, aches and pains, nausea, headache, dizziness. These issues usually go away within a few days, and most people can still go about their daily activities.

Some of the **rare risks** include allergic reactions such as hives or difficulty breathing.

Throughout the study we will be monitoring the participants closely for any side effects. I'll have more information about this coming up in a few slides.

## The risks of the study vaccine

- Over 300 volunteers have received at least one dose of this study vaccine in 2 other studies that began in March, 2020 (Phase 1) and May, 2020 (Phase 2).
- There have been no serious safety concerns seen with the dose used in this study so far.
- The side effects reported by participants in those studies have been rated “mild” or “moderate.” They include:
  - Fever
  - Pain at the injection site
  - Headache
  - Muscle aches & pains
  - Chills
  - Redness and hardness of the skin at the injection site
  - Joint aches & pains
  - Fatigue (tiredness)
  - Nausea/vomiting
  - Under arm gland swelling on the same side of the body as the injection was given
- The early data from those 2 studies shows that people do create an immune response after getting the study vaccine. We don’t know yet if that immune response will provide protection against SARS-CoV-2 infection, or if it will help reduce the severity of COVID-19 illness.



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**\*\*Note to Sites:** some potential participants may want to read published reports about Moderna’s early stage trials for themselves. Here is Moderna’s press release that can be shared:

<https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-positive-interim-phase-1-data-its-mrna-vaccine>

## Study groups

Number of people	Group	First Injection (Day 1)	Second Injection (one month later)
15,000 people	1	mRNA Vaccine	mRNA Vaccine
15,000 people	2	Placebo (sterile salt water)	Placebo (sterile salt water)

The clinic visits and safety follow-up will take place over about 2 years.



## Who chooses which group you are in?



The group you are assigned to is completely **random**, like flipping a coin or rolling dice. This process is called **randomization**.



You will be assigned to a group randomly by a computer. The process is like flipping a coin. This process of randomly assigning people to the vaccine or placebo groups means that there will be no bias or preferential treatment about who gets which product. This randomization process is important for a research study because it allows the researchers to compare fairly equal groups.

## This study is “blinded”

This means that neither you or the study doctors and nurses know who is getting the study vaccine or the placebo.

A study is blinded so that everyone is treated the same at the research clinic.

The pharmacist at each research clinic is the only person who knows what a participant gets, just in case there is a need to “unblind.”



Image from Google images.



This study is blinded.

This means that neither the participants nor the study doctors and nurses know who is getting the study vaccine or the placebo. This helps to make sure everyone gets treated the same way by the staff of the research clinic. It also reduces the chance that participants will change their behaviors because they think they might be getting protected by the vaccine. We don't want anyone to assume they are protected from SARS-CoV-2! The study vaccine is experimental, so we want everyone to continue to follow the guidelines for protecting yourself.

The pharmacist is the only person who knows which product each participant gets, just in case there is a need to “unblind,” such as if a person has a medical emergency. Otherwise, the pharmacist must keep this information confidential.

## Joining is up to you!

- Do you have to join?
- **NO!** It is your choice to join the study. Take your time in deciding.
- If you do want to join this study:
  - You can leave whenever you wish.
  - You may not be able to join another study for a different SARS-CoV-2 vaccine.



Deciding to join a study is completely voluntary. You do not have to join if you don't want to. Also, if you do join the study but change your mind later, you may also leave. But we hope you stay for the entire study so that your participation can have the greatest impact in helping us understand how the products are working. Please take time in deciding if study participation is right for you.

Also, if you join this study it may mean you are not eligible to join other studies for different SARS-CoV-2 vaccines. Please consider this before deciding to join.

It can be helpful to talk to your family, friends, health care providers, and religious leaders before deciding to join.

## Joining the study

- We will see if you are eligible.
- We will need to check your general health. This includes:
  - **A physical exam.** A physical exam means checking things like your weight, temperature, blood pressure, mouth, heart, urine, blood and other basic health screens, and asking about the medicines you take.
  - Talking to you about your **health history** (previous medical issues, etc.).
  - Talking to you about your **risk for infection** with SARS-CoV-2.



