REGENERON
IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
AS MODIFIED
Aug 12, 2020

MAIN STUDY INFORMED CONSENT FORM

TITLE: A MASTER PROTOCOL ASSESSING THE SAFETY, TOLERABILITY, AND EFFICACY OF ANTI-SPIKE (S) SARS-COV-2 MONOCLONAL ANTIBODIES FOR THE TREATMENT OF AMBULATORY PATIENTS WITH COVID-19

PROTOCOL NO.: R10933-10987-COV-2067
WIRB® Protocol #20201543
NCT: NCT04425629
EudraCT: 2020-003690-21

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: _____

Summary

This research study is looking at an experimental drug for patients who have the virus that causes COVID-19. The study drug targets the virus that causes COVID-19, and may make it harder for the virus to infect you further. The goals of the study include seeing whether the drug lowers infection by the virus, whether it reduces the need for medical visits due to COVID-19, and whether it can cause serious side effects.

If you agree to join, you will be in the study for about one month. You will be randomly assigned to receive one dose of the study drug or a placebo. You will be given this intravenously (in a vein). During the study, you will have tests done at several times, including having nasopharyngeal (NP) swabs taken and having blood drawn.

Because this is a research study with an experimental drug, you may or may not benefit from being in the study. There is also only a limited amount of data about the study drug in people. Even though patients will be carefully watched, the risks of receiving the drug are unknown. Some of these risks may be serious or life-threatening. Finally, keep in mind that you may have other treatment options if you choose not to join the study.

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. 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 or withdraw at any time, you will not be penalized or lose any benefits to which you are otherwise 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 the study doctor will be paid by Regeneron.

Regeneron, its collaborators or those developing the study drug, 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.

Why is this study being done?

This study is researching the experimental drugs REGN10933 and REGN10987, given together as a single treatment in people who have the virus that causes COVID-19 (coronavirus disease 2019). The study is focused on patients who are well enough to go home after they have been confirmed to have the virus. The treatment will be referred to as "study drug" in this consent form.

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

- Whether the study drug can reduce levels of infection by the virus
- Whether the study drug reduces the need for medical visits due to COVID-19
- Whether any serious side effects may happen because of the study drug
- How much study drug is in your blood at different times
- Whether the body makes its own antibodies against the study drug

What are REGN10933 and REGN10987?

REGN10933 and REGN10987 are "monoclonal antibodies." Antibodies are proteins made by immune cells in your body, and they travel in the blood to fight infections. A monoclonal antibody is a special kind of antibody that is made in a laboratory. Researchers can design these antibodies to fight specific types of infections, such as viruses.

COVID-19 is caused from infection by a coronavirus called SARS-CoV-2. There is a lot that still is unknown about this new virus. However, coronaviruses are known to use "spike" proteins on their surface to attach to the cells they are infecting. It is believed that the spike protein allows the virus to infect cells in the nose, throat, lungs, and other tissues, leading to COVID-19 symptoms and illness.

The antibodies being tested in this study block the spike protein from attaching to host cells in laboratory tests. When the spike protein is blocked, the virus may not be able to infect cells. REGN10933 and REGN10987 work together to block the spike protein at two different places on the protein. By lowering the ability of the virus to infect cells, the study drug may help to stop COVID-19 symptoms from getting worse.

The study drug combination is considered experimental, because it has not been approved by any health authority (such as the U.S. Food and Drug Administration, or FDA) to treat COVID-19.

The study may eventually test other study drugs containing antibodies that work in a similar way. Currently, however, only REGN10933 and REGN10987 will be tested in this study.

How big is the study?

The study will include about 780 people 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 drug?

You will be given the study drug into a vein using a needle. This is called an intravenous (IV) infusion. You will be given an IV infusion only once, on the first day of the study.

The possible risks of being given study drug are described later in the consent form.

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

After you give your consent, the study doctor will check the conditions of the study to see if you qualify. This may involve running tests. This period, called screening, will happen either on the same day, or the day before, you are given the IV infusion (day 1 of the study).

Once the doctor confirms that you qualify, you will be randomly chosen to receive one of three possible IV infusions: REGN10933 + REGN10987 at a lower dose (1.2 grams of each antibody), REGN10933 + REGN10987 at a higher dose (4 grams of each antibody), or placebo. A placebo looks like a real treatment but does not contain any active medicine. You will have an equal chance of receiving any one of these.

This study is double-blinded. This means that that neither you nor the study doctor or the staff giving you the infusion will know whether you are being given study drug or placebo. You will have a one-in-three chance of receiving REGN10933 + REGN10987 at a lower dose, a one-in-three chance of receiving REGN10933 + REGN10987 at a higher dose, and a one-in-three chance of receiving placebo.

Before and right after the infusion, you will have blood taken. Once this is done, if there are no side effects within 2 hours of the infusion, and if the doctor believes you are healthy enough, you will be sent home.

