

MAIN INFORMED CONSENT FORM (ICF) AND PARENTAL PERMISSION FORM FOR AGES 12 - 17 YEARS OLD

TITLE: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Assessing the Efficacy and Safety of Anti-Spike SARS-CoV-2 Monoclonal Antibodies in Preventing SARS-Cov-2 Infection in Household Contacts of Individuals Infected with SARS-CoV-2

PROTOCOL NO.: R10933-10987-COV-2069
WIRB® Protocol #20201773
NCT No.: NCT04452318
EudraCT No.: 2020-003654-71

SPONSOR: Regeneron Pharmaceuticals, Inc.

INVESTIGATOR: Name
Address
City, State Zip
Country

**STUDY-RELATED
PHONE NUMBER(S):** Phone Number
Phone Number (24 hours)
[24 hour number is required]

Participant's Printed Name: _____

This research study involves both adults and children/adolescents (<18 years of age). For purposes of this form, “you” refers to the person (adult or adolescent [ages 12 to 17]) participating in this study. If you are the parent/caregivers reviewing this ICF on behalf of your child, “you” refers to your adolescent participating in this research study.

Summary

This research study is looking at experimental drugs to prevent the COVID-19 disease from occurring in people who have been exposed to the SARS-CoV-2 virus. The study drugs target the virus that causes COVID-19 and are designed to make it harder for the virus to infect you. The goals of the study include seeing REGN10933+REGN10987 lowers infection by the virus, whether they reduce the need for medical visits and the amount of time you spend away from your day-to-day activities (i.e., work, school, caring for others) due to COVID-19, and whether they can cause side effects.

If you agree to join, you will be in the study for about 32 weeks. You will be randomly assigned to receive 1 dose of either REGN10933+REGN10987 or a placebo. This will be done subcutaneously (under the skin). During the study, you will have tests done at several times, including having nasopharyngeal swabs taken, as well as having blood drawn.

Because this is a research study with experimental drugs, you may or may not benefit from being in the study. There is also only a limited amount of data about these REGN10933+REGN10987 in people. This is the first time that REGN10933+REGN10987 have been given to humans subcutaneously. There are other clinical trials by the sponsor with REGN10933+REGN10987 given intravenously (in a vein). Even though participants will be carefully watched, the risks of receiving the drug are unknown. Some of these risks may be serious or life-threatening.

The choice to join is up to you. You will not be penalized in any way if you decide not to join or if you leave the study. Regardless of study participation, you can continue to receive any standard-of-care treatment. The rest of this form provides more information to help you decide if you want to join.

What is the purpose of this form?

You are being asked if you would like to join a research study (also called a clinical trial). This consent form explains why the study is being done, possible risks and benefits to you, your rights, and what you will have to do if you join. The choice is up to you, and you do not have to join the study if you do not want to. If you decide to join, you will be asked to sign and date this form, stating that you understand what was explained to you and that you agree to be in the study. This is called informed consent.

The informed consent form may be delivered and signed in paper format. It may also be delivered and signed electronically (eConsent) if local laws, regulations, and study site policies allow this.

Please read this form carefully. Ask the study doctor or staff any questions you have about the study. You can take an unsigned copy to review with your personal doctor, family, and friends. If you agree to join, you will be given a signed and dated copy. No tests will be done until this form is signed.

If you decide not to join, you will not be penalized or lose any benefits that you would otherwise be entitled.

Who is sponsoring this study?

Regeneron Pharmaceuticals, Inc. (“Regeneron”) is the sponsor of the study. This means that Regeneron is paying for the study, and overseeing study conduct according to the requirements of the U.S. Food and Drug Administration (FDA) and other regulatory agencies, and the study doctor will be paid by Regeneron or its collaborators.

Regeneron, its collaborators or those developing REGN10933+REGN10987, and their affiliates, representatives, agents, and contractors (the “Regeneron Parties”), are involved in the study. Some or all of these groups may use the information collected in the study to carry out the research described in this consent form.

This study is being reviewed by an independent group called an institutional review board (IRB) or ethics committee (EC). This group, which is not a part of Regeneron, looks out for the safety, welfare, and rights of people taking part in research studies. The IRB or EC reviewing this study has approved the study/given the study a favorable opinion.

Why is this study being done?

The study is researching an experimental drug combination casirivimab (REGN10933) and imdevimab (REGN10987), given as separate subcutaneous (SC, under the skin) injections. REGN10933 and REGN10987 will sometimes be collectively referred to as the “REGN10933+REGN10987” in this consent form.

The aim of the study is to see how safe, tolerable, and effective REGN10933+REGN10987 may be in preventing SARS-CoV-2 infection and/or COVID-19 in people who have been exposed to SARS CoV-2 by someone with whom they live with and have tested negative or positive for SARS-CoV-2 virus but are not showing any signs of infection.

The study is trying to answer several specific research questions. These include:

- Whether REGN10933+REGN10987 can reduce the likelihood of a person getting the SARS-CoV-2 infection who tested negative
- Whether REGN10933+REGN10987 can prevent the SARS-CoV-2 infection from developing into COVID-19 disease for people who tested positive
- Whether REGN10933+REGN10987 can help reduce the number days a person is away from work who tested positive or negative to the SARS-CoV-2 virus
- Whether REGN10933+REGN10987 can help reduce the number of visits to the doctor’s office for people who tested positive or negative to the SARS-CoV-2 virus
- Whether any side effects may happen from taking REGN10933+REGN10987
- How much REGN10933+REGN10987 are in your blood at different times
- Whether the body makes its own antibodies against REGN10933+REGN10987 (which could make them less effective or could lead to side effects)

What is REGN10933+REGN10987?