If you think you do want to join, we will need to screen you to make sure you are eligible. This means we will need to check your general health.

To screen you we will need to do a physical examination. This means checking things like your weight, temperature, blood pressure. It also may involve touching parts of your body like your chest to check your heart. We will also ask you about any medicines you take.

We will talk with you about your risk for infection with SARS-CoV-2.

After we finish all of these screening procedures, we will tell you if you are eligible. Then it will be up to you to decide if you want to continue with the enrollment process.

## There is no cost to be in the study

- You do not have to pay anything to be in the study.
- If the study vaccine later becomes approved and sold, there are no plans to share any money with you.



You do not have to pay anything to be in the study. All study related services are provided free of charge.

However, later on if the study vaccine actually does become approved and sold, there is no way for that money to be shared with you either.

## We will reimburse you

We do not pay study participants, but we do reimburse you for your time, travel, and the inconvenience.



time



travel



inconvenience



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However, we will be able to offer you some compensation for your time, travel and inconvenience. We realize it takes a lot of time to come for study visits so we want to make sure this is not too much of a burden for you.

**[Note to Sites: You may want to include the actual amount of compensation at your site, or mention other services that your site provides]**

## At your visits we may...

- Do a physical exam
- Collect blood samples
- Collect swabs of the back of your nose
- If we are unable to collect the swabs, we may ask for a swab of the front of your nose or a saliva sample instead.
- Test you for pregnancy (if applicable)
- Talk to you about your health and any medications you're taking
- Review your symptom diary (electronic or paper) after each injection visit



- There will also be phone calls to check on you.
- Some visits may be done by a staff member who comes to your home.



Most of the study visits will be similar to the screening visits. The clinic staff will want to check on your general health, review your medications, and test you for pregnancy (if that applies to you).

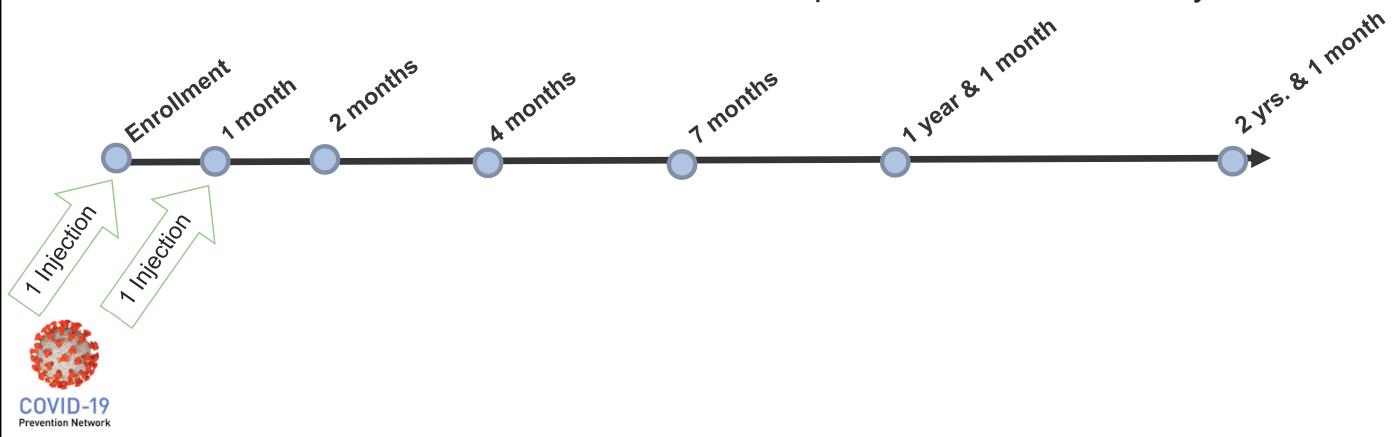
We will also take more blood samples. When we take blood, the amount will depend on the lab tests we need to do. It will be less than 75 mL. Your body will make new blood to replace the blood we take out. By comparison, when you donate blood at the Red Cross, you donate about 500 mL, so this is a lot less!