As part of the study, you will have blood taken several times. You will also have nasopharyngeal (NP) swabs taken. These samples will be taken at the study site, a designated medical center, by having study staff come to your home, or by some other method that will be explained to you. The swabs will be taken every other day for the first two weeks of the study, then twice a week after that until day 29.

Throughout the study, you will also report on your symptoms using an electronic app every day, and study staff will contact you weekly to ask information about your health.

The study will end on day 29, when you will have a study visit for final tests.

Study tests, procedures, and what you will be expected to do

The study has certain rules about visits you will have, tests that need to be done, and other things you will be asked to do. 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.

Since most of the study will happen while you are at home, you must be willing and able to provide the information and samples described below, when asked. This will ensure that the research questions of the study can be answered. The study doctor or staff will give you more information to help you do this.

Nasopharyngeal (NP) swabs

To measure infection by the virus, samples will be collected by taking what are called NP swabs. The study doctor or staff will take these samples. Each time a sample is collected, a swab will be gently inserted about three 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 NP swab samples 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.

As described later in this consent form, please note that the results of your tests, including virus infection measured with NP swabs, will not be provided to you.

Blood draws

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 6 milliliters (half tablespoon) to 79 milliliters (5 tablespoons).

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.

Returning to the clinic for assessments

In some cases, you may need to visit the study clinic one or more times so that tests and sample collections can be done.

Possible Risks: By coming back to the clinic, you may be exposed to others who may have COVID-19 or other illnesses. It is currently not known whether having prior COVID-19 disease will make someone immune from getting it again, so it is possible that even if you have had COVID-19 and recovered, you could become re-infected from exposure to someone who is still sick.

Having medical visits at home
In some cases, it may be possible 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) or by a member of the study site team. 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.

Having medical visits electronically
Your consent to join the study, as well as some of your medical visits, may be done by phone or electronically (on a smart phone, tablet, or computer). This type of visit is also called telemedicine. The remote medical visits will allow the doctor or staff to check on your health, so that you can have fewer in-person visits during the study. The study doctor or staff will tell you more about these types of visits.

Reporting symptoms with an electronic survey
Throughout the study, you will use an electronic app to fill out surveys about any COVID-19 symptoms you may have.

Vital signs
Several of your vital signs will be measured at different times on the first day of the study, including your body temperature, blood pressure, and blood oxygen levels (the amount of oxygen in your blood). Your body temperature will be measured using a thermometer that goes either in your mouth, ear, armpit, or on your forehead. Your blood pressure will be measured using a cuff that inflates around your arm. Blood oxygen levels will be measured using a small device that clips onto your finger.

Pregnancy test
If you are a woman who is able to have children, you will have to take a pregnancy test before receiving the study drug and at the end of the study. The test will be done using either a blood or a urine sample. Risks related to the study drug and pregnancy are described later in the consent form.

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 (including prior COVID-19 symptoms). Your weight and height will be measured.

Throughout the study, the doctor or staff will also collect information about side effects and other health changes related to COVID-19 illness. They may also ask about any medicine or supplements you are taking (prescribed and over-the-counter).

Reporting any medical visits you have due to COVID-19
Each week, you will be asked whether you had any medical visits related to COVID-19. It is important that you describe any medical visits you had and any details about the visit (for example, where the visit occurred, the date you went and the symptoms you felt).

If you see a doctor or have any medical visit during the study, even if it is not with the study doctor or staff, you will be asked to contact the study staff as soon as possible to tell them about the visit.

Is genomic material collection required in this study?

DNA is what makes up the genes you inherit from your parents. It acts like an instruction book for the cells in your body and helps form your traits (like eye color or height). RNA is made using your genes and carries out the instructions of DNA. Coronaviruses like the one that causes COVID-19 work a little differently, and only contain RNA.

An important goal of the study is to see whether the study drug lowers the amount of virus you have. To do this, 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 sequence can affect whether or not the study drug works.

If necessary, the samples may be re-analyzed in the future. These samples will be stored for up to 15 years following completion of the study.

Genomic Testing Risks

The samples that are collected will only be used to study virus RNA and not human RNA. However, human RNA cannot always be completely removed from the samples, and there is a chance that some of your RNA sequences could be identified and analyzed.

While every effort will be made to protect your identity, it is possible that the RNA sequences that describe your genes could potentially identify you. Because the specific genes you have can make it more or less likely that you might develop certain medical conditions, knowledge of this information could also lead to unwanted psychological and financial consequences if it were released to you or any third party. There may also be other privacy risks that have not predicted.

There is a U.S. federal law called the Genetic Information Non-Discrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information. This law does not protect against discrimination by companies that sell life, disability or long-term care insurance but the chances that your information would be released to these companies are very small.