The study drug made of monoclonal antibodies, called REGN10933 and REGN10987.

Antibodies are made by your immune system to fight infections. A monoclonal antibody is made in a laboratory to fight specific types of infections, such as viruses.

COVID-19 is caused by a coronavirus called SARS-CoV-2. This virus uses “spike” to attach to the cells it infects. It is thought that the spike protein helps the virus infect cells in the nose, throat, lungs, and other tissues, leading to COVID-19 symptoms.

The antibodies in this study block the SARS-CoV-2 spike protein. When the spike protein is blocked, the virus may not be able to infect your cells. By making it harder to infect cells, the antibodies may stop COVID-19 symptoms from developing or getting worse. The two antibodies are given together to block the spike protein in two different ways. This may make it harder for the virus to mutate and escape the effects of REGN10933+REGN10987.

It is very important to not participate in other clinical studies while you are in this study. This includes not participating in other studies of investigational antibodies or vaccines. This is necessary for your safety and to avoid interference between study products in different studies. Even if you leave the study early, you must not participate in other clinical studies for the length of this study, about 32 weeks. Please speak with the study doctor if you have any questions or concerns about this.

The study drug is not approved by any public health agency to treat or prevent COVID-19.

The United States Food and Drug Administration (FDA) has made the study drug available as a treatment for COVID-19 under an emergency access mechanism, called Emergency Use Authorization (EUA). The study drug has not undergone the same type of review as an FDA-approved or cleared product. The EUA only applies in the United States during the COVID-19 pandemic, and (like any EUA) can be revoked before the pandemic is over.

If you decide to get the EUA COVID-19 vaccine, you must wait until after week 4 of the study before you should get the EUA COVID-19 vaccine. This is necessary for your safety and to avoid interference between the study drugs and the vaccine.

If you want to learn more about this EUA and its conditions, talk to the study doctor.

How big is the study?

This study will include up to approximately 3750 participants in the United States and worldwide.

How will I know if I can join this study?

There are certain conditions you must meet to enter the study. The study doctor will go over these with you before you can join. There is a chance that you may not qualify or be able to join the study.

How will I be given the study drugs?

This is a randomized, double-blind, placebo-controlled study. “Randomized” means that which study drug you will receive will be by chance, similar to drawing numbers out of a hat or flipping a coin. “Double-blind” means that neither you nor the study doctor will know which study drug you have been given (i.e., if you are receiving study drugs or placebo). This is done to make sure the results of the study cannot be influenced by anyone. If there is an urgent need, the study doctor can find out quickly drug you received. A placebo is an inactive substance, that looks like the medicine, but which contains no medicine. If you agree to take part in this study, you will receive REGN10933+REGN10987 or placebo.

You will have a 1 to 1 or 50/50 chance of getting either one dose of the REGN10933+REGN10987 or placebo. The “one dose” is made up of 4 SC injections of either:

- REGN10933 and REGN10987, 1200 mg (2 doses each of 300 mg of each REGN10933 and REGN10987)

OR

- Matching placebo

The injections will rotate between different locations on your lower abdomen and upper legs. The possible risks of being given the study drugs are described later in the form.

What will happen in the study, and what will I have to do if I join?

After you sign this document, testing will be done to determine if you are eligible to participate in this study. You must meet certain requirements to be able to participate in this study. The study doctor will review all of the restrictions and requirements of the study with you to determine if you qualify for the study. This period, called the screening period, will last for about 1 day. During this time, you will be tested for SARS-CoV-2 infection. You will be tested for SARS-CoV-2 infection at most visits to confirm your negative or positive status.

The exact numbers of days or visits and study procedures that you will have in this study will vary upon when you join the study and if you test negative or positive for the SARS-CoV-2 infection during your participation.

This study is divided into 3 groups. In order to increase safety, the first 30 participants enrolled (Group 1, participants 1 through 30) had a number of additional procedures done to collect safety data. If you were part of this first group, you were asked to stay longer in the clinic on the first day of dosing and asked to return to the clinic for extra site visits to complete blood draws.

If you were enrolled into the second group (Group 2, participants 31 through 400), you also had additional visits and procedures done to collect safety data.

Enrollment into Groups 1 and 2 have been completed. If you decide to join the study you will be placed in the third group (Group 3, participants 401 to 2000).

Your participation will last about 32 weeks. Participants in Group 1 are having about 14 clinic visits and at least 1 telephone visit. Participants in the second group are having about 12 clinic visits and at least 1 scheduled telephone visits, while Group 3 will have about 12 clinic visits. The exact number of clinic visits may change if your SARS-CoV-2 status changes and you need to come in for additional SARS-CoV-2 testing and/or blood draws. It is possible that some of the clinic visits are replaced by a visit at your home or another location. In this case the site staff may also give you a phone call on those days.

The length of the study is based on the currently available information for how long the study drugs last in your body. The follow-up duration may change as more information becomes available from ongoing studies (e.g., clinical trials, laboratory and animal studies).