**[Note to sites: you may want to show examples of this quantity by showing the blood collection tubes, or something like a small container of hand lotion, to help contextualize the blood volumes.]**

At some visits we will do swabs of the back of your nose to test for SARS-CoV-2. If we are unable to collect these swabs for some reason, we may ask you for a swab of the front of your nose or a saliva sample instead.

## Study visits

- You will come to the clinic for visits about 7 times over about 2 years.
- At the first 2 visits you will get study injections in the muscle of your upper arm (Day 1 and 1 month later).
- Other visits for safety follow-up are scheduled at 4 months, 7 months, 13 months, and 25 months. In between visits there will be phone calls to check on your health.



In total you will come to the clinic about 7 times over a period of about 2 years. You will only get injections at the first 2 visits as shown here. In between the clinic visits, there will also be phone calls for the study team to check on your health.

The total number of visits may vary depending if we need to run extra tests or if you are having any problems. The study staff will review the schedule of all study procedures with you, so that you know what to expect at each visit.

There will be a total of about 24 phone calls to check on you during the study. After each injection visit there will be calls 1 week, 2 weeks, and 3 weeks after to see how you are doing. Other calls will happen monthly during the months when no clinic visit is scheduled.

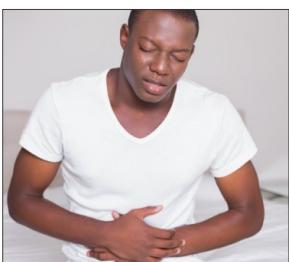
## Checking on you after injections

- After your injections, you will wait in the clinic for about 30 minutes to see if there are any problems.
- For 7 days after each injection we will ask you to note how you are feeling and if you have any symptoms. You will use an eDiary or a paper form to keep track. We will also ask you to take your temperature.

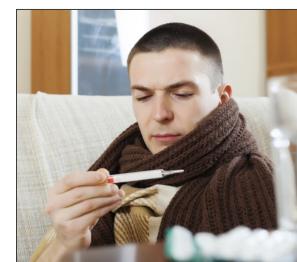
*Headache?*



*Sore arm?*

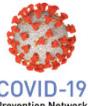


*Upset stomach?*



*Feeling Tired?*

*Fever?*



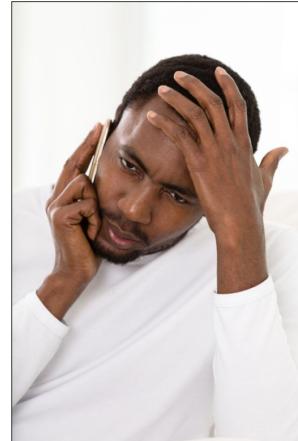
It is very important for the study team to see how you are feeling immediately after you get the injections. So at those 2 visits you will wait in the clinic for about 30 minutes after your injection to see if there are any problems.

You will be asked to use an eDiary to keep track of any side effects you have for 7 days after your injection. You will also be asked to contact the clinic staff if you aren't feeling well. The staff will give you a ruler and show you how to measure if you have any arm swelling. They will also give you a thermometer and show you how to take your temperature. These are some of the details you will keep track of in your diary. You will review the diary with the clinic staff at your next visit, so if you are using the paper diary be sure to save it and bring it with you. Your diary becomes part of the study data to answer the research questions.

And as I just mentioned, the clinic staff will also be in contact with you by phone 1 week, 2 weeks, and 3 weeks after each injection to see how you are doing.

## If you get sick or injured, contact us *immediately!*

- Your health is important to us. We will help you get the medical care you need.
- We will tell you about the care that we can give you and about the care that we can help you get outside of this clinic.
- We will give you a card with the symptoms of COVID-19 illness. If you think you have any symptoms, call us right away.



During the study, your health is the most important thing. If you should feel sick or get injured during the study, please contact us immediately. We will tell you about the care that we can provide at our clinic, and we will tell you about the care that we can help you get or refer you to outside of our clinic.