Will additional samples be collected?

As described above, biological samples, including samples from your mouth or nose as well as blood, 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 the study drug works in the body
- Why some people respond better to the study drug
- Why some people develop side effects
- Information about COVID-19

These samples will be kept for up to 15 years after the study ends. During that time, 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.

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

There is currently a limited amount of data about this study drug in people. To date, no serious safety concerns have been seen. Laboratory studies in cells and monkeys are currently being done to look for potential safety risks of the study drug. Patients will also be carefully monitored for any possible safety concerns during this study, and you will be told if there are any important safety findings. At this time, however, the risks of the study drug are unknown. Some of these unknown risks may be serious or life-threatening.

The possible risks described 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 (through IV infusion).

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.

Intravenous (IV) infusion risks and allergic reaction risks

You may have bruising, pain, or discomfort at the site where the study drug is given.

There is also a chance that you will have an allergic reaction to the study drug. This could include side effects that occur during the infusion or within a few hours to days after the infusion. These reactions, known as infusion reactions, could include rash, hives, cough, chills, sweating, shortness of breath, nausea, or feeling flush.

Although rare, there is a chance you may have more serious symptoms, including a severe allergic reaction (called anaphylaxis). Severe symptoms require immediate medical care and could result in permanent disability or death.

Risk of unexpected immune response
It is possible that your immune system could make its own antibodies against study drug. This can cause side effects or make the drug work less effectively.

Theoretical risk of virus infection getting worse
In some animal studies, antibodies and vaccines can make an infection worse. In humans, this has only been seen in rare cases with vaccines. The reason for this is not fully understood, but it is thought that this can happen when the amount of antibody in circulation gets low. As of today, this has not been seen with antibodies used against SARS-CoV-2 (the virus that causes COVID-19), in either animal studies or humans. At this time, though, the theoretical risk cannot be ruled out with this study drug. Signs and symptoms of COVID-19 infection may get worse weeks to months after receiving the study drug, and will be monitored throughout the study.

What happens if my partner or I get pregnant?

The study drug has not been tested in pregnant or nursing women so taking part in this research may hurt a pregnancy or fetus in unknown ways. It is not known if they can cause harm to you or your baby if you become pregnant, or whether you may lose your pregnancy. Women who join this study cannot become pregnant or breastfeed during the study. If you are pregnant, you cannot join the study and cannot receive study drug.

Women who are in this study must use medically acceptable birth control for 6 months after receiving the study drug infusion. If you become pregnant during that time, you must tell the study doctor right away. The study doctor will follow up with you about outcome of your pregnancy.

Men who are in this study must also use medically acceptable birth control for 6 months after receiving the study drug infusion, unless your partner is unable to become pregnant (for example, if your partner is medically sterile). If your partner becomes pregnant during that time, you must tell the study doctor. The study doctor will ask to speak to your partner. If your partner agrees, Regeneron will collect information about the pregnancy and its outcome.

The study doctor can answer any questions you have about acceptable birth control.

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

There are currently no treatments approved by any health authority to treat COVID-19. However, there may be other options if you decide not to join this study:

- There may be studies in your area researching other experimental treatments for COVID-19.
- You can receive the standard care that hospitals or doctor's offices in your area are using to try to treat COVID-19.
- You can choose to receive no treatment or to treat only your symptoms (for example, with over-the-counter medicine for fever).

Each option has possible benefits and risks, which may be different depending on your illness and overall health. There may be other options as well. If you have questions about your options, talk to the study doctor. You and the doctor can discuss the best treatment plan for you.

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. But, by joining the study you may help us learn things about the study drug that could help other people who have COVID-19.

Will I be paid to participate in this study?

You will be given $[XX] for each day that you spend at the infusion site. After you are sent home, you will be given a stipend of $[XX] for each study visit that occurs.

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 and study doctor can treat you or refer you to where you can obtain treatment.

If you have an injury that is directly caused by taking the study drug 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 will not 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 drug 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 drug or study procedures. However, you may be able to seek compensation from the Human Resources and Services Administration (HRSA) 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 rights to pursue a claim through the legal system. 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 receive 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 and devices to the study site. The study doctor or study staff may also ask to have a final phone call to check your health.

You will be told of any important new information about the 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 and for any reason, including: if the study is no longer in your best medical interest, if you experience unusual or serious side effects, if you become pregnant, or if you do not follow the study rules. The study may also be stopped by Regeneron, an IRB/EC, 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 me 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 includes:

- 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 U.S. FDA, other U.S. government agencies, and government authorities in other countries
- The IRB/EC overseeing the study

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, symptom survey apps, 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 such as FDA, IRB, 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 Regeneron must follow.

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.

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, study drug, 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, Regeneron does not provide individual results to you. In some circumstances, Regeneron 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 Regeneron 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, Regeneron 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 Regeneron's