- Screening period: 1 day (1 visit) – All groups
 - During this period, you will undergo a physical examination (including vital signs), a review of any medications you are taking, medical history, and any changes that occurred in your health recently. Nasopharyngeal swabs (NP) will be collected for SARS-CoV-2 infection testing. The study staff may also collect an additional sample to perform a local test on-site to see if you have SARS-COV-2. This sample may be either a NP, throat, or nasal swab or saliva sample. Blood and urine samples for safety assessments and research samples will also be collected. If you are a woman who can become pregnant, a urine pregnancy test will also be performed. While participating in the study, you will be asked to keep a Participant Identification Card on you at all times. This card has the clinic’s contact information and instructions on when to call the clinic when you are feeling unwell during the study.
 - You will also be given the study drugs at this time.
 - The amount of time that you will have to spend in the clinic will vary depending upon the assessments for that day and your SARS-CoV-2 test status (positive or negative). The study staff will go over with you what the time commitment is for this visit.
 - You will be given a thermometer to take home. It is recommended that you take your temperature daily until the end of the Assessment period and if you start to feel unwell. The study doctor or the study staff will go into more details about how and when to take your temperature at home.
- Assessment period will last up to 4 weeks. Participants in the first group had about 7 visits and at least 1 telephone visit. Group 2 will have about 4 visits and 1 telephone visit, and Group 3 will only have 4 visits and no scheduled telephone visits.
 - Group 1: The assessment period starts as part of day 1 (screening)
 - Clinic visits (days 1, 2, and 4): You underwent physical examinations (including vital signs) at these clinic visits. There was also a review of any medications you are taking and any changes that occurred to your health. Nasopharyngeal swab, nasal swab and/or saliva samples were collected for SARS-CoV-2 infection testing. The study staff also collected blood and urine samples for safety assessments and research samples on each of your clinic visits.
 - Telephone visit (day 3): There was a review of any medications you are taking and any changes that occurred to your health.
 - If you tested negative for SARS-CoV-2 infection and you start feeling unwell during the assessment period, you will need to call the study clinic as soon as possible. You may be asked to check your temperature. The study staff may ask you to come to the clinic to get tested for SARS-CoV-2 infection. Some blood maybe collected at this visit for research samples.
 - Group 2: The assessment period starts on day 4 with a telephone visit.

- Group 3: The assessment period starts on day 8.
- All Groups:
 - You will undergo physical examinations (including vital signs) at day 29. A review of any medications you are taking and any changes that occurred to your health, and nasopharyngeal swabs (or nasal swab and saliva samples for some participants in Group 1) will be collected for SARS-CoV-2 infection testing at each visit (weekly). The study staff will also collect blood and urine samples for safety assessments and research samples on day 29. If you are a woman who can become pregnant, a urine pregnancy test will also be performed on day 29.
 - If you tested negative for SARS-CoV-2 infection and you start feeling unwell during the assessment period, you will need to call the study clinic as soon as possible. You may be asked to check your temperature. The study staff may ask you to come to the clinic to get tested for SARS-CoV-2 infection. Some blood may be collected at this visit for research samples.
 - If you test positive for SARS-CoV-2 infection at any time during this period, you will be asked about any different symptoms related to the SARS-CoV-2 infection you are experiencing. The study staff will also ask you questions about how the COVID-19 disease is affecting your day-to-day activities, like if you are missing days from work or cannot complete routine activities because you are sick and if you had to make trips to the doctor's office or urgent care.
- If you start feeling unwell or your current symptoms are getting worse during the assessment period and you feel like this is a true medical emergency, please seek urgent care at a local hospital/emergency room first before contacting the study clinic.
- The amount of time that you will have to spend in the clinic will vary depending upon the assessments for that day, the group you are in, and your SARS-CoV-2 test status (positive or negative). The study staff will go over with you more on what procedures will take place and the time commitments are for each visit.
- Follow-up period will last up to 28 weeks. All groups will have about 7 visits. The follow-up period will start after day 29.
 - Everyone will undergo a physical examination (including vital signs) on the last day of the study. If you are a woman who can become pregnant, a urine pregnancy test will also be performed on the last study visit.
 - A review of any medications you are taking, and any changes that occurred to your health will occur at every visit.
 - If you are in the first or second groups, blood and urine samples for safety assessments and research samples will be collected monthly. If you are in the third group, you will only have blood taken on 3 visits.
 - If you tested negative during the study and you start feeling unwell during the follow-up period, you will need to call the study clinic as soon as possible. You may be asked to check your temperature. The study staff may ask you to come to the clinic to get tested

for SARS-CoV-2 infection. Some blood maybe collected at this visit for research samples.

- If you test positive for SARS-CoV-2 infection before the end of the follow-up period, nasopharyngeal swabs (or nasal and saliva samples for some participants in Group 1) will be collected for SARS-CoV-2 infection testing until you have 2 negative tests in a row or until the end of the study, whichever is earlier. The study staff will continue to ask you questions about how the COVID-19 disease is affecting your day-to-day activities, like if you are missing days from work or cannot complete routine activities because you are sick.
- If you start feeling unwell or your current symptoms are getting worse during the follow-up period and you feel like this is a true medical emergency, please seek urgent care at a local hospital/emergency room first before contacting the study clinic.
- The amount of time that you will have to spend in the clinic will vary depending upon the assessments for that day and your SARS-CoV-2 test status (positive or negative). The study staff will go over with you what the time commitments are for each visit.