# Pregnancy and study participation

We do not know how the study vaccines could affect eggs or sperm, or the developing baby. So:

- If you or your partner could become pregnant, we will ask you to use birth control during the study.
- If you or your partner do become pregnant during the study, we will stop your injections.
- We would also like to talk with you after the baby is born to ask some questions about the pregnancy and delivery.



The study vaccines and adjuvant are experimental and we do not know if they will have any effect on eggs or sperm, or a developing baby. We do not want any study participants or their partners to become pregnant during the study.

While in the study, we ask that you use birth control from 4 weeks before their first injection until 3 months after the last injection. This is a total of about 5 months. We will review the acceptable forms of birth control with you.

However, sometimes pregnancies happen anyway. If you or your partner becomes pregnant, we will stop giving the study injections but we may still do other study visits. If the pregnancy goes through until delivery, we will contact you after the baby is born to learn more about the pregnancy and delivery.

## We will keep your information private

- Your study records and samples will be kept in a secure location. They will be labeled with a code number, not your name.
- Clinic staff will have access to your study records. Your records may also be reviewed by groups who watch over this study to see that we are protecting your rights, keeping you safe, and following the study plan.



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Your privacy is very important. Personal study information is kept confidential. Most study documents that contain personal information use a code instead of your name, then they are placed in secured, locked cabinets or password-protected computers.

There are a few groups of people who will have access to your study records. They want to make sure your rights are being protected, you are safe, and that the clinic is following the study plan and all the rules about proper study conduct. The informed consent form provides a list of who these groups are.

# Stopping your injections or taking you out of the study

This may happen:

- If you develop COVID-19 illness (we will help you get care and support)
- If you or your partner become pregnant (no more injections but you may be able to stay in the study)
- If you do not follow instructions
- If staying in the study may harm you
- If you enroll in another study where they give you a study product
- If the study is stopped



Once in a while we have to stop giving study injections to participants. This can happen for a variety of reasons.

This may happen:

- If you develop COVID-19 illness. We will help you get care and support. (I'll tell you more about this in a few minutes.)
- If you or your partner become pregnant (no more injections but you may be able to stay in the study)
- If you do not follow instructions
- If staying in the study may harm you
- If you enroll in a study where they give you another study product
- If the study is stopped for any reason

# Other risks of joining a study

**There are some possible risks to being in this study.**

For example:

- Risks of routine medical procedures (taking blood samples, getting shots)
- Risks of the study vaccine
- Developing SARS-CoV-2 vaccine antibodies
- Anxiety
- Having your personal information shared
- Things we don't yet know about, even serious risks



Joining a research study has some risks involved. There are the risks of the vaccines and injections, but there are other types of risks too.

- Risks of routine medical procedures (taking blood samples, giving shots).
- Risks of the study products (we talked about this earlier)
- Developing vaccine antibodies (we will talk about this more in a minute). Antibodies can protect you from diseases but it is possible your body will create antibodies as a result of the vaccines. Until we have a vaccine that works, the antibodies from the vaccines may not protect you from SARS-CoV-2 at all.
- Anxiety- some people get anxious waiting for test results like their SARS-CoV-2 tests.
- Having your personal information shared.
- There may also be risks that we don't know about. But if we learn any new information that could affect your decision to stay in the study, we will tell you immediately.

## Vaccine antibodies

- Creating an antibody response is one *goal* of a vaccine. But...
- VISP = Vaccine-Induced Sero-Positivity
- VISP occurs when the antibodies you develop in response to the vaccine cause a positive result on antibody tests (usually using a blood sample) that look to see if you have ever had a SARS-CoV-2 infection. Your health care provider or others who are unfamiliar with vaccine studies may think your test result means you have had SARS-CoV-2 infection, instead of having antibodies from the study vaccine.
- We don't know yet if these antibodies will protect you. That is what this study will tell us.
- We don't recommend that you get tested outside of this study, but if you need to, we can give you information about the type of test you should ask for to avoid VISP.

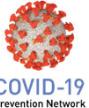
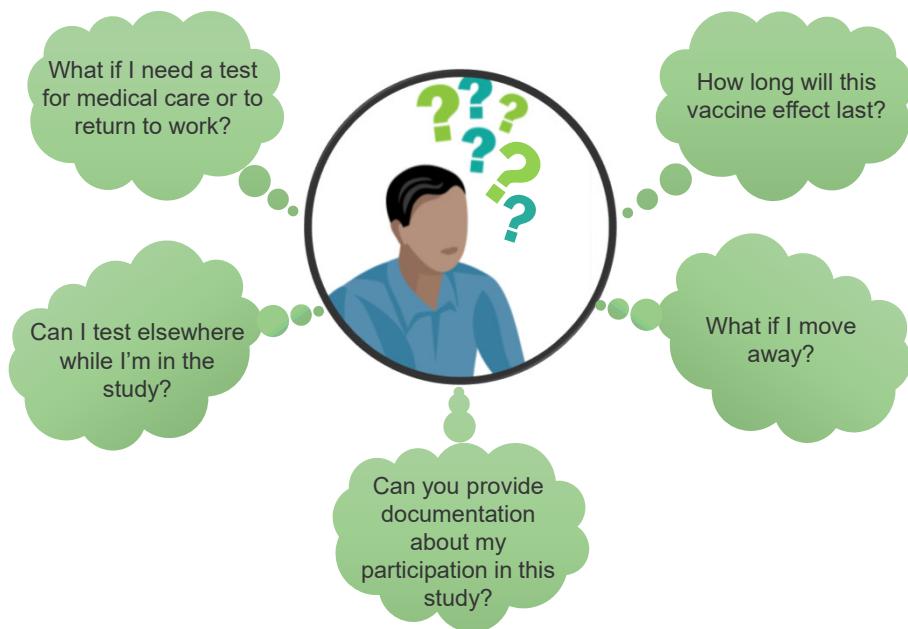


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Your body may develop antibodies against SARS-CoV-2 as a result of getting this study vaccine. However the vaccine is still experimental, and we don't know if the antibodies will actually be able to protect you. This means that if you get the study vaccine (not the placebo), and then you get an antibody test to see if you have ever been infected with SARS-CoV-2, it could come back positive just because of the vaccine and not because you were ever actually infected.

Because of the potential for a testing center or health care provider to misinterpret your test results, we recommend that study participants don't have tests done outside of the study site. If you do need to get tested for some reason, such as if your employer requires a test for you to return to work, please let us know. We can tell you more about the type of test to ask for so that you can avoid VISP.

# Common questions about VISP



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1. **What if I need a test for medical care or to return to work?** The research clinic can provide you with information about the type of test you should ask for in order to avoid VISP results.
2. **Can I test elsewhere while I'm in the study?** While you are in the study it is best not to get tested outside the study. That way there is no chance that someone will misinterpret your test results.
3. **Can you provide documentation about my participation in this study?** Yes, we can provide documentation with a letter explaining your study participation and the type of testing you should get.
4. **What if I move away?** If you move away and need to get tested, just call us! We can send you a letter to confirm your study participation, and we'll remind you about the type of testing to ask for.
5. **How long will this vaccine effect last?** We are not sure. It could last for years or it might go away after a short time.

## Benefits

**This study may be of no direct benefit to you.**

However, you and others may benefit in the future from information learned in this study.

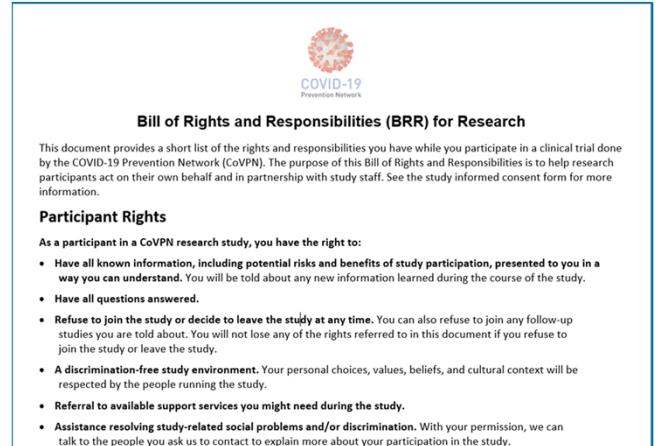


Joining a research study is an important step in finding a safe and effective vaccine for SARS-CoV-2, and it can help your community in the long term. In the short term, the study may not provide you any direct benefits.