Study Tests, Procedures, and What You Will be Expected to Do

If you decide to participate, you will be asked to do the following things at different times. Some of these may involve risks, which are described below. Because the study involves experimental research, there may be other risks that we cannot predict ahead of time.

Nasopharyngeal swabs

To measure infection by the virus, samples will be collected by taking what is called an NP swab. The study doctor or staff will take these samples. Each time a sample is collected, a swab will be gently inserted about 3 inches into one nostril until the swab reaches the back of your throat. The swab will be rotated a few times and removed. This will then be repeated in the other nostril using a fresh swab.

Possible risks: Collecting nasopharyngeal swabs can be uncomfortable, but not painful. You may gag or feel the urge to sneeze or cough while the sample is being collected. You may also have a minor nosebleed after the sample is taken.

Local on-site SARS-CoV-2 testing

During the screening visit, there is a chance that an additional sample may be collected (nasal, throat swab, NP, saliva) based on the study clinic's procedures for testing if you have SARS-CoV-2 infection before you are given the study drugs.

This local test result may be available within hours of performing the test. The test is for research purposes. You may be told the result of this test based on local regulations and procedures. However, further testing is needed to look for infection. Another sample will be sent out to a contract lab which uses a standard clinical test, this may take a few days. If you have any questions or concerns about these tests, please talk to your study doctor or staff.

Possible risks: Risks related to nasal and throat swabs are similar to the NP swab risks, as mentioned above. There are no expected risks associated with giving saliva samples.

Providing Information About Your Health to the Study Doctor and Staff

At the start of the study, the study doctor or staff will ask you questions about yourself, your health, and your medical history. You will also be asked questions to determine your overall risk of SARS-CoV-2 infection.

Throughout the study, the doctor or staff will continue to collect information about any changes in your health. They may also ask about any medicine or supplements you are taking (prescribed and over-the-counter).

If you test positive during the study and require urgent care or have to go to the hospital/emergency room while you are in the study, please contact the study staff **after** any visit(s) to the hospital/emergency room. The study staff will ask you questions about the trip and will ask you to provide documentation about any treatments you received.

You will be provided a Participant Identification Card to keep on you, to help you contact your study doctor at any time during the study. On the Participant Identification Card will be a telephone number and guidance for when to call the study clinic if you are feeling unwell during the study. The study staff will give you more details at the first study visit.

You will also be asked questions about any missing days of work or any impact on your daily activities (this includes things like not being able to go to school or take care of others because you are sick).

Possible Risks: There are no expected physical risks to occur from answering questions. Information about privacy and confidentiality of your information is included later in this form.

Limited Physical Exams

A physical exam is an exam used to check your overall health. Your weight and height will also be taken.

Possible Risks: There are no expected risks to occur.

Vital Signs

The study staff will take your vital signs, which will include measuring your blood pressure, pulse rate, and breathing rate.

Possible Risks: The inflation of the blood pressure cuff may cause discomfort.

Body Temperature

Your temperature may be measured, or you may be asked to measure your own temperature from your mouth, ear, or forehead.

Possible Risks: There may be slight discomfort when your temperature is measured in the ear. There is no discomfort expected when taking your temperature from under your arm or mouth.

Urinalysis

You will need to provide a urine sample for regular lab testing.

Possible Risks: There are no expected risks or pain expected for taking urine samples.

Pregnancy Test

If you are a woman of childbearing potential, a urine pregnancy test will be required at screening and throughout the study. If you have a positive pregnancy test, then a blood pregnancy test will be performed to confirm positive test.

Possible Risks: There are no expected risks or pain expected for taking a pregnancy test.

Having Medical Visits at Home

In some cases, it may be possible to have a study visit at your home, rather than at the study site or other location. These home visits may be done by a third-party company (a company not affiliated with the study site or Regeneron). The study doctor or staff will talk with you to see if you qualify for these visits. It is your choice whether to allow these kinds of visits or not.

The third-party service may arrive by car or mobile medical unit. The third-party staff who performs the home visits may wear personal protective equipment as they enter and leave your home.

Possible Risks: There could be a loss of privacy due to third-party being used to conduct the home health visits. If you are concerned about these risks, you can come into the study clinic for these visits. Information about privacy and confidentiality of your information is included later in this form.

Having Medical Visits Electronically

Some of your medical visits may be done by phone or by using an electronic app (on a smart phone, tablet, or computer). This type of visit is also called telemedicine. These visits will be done to check on your health, so that you can have fewer in-person visits during the study. The visits may involve video chats with the study doctor and/or staff. The study doctor or staff will talk to you about these types of visits.

Possible Risks: There could be a loss of privacy due to third-party being used to conduct the electronic (telemedicine) visits. If you are concerned about these risks, you can come into the study clinic for these visits. Information about privacy and confidentiality of your information is included later in this form.

Automated Reminders

As part of the study, you may receive automated reminders a few times a week between clinic visits to remind you to call the study clinic if you start to feel unwell during the study.

Possible Risks: There are no expected physical risks to occur from receiving automated reminders. Information about privacy and confidentiality of your information is included later in this form.

Subcutaneous injection risks

Like any injection, this procedure may hurt for a brief moment when the study drugs are injected under the skin. In some cases, reactions such as redness, itchiness, swelling, warmth, pain, and tenderness/discomfort may occur at the injection site. Injection site reactions are generally mild to moderate in severity and generally go away without any treatment.