# Rights and responsibilities

You have rights and responsibilities if you join this study. We list these in the Bill of Rights and Responsibilities for Research.

We will review this with you and give you a copy.



The document cover shows the COVID-19 Prevention Network logo at the top. Below it is the title "Bill of Rights and Responsibilities (BRR) for Research". A short description follows: "This document provides a short list of the rights and responsibilities you have while you participate in a clinical trial done by the COVID-19 Prevention Network (CoVPN). The purpose of this Bill of Rights and Responsibilities is to help research participants act on their own behalf and in partnership with study staff. See the study informed consent form for more information." Under the heading "Participant Rights", it says: "As a participant in a CoVPN research study, you have the right to:" followed by a bulleted list of rights.

**Participant Rights**

As a participant in a CoVPN research study, you have the right to:

- Have all known information, including potential risks and benefits of study participation, presented to you in a way you can understand. You will be told about any new information learned during the course of the study.
- Have all questions answered.
- Refuse to join the study or decide to leave the study at any time. You can also refuse to join any follow-up studies you are told about. You will not lose any of the rights referred to in this document if you refuse to join the study or leave the study.
- A discrimination-free study environment. Your personal choices, values, beliefs, and cultural context will be respected by the people running the study.
- Referral to available support services you might need during the study.
- Assistance resolving study-related social problems and/or discrimination. With your permission, we can talk to the people you ask us to contact to explain more about your participation in the study.

While you are in the study, you have rights as a study participant and also responsibilities. The staff of the clinic have responsibilities as well. We will go over this list with you and give you a copy to keep.

An example of a **right** is:

**Have all known information, including potential risks and benefits of trial participation, presented to you in a way that you can understand.**

An example of a **responsibility** is:

**Review and demonstrate an understanding of all the materials given to you, including the informed consent documents.** Ask for explanation about any information you do not understand before you agree to participate in the study. You can also ask questions anytime during the study.



# What happens if you get COVID-19 illness?



## Checking for SARS-CoV-2 infection

- During the study we will ask you to check your health for about 17 symptoms of COVID-19 illness, including:
  - Fever (Temperature  $\geq 38^{\circ}\text{C}/100.4^{\circ}\text{F}$ )
  - New loss of taste
  - Chills
  - Cough
  - Shortness of breath
  - Difficulty breathing
  - Fatigue
  - Muscle aches
  - Body aches
  - New loss of smell
  - Sore throat
  - Congestion
  - Runny nose
  - Nausea
  - Vomiting
  - Diarrhea
  - Headache
- If you think you may have an infection, call the study doctor as soon as possible, or within 3 days to schedule an “illness visit.”
- Complete an eDiary to track your daily COVID-19 symptoms, including any medicine you take. We will do a second illness visit about a month later.



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If you think you have any of the symptoms of COVID-19 illness, please call the study clinic as soon as possible, ideally within 3 days of when the symptoms start, so that we can schedule you for an “illness visit.”

At the “Illness Visit” you will have a physical exam and the study staff will collect 2 swabs from the back of your nose to see if you have been infected with SARS-CoV-2. We will also collect a blood sample of about 20 mL to study your immune responses. If you cannot make it to the clinic for any reason for the illness visit, and if you agree to it, a member of the study team can do a home visit as soon as possible to collect the swabs.

We will also ask you to complete an eDiary to track your COVID-19 symptoms every day, including any medicine you take. It is important for us to understand how long symptoms last. We will do a second illness visit about a month later, to see how your recovery is going.

## Monitoring your health

- If we confirm that you have COVID-19 illness, we will tell you and your primary healthcare provider as soon as the test results are available.
- We will advise you about any steps you should follow to stay quarantined away from other people, and about your medical care.
- We will also give you a device to help monitor your health while you are sick. It sends information to the study team electronically. We will also do daily telemedicine visits to check on you for 2 weeks, and collect saliva samples.
- If the device alerts the team that any of your symptoms are of concern, they will try to call you. If they can't reach you, they may visit your home.
- If you need additional medical care at any time, they will help you get the care you need, including if you need to go to the hospital.



Your safety and well being is our top priority. If we confirm that you have COVID-19, we will work with you and your healthcare provider to make sure you get the care you need. We will talk with you about being in quarantine and staying away from other people.

We will also ask you to wear a device on your arm that monitors your health and sends information to the study team electronically. As you can see in the picture, it looks like the sort of arm band people wear to carry a cell phone when jogging. This device weighs about half as much as a typical iPhone.

If the device alerts the study team that any of your symptoms are of concern, we will try to call you to check on you. If we can't reach you, we may visit your home to make sure you're OK. And if we think that you need additional medical care, we will help you to access that care, including if you need to be hospitalized. The cost of your medical care to treat COVID-19 illness is not paid for by the study. That will be paid for by you or your health insurance. The staff will talk with you more about this.

You will also have daily telemedicine calls for the first two weeks, or until your symptoms go away, whichever is longer. During the first month you will also collect 6 saliva samples.

## If you are hospitalized

- Some people who get COVID-19 will have symptoms that get worse and they need to be hospitalized.
- If this happens, we will pause your study participation. We will check your hospital medical records for information we need about your health and the care you received. We may also try to collect a sample.
- When you are released from the hospital, please call us. We would like to have you continue to participate in the study so that we can follow your safety for the full study period.



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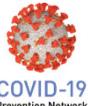
If you need to be hospitalized, your study participation will be paused. If we are able to see you in the hospital, we may try to collect a sample. If this is not possible, we will use your medical records to learn the information we need about your health and the care you received.

After you are released from the hospital, we would like to bring you back into the study on the regular visit schedule. This is so that we can continue to follow how your body responds to getting the study injections. We would like to follow you for the whole study period of about 2 years. Please let us know when you have been released from the hospital.

# Visit schedule for people with COVID-19

Procedure	Illness Visit	Day 3	Day 5	1 week	Day 9	2 weeks	3 weeks	4 weeks- Illness Visit
Update medical history	X							
Complete physical	X							X
Blood drawn	X							X
Collect a swab from the back of your nose	X (2)							
Collect a saliva sample	X	X	X	X	X	X	X	X

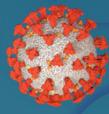
You will also have daily telemedicine calls to check on your health for the first 2 weeks, or until the symptoms go away, whichever is longer.



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Study participants who develop COVID-19 illness will have a more intensive visit schedule to monitor their health for a month while they are sick. During this time, we will do frequent tests for SARS-CoV-2, because we want to understand how long your infection lasts.

At the end of this intensive monitoring, you will go back to having clinic visits and phone calls on the same schedule I described earlier. Those visits are for monitoring your safety after injections, and so that we can collect blood samples to see how your immune system responded to the injections. We want to monitor your safety for the full study period.