In rare occasions, severe reactions could occur, such as the fat tissue around the injection site can become uneven (either too much fat tissue collects around the injection site or none) which is called lipodystrophy. Tissue damage could occur around the injection site that could lead to lesions (sores) or skin discoloration (purple, deep red, or black) which could be signs of skin cell death (necrosis).

What types of blood tests will be done during the study?

Blood will be taken to check your health and carry out the research described in this consent form. The amount of blood taken during a visit will range from approximately 7 mL (half a tablespoon) to 53 mL (about 4 tablespoons). The exact amount of blood collected from you during the study will depend upon how long you are in the study and if you had any unscheduled visits.

Possible risks: Blood draws may cause discomfort, bruising, or infection at the site where blood was taken. Some people become faint or dizzy when giving blood.

The following will be tested: standard hematology, blood chemistries for safety testing, amount of drug in your blood and antibodies to the drug.

What types of tests will be done on the nasopharyngeal swabs during this study?

Nasopharyngeal swabs will be taken to test for the SARS-CoV-2 virus and to study the amount of virus you may have in your body. To do this, the samples collected from you will be used to measure levels of virus RNA. In addition, tests will be done on the virus RNA to look at its sequence (the genetic code of the virus). These tests will look at whether the viral sequence can affect whether or not the study drugs work.

Possible risks: The samples that are collected will only be used to study virus RNA and not human RNA. Information about privacy and confidentiality of your information is included later in this form.

Will additional samples be collected?

As described in this form, biological samples will be collected as part of this study. Your coded samples will be used by Regeneron Parties for the purposes of the study, including exploratory research, to identify new learnings, such as:

- How REGN10933+REGN10987 work in the body;
- What makes some people respond better to REGN10933+REGN10987 ;
- Why some people develop side effects;
- To study COVID-19 and the SARS-CoV-2 virus.

These samples will be kept for up to 15 years after the study ends. During that time, the samples may be used for the research described in this form. The samples will be kept in a secure storage area at a Regeneron facility or at a storage facility designated by, and under the supervision of Regeneron in the United States. Unused samples will be destroyed.

If you wish to withdraw your consent to use and store your samples, please notify the study doctor. If you withdraw from the trial, but do not withdraw your consent to use and store your samples, your samples will continue to be used as described in this form. If you withdraw your consent to use the sample and you wish to have the samples destroyed, your study doctor, Regeneron, and the laboratory responsible for processing the samples will make every reasonable effort to ensure your samples are destroyed. However, it is important that you understand that if your sample has already been processed and analyzed, the results and information obtained cannot be destroyed and will continue to be available to the Regeneron Parties.

Will this study benefit me?

The main purpose of this study is research. Because of this, you may or may not get any health benefit from being in the study.

What are the possible risks and side effects of the study drug?

The study drug is being tested in several different studies. The safety of all study participants is carefully watched, both by Regeneron and by an independent review board that is separate from Regeneron. You will be told about any important safety findings related to the study drug.

Study Drug Risks

The risks below are based on what is known about drugs that work in a similar way to the study drug or are given in the same way. Talk to the study doctor if you have any questions about these risks.

Risk of allergic reaction

You may have an allergic reaction. This can happen while you are getting the study drug or within a few minutes, hours or days after. The symptoms can include rash, hives, itch, cough, chills, sweating, shortness of breath, nausea, abdominal (stomach) pain, or feeling flush.

Although rare, you could have a severe allergic reaction such as anaphylaxis. Symptoms can include the ones above but are usually more severe and can happen quickly (within minutes to hours after injection). Other symptoms include dizziness, paleness, loss of consciousness or death. **Get medical help right away** if you think you are having severe symptoms of any kind. Severe symptoms can result in permanent disability or death.

Risk of unwanted immune response

Your body could make its own antibodies against the study drug. Antibodies are the body's normal defense against a foreign substance (like the study drug). If your body makes antibodies against the study drug, however, it could cause side effects or make the drug work less effectively.

Possible risk of the study drug interfering with vaccines or your immune system's memory

It is possible that the study drug could interfere with your body's own ability to fight a future infection of COVID-19. It could also interfere with a vaccine for COVID-19. This has not been seen with any antibody treatment used against the virus that causes COVID-19. However, this risk cannot be ruled out with the study drug.

Possible risk of virus infection getting worse

Antibodies can sometimes make an infection worse. This has mostly been seen in studies of animals. This has not been seen with any antibody treatment used against the virus that causes COVID-19, but the risk cannot be ruled out with the study drug. It is possible that symptoms of COVID-19 could get worse weeks to months after receiving the study drug. Participants will be monitored throughout the study for any possible negative outcomes like this.

Unknown Risks

There may be other side effects related to the study drug that are unknown at this time. Some of these unknown side effects could be serious or life-threatening.

For your safety, it is important that you **promptly** tell the study doctor or staff about any side effects that you are feeling or any changes in your health. You should also report any new medicine or supplements you start taking, including vitamins, herbal remedies, over-the-counter drugs, or prescription drugs.

Pregnancy Risks

The study drug has not been tested in women who are pregnant or breastfeeding. Studies in monkeys did not show any toxic effects on reproductive organs. However, antibodies like the ones in the study drug can sometimes cross the placental barrier (the lining around a fetus during pregnancy) or get into breast milk. Because of this, it is possible that the study drug could travel from a mother to a developing fetus or newborn baby.

Laboratory tests have been done on human fetal tissue donated for research. These tests showed that the study drug did not react with fetal tissue. However, it is not known if the study drug can harm you or your baby if you become pregnant or breastfeed, or whether you could lose your pregnancy.

What happens if I get pregnant?

If you become pregnant during the study, you must tell the study doctor right away. If you are pregnant at the start of the study or become pregnant while in the study the study doctor will follow-up with you on the outcome of your pregnancy.

Because the study drug has not been tested in women who are pregnant, you may want to consider not becoming pregnant while in the study. There may be unknown risks to the fetus.

What other choices do I have if I do not join this study?

Since this study is not intended to provide any therapeutic or other health-related benefit, you may choose to not participate in this study. If you decide not to take part in this study, you should follow advice from your doctor about minimizing your risk of SARS-CoV-2 infection.

There are now vaccines available for COVID-19. If you have received or are planning to receive a vaccine for COVID-19, tell the study doctor. The doctor will explain whether you are eligible for this study and what this could mean while you are in the study.

Your doctor may know of potential treatment plans that are available for you outside of research studies. You and the doctor can discuss what is best for you.

Will I be paid to participate in this study?

For your participation in the clinical study, you will receive a financial compensation of \$[Amount]. If you are part of the first group, you will be compensated with an additional \$[Amount].

If you are signing to allow your child to participate in this study, you will receive a financial compensation for your time, unfortunately, your child cannot be paid for their participation.

The investigator and/or other site staff will discuss the payment schedule with you.

Please note that if you withdraw from the clinical study for non-medical reasons or for reasons non-confirmed by the investigator, you may be paid pro-rata depending on our investigator's decision.

Will I have to spend money to be in this study?

There will be no cost to you for the study drug, study doctor's time or certain procedures and supplies required by this study. However, you are responsible for the cost of your standard medication, in addition to any costs related to procedures and supplies not required by the study.

As part of the study, you may have travel arrangements made for you to travel to and from the study site or testing centers using a third-party company. You will not need to pay for these travel arrangements.

What happens if I get injured while I am in the study?

If you think you have been injured as a result of participating in the study:

- Promptly seek medical treatment, and
- Call the emergency contact number on the first page of this form.

If you have an injury that is directly caused by taking the study drugs or any properly performed study procedures included in the study (procedures you receive only because of your participation in the study) and you have followed the directions of your study doctor, Regeneron will provide reimbursement for reasonable and necessary medical costs to treat your injury that are not covered by your medical or hospital insurance, or from third party or other programs providing such coverage.

Regeneron and its collaborator's will not routinely provide monetary or financial compensation for:

- Other injury- or illness-related costs (such as lost wages, disability or discomfort due to an injury),
- Medical expenses that are paid for by a third party,
- Medical expenses that happen due to a violation of the study or other misconduct or negligence, in each case by any agent or employee of the Institution conducting the study (including the study staff), or
- Medical expenses for injury or illness unrelated to the study drugs and unrelated to the proper performance of any other procedure required by the study or Regeneron's written instructions to the Institution conducting the study, including, without limitation, medical expenses associated with a pre-existing medical condition.

This research is covered by the Public Readiness and Emergency Preparedness (PREP) Act. The PREP Act limits your ability to sue if you are injured by the study drugs or study procedures. However, you may be able to seek compensation from HRSA's Countermeasure Injury Compensation Program for certain serious physical injuries. The declaration is available at:

<https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf>

No funds have been set aside to provide you with any further monetary or financial compensation in case of injury. By agreeing to participate in this study, you do not waive any of your legal rights.

For more information, please contact the study doctor or a member of the study staff.

Can I leave the study after I join?

Yes. You can change your mind and leave the study at any time. You do not need to give a reason. If you leave the study, your medical care outside of the study will not be affected by your decision. You will not be penalized or lose any benefits that you would otherwise be entitled if you were not in the study.

If you decide to leave, it is important to let the study doctor know as soon as possible so you can stop safely. If you already received the study drug, you will be asked to come back for a follow-up visit so that tests can be done to check your health. You will also be asked to return all study-related items to the study site. If you do not return for a follow-up visit, the study doctor or study staff may want to contact you to check your health.

You will be told of any important new information about the study or study drug, or any changes to the study, that may affect your decision to stay in the study.

Is it possible that I might be asked to leave the study?

Yes. You can be taken out of the study without your consent at any time by the investigator or the sponsor for reasons, including: if the study is no longer in the best interest of your health, if you experience unusual or serious side effects, or if you do not follow the study rules. The study may also be stopped by Regeneron, an IRB, or a health authority such as the U.S. FDA.

DATA PROTECTION: YOUR RIGHTS AND CHOICES

What information will the study staff collect from or about you in connection with this study?

As part of this study, the study doctor and study staff (“Researchers”) will collect and review information about you that contains your name and other personal information. In addition, your treating physicians and other healthcare providers may disclose information from your medical records to the Researchers. The information collected from or about you (“Personal Information”) for this study may include:

- Your medical information, including how you feel, medical and surgical history, your food intake, smoking and alcohol habits, menopausal history (women only), physical activity, sexual habits or behavior, contraception and previous and current medications
- Other personally identifying information, including your name and other information (such as your age, race or ethnicity, gender and country location)
- Results of examinations and laboratory tests
- Biological samples

Regeneron or its representatives may conduct site visits to monitor and ensure that the trial is executed according to the study protocol and applicable local laws and regulations.