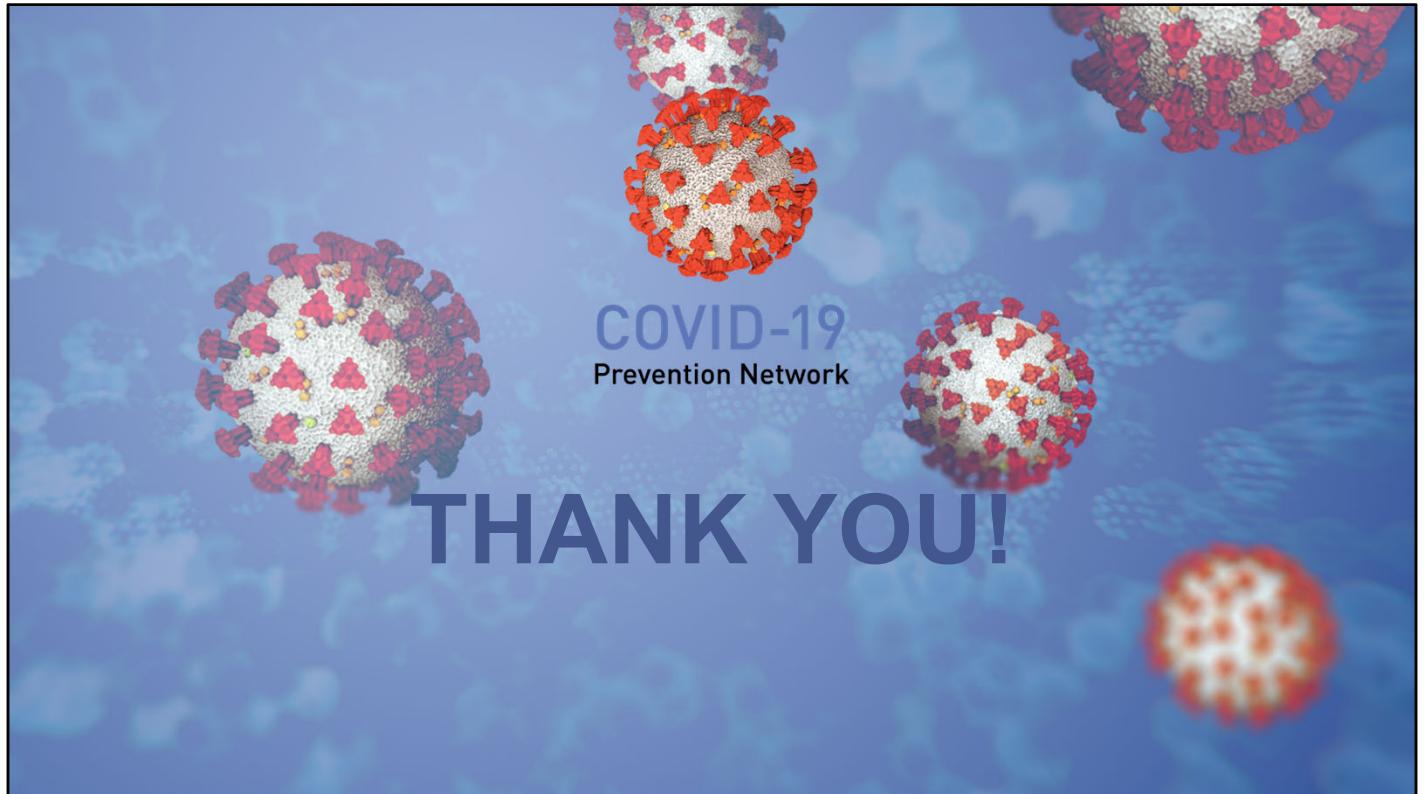
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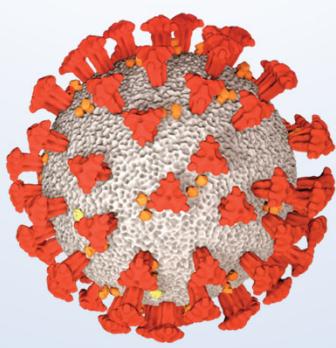
# Questions?

That was a lot of information! Let's be sure all your questions have been answered.

# Acknowledgements

- Members of the CoVPN Operations Center staff: *Gail Broder, Michele Andrasik, Jessica Andriesen, Giulio Corbelli, Lisa Donohue, Aziel Gangerdine, Huub Gelderblom, Daciana Margineantu, Rachael McClenen, Stephaun Wallace*
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- Study Co-Chairs: *Dr. Lindsey Baden and Dr. Hana El-Sahly*
- Moderna: *Diane Montross, Conor Knightly*
- Operation Warp Speed Community Engagement team: *Chris Beyrer, Jessica Cowden, Jontraye Davis, Liza Dawson, Risha Irvin, Robin Mason, Nelson Michael, Rona Siskind, Jordan White*
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- Seattle-King County Dept. of Public Health





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