Who else will be able to look at my personal information?

The Researchers will use and disclose your Personal Information to the following organizations:

- Regeneron, its collaborators or those developing the study drug; and their affiliates, representatives, agents and contractors (the “Regeneron Parties”)
- The FDA, other U.S. government agencies, and government authorities in other countries
- IRB/EC, a group that looks out for the rights and welfare of research participants

Your personal data may also be shared with third-party companies that help run the study. This may include companies that provide travel services, home health services, as well as companies that develop systems for electronic consent and telemedicine. This data may include personally identifying information, such as your name, address, phone number, and email address. These companies are responsible for the confidentiality of your identifying information and will not share it with Regeneron.

Access to your records may be provided to regulatory authorities, monitors, auditors, and representatives of Regeneron, in order to monitor, audit, and verify research procedures and/or study data. In some cases, this may involve having your records reviewed at the study site. In other cases, your records may be reviewed remotely over the internet, but only if the laws and regulations in your country allow this.

Generally, your permission to use and/or share your Personal Information for the purposes described in this form does not have an expiration date, subject to applicable law, unless you withdraw your permission in writing to the study doctor at the address listed on page 1 of this form.

What precautions will be taken to protect my privacy?

Every effort will be taken to maintain your privacy. Your name will not be attached to records or samples released for research purposes. Instead, your records and samples will only be identified by a code. Only the study doctor and authorized personnel will be able to connect this code to your name. Your Personal Information will be protected by your study doctor and site in accordance with relevant data protection laws.

All data will be stored in locked cabinet files and restricted-access computers. While these security measures reduce the risk of your personal information being misused or accessed by unauthorized individuals, such risks cannot be eliminated entirely. Although we believe that these risks are low, absolute confidentiality cannot be promised. However, all information will be collected and shared in accordance with applicable law and data sharing guidelines that the Sponsor must follow.

Since identifiers are removed from the identifiable private information or identifiable samples, the information or samples could be used for future studies or be distributed to another investigator for future studies without additional informed consent.

How will my personal information and results from this study be used?

The Researchers and organizations listed above will use and disclose your Personal Information in connection with the study to assure quality control, analyze the data, and comply with regulatory duties. This includes the submission of the study results, regulatory approvals of the study drug, to report adverse events, and government reporting, if applicable. In addition, Regeneron Parties will use the study data to assess the safety and efficacy of the study drug.

Your coded Personal Information will be added to a computerized database. This database will be part of the study results. Data and results from this study will be presented at meetings or published in journals. To fulfill regulatory requirements and industry guidelines, the results from this study will also

be provided to qualified researchers who request it for legitimate research purposes. While your coded information may be shared with these researchers or publications, your identity (such as your name, address and email) will not be shared with these researchers and will not be in any presentation or publication.

Researchers may link your data with the data from other household members who volunteered for this study or other Regeneron COVID related studies to help us understand how COVID-19 infection is spread.

As advancements in medical technology continue, Regeneron Parties may reanalyze the study data and the results in future research projects to find new scientific information about the study, REGN10933+REGN10987, COVID-19, or other related diseases.

Once your personal information is disclosed to the Regeneron Parties and to the other organizations identified above, it may be subject to further disclosure and no longer protected by federal privacy law.

Will I have access to my results?

The results produced as part of this study are for research purposes only. The results are not reviewed for medical diagnosis of any disease. Because the results obtained during the course of the research have only clinical research value and are not for medical diagnosis, the Sponsor does not provide individual results to you. In some circumstances, the Sponsor may provide certain results to your study doctor. If, during the course of the study, the study doctor learns information related to your health from the study procedures, the study doctor may discuss this information and your options with you.

What are my privacy rights?

Your Right to Access and/or Correct Your Information

You have the right to access, through your study doctor, all of the information collected about you in your medical record, and to ask for corrections, according to the rules of the study site. You have the right to request information on how the Personal Information reported to the Sponsor are being used and with whom the data have been shared. Please note that your right to access certain information in your medical records may be suspended during your participation in the study. Therefore, if you would like immediate access to your records, you may not be able to continue participating in the study.

Your Right to Object/Withdraw

In order to participate in this study, the Sponsor must collect and use your Personal Information. Your decision to allow the collection and use of your health information is completely voluntary but if you do not allow it, you may not participate in the study. If you change your mind about your Personal Information being used, you can voluntarily withdraw from the study at any time. If you choose to withdraw your permission, you will not be punished in any way or lose any right to access care, treatment, or services outside of the study.

If you withdraw your permission to use your Personal Information, the Personal Information collected prior to your withdrawal will still be processed along with other data collected as part of the study in order to preserve the integrity of the results and in accordance with regulatory requirements. The information collected about you up to the point when you discontinue from the study, or information obtained after you withdraw in connection with a safety issue related to the study, will continue to be used, including lab results, clinic notes, and any other information collected. However, no new information will be collected unless you specifically consent to that.

Your Right to Request Deletion

If you withdraw from the study, you may also request that the Personal Information already collected from you in connection with the study be deleted. However, your right to deletion is limited due to regulatory requirements and to preserve scientific integrity, as your Personal Information must be managed in specific ways in order for the research to be reliable and accurate. The study results and coded data will be kept as long as they are needed for research purposes, any regulatory requirements, and the Sponsor's Data Retention Schedule.

Please be aware that because the Sponsor only maintains coded study data, it generally cannot respond directly to individual requests regarding your privacy rights. Therefore, you should address any of these requests regarding these rights to the study site using the contact information on the first page of this consent form. If you have any questions, concerns, or complaints as to how your **Personal Information** has been handled, you can contact the Sponsor's Data Protection Officer at DataProtection@Regeneron.com.

Will my information be on the internet?

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. Some regulatory authorities and ethics committees may make information available on their websites.

What if something is developed from this research?

By participating in this study, you do not acquire any ownership rights in the samples you contribute or in any medical tests, drugs or other commercial products that may be developed through this research.

Who do I call if I have questions?

The people to contact for any questions, concerns, complaints, research related injury or problems in the study are listed on the first page of this consent. You may ask questions before you sign the consent, at any time during your participation in the study, and after you are finished with the study.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Protocol Title:	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Assessing the Efficacy and Safety of Anti-Spike SARS-CoV-2 Monoclonal Antibodies in Preventing SARS-Cov-2 Infection in Household Contacts of Individuals Infected with SARS-CoV-2
Protocol Number: Sponsor: Research Site:	R10933-10987-COV-2069 Regeneron Pharmaceuticals Inc. [Site]

Participant's Agreement

- I have read and understand this Informed Consent Form. This study has been explained to me in detail and all of my questions have been answered to my satisfaction. I have been given ample time to decide whether to participate.
- I authorize the collection, use, disclosure and storage of my Personal Information and biological samples for the purposes of this study as described in this form.
- I volunteer to participate in this research study.
- I have been informed of my privacy rights related to the collection, use and disclosure of my Personal Information and consent to such collection, use and disclosure.
- I am free to withdraw my consent to the collection, use, and disclosure of my Personal Information at any time without penalty and without affecting my medical treatment; however, I will not be able to continue my participation in the research study after I withdraw consent, and data already collected will continue to be included in study analyses, in accordance with regulatory requirements.
- I agree that my GP/personal physician can be informed of my participation in this study.
- By signing this form, I have not waived any of the legal rights that I otherwise would have as a participant in a research study. I understand that I will receive a signed copy of this form for my records.

CONSENT/ASSENT REQUIREMENTS

- All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
- If assent is obtained, have the person obtaining assent document assent on the consent form.

A copy of the information sheet and your signed consent form will be given to you to keep

_____ Name of Study Participant (Print Name)	_____ Signature	_____ Date (DDMMYYYY)
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Study Investigator or Person Obtaining Consent or Assent

I have fully informed the participant about the study:

_____ Name of Study Investigator or Person Obtaining Consent (Print Name)	_____ Signature	_____ Date (DDMMYYYY)
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OR

I have explained the study to the extent compatible with the subject’s capability, and the subject has agreed to be in the study.

OR

The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Name of Study Investigator or Person
Obtaining Consent (Print Name)

Signature

Date (DDMMYYYY)

Legally Authorized Representative

The Legally Authorized Representative signature should be added if the participant is unable to sign for himself or herself. The relationship between the participant and the Legally Authorized Representative should be stated.

Name of Legally Authorized
Representative (Print Name)

Signature

Date (DDMMYYYY)

Relationship to Study Participant

Witness Signature

[Site should decide whether witness section is required. This section is not mandatory.]

- Not Applicable: witness agreement is not required.
- Applicable: witness agreement and signature are provided below.

As an impartial third party, I witnessed the entire consent discussion. I attest that the above-named participant received a verbal and written description of the study. This individual had sufficient time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

Name of Impartial Witness
(Print Name)

Signature

Date (DDMMYYYY)

Parent or Legal Guardian (site: include this page only if parent is signing for a child [ages 12-17], if not remove)

As a parent or legal guardian of the participant, I confirm that the participant is below the age of consent. I have read and agree with the parental permission agreement and provide permission on behalf of the participant.

Name (Print)

Signature

Date

Relationship to Study Participant

Name (Print)

Signature

Date

Relationship to Study Participant

Permission should be provided by two parents. If permission cannot be provided by the second parent, provide the reason(s) below.

- The second parent: Is deceased
 Is unknown
 Is not legally competent
 Does not have legal custody
 Is "not reasonably available"
 Other reason: _____

Study Investigator or Person Obtaining Permission

I have fully informed the parent(s)/caregiver(s) of the participant about the study:

Name of Study Investigator or Person Obtaining Permission (Print Name)

Signature

Date (DDMMYYYY)

Legally Authorized Representative

The Legally Authorized Representative signature should be added if the parent of the participant is unable to sign for himself or herself. The relationship between the parent of the participant, the participant and the Legally Authorized Representative should be stated.

Name of Legally Authorized Representative (Print Name) Signature _____ Date _____
(MMDDYYYY)

Relationship to the Parent of the Study Participant and the Study Participant

Witness Signature

Site should decide whether witness section is required. This section is not mandatory.

- Not Applicable: witness agreement is not required.
- Applicable: witness agreement and signature are provided below.

As an impartial third party, I witnessed the entire discussion. I attest that the above-named participant received a verbal and written description of the study. This individual had sufficient time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participate in this study.

Name of Impartial Witness (Print Name) Signature _____ Date (DDMMMYYYY)

****For Sites in California******AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES****What information may be used and given to others?**

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?

The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

Who might get this information?

The sponsor of this research. “Sponsor” means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

Authorization:

I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Subject/LAR

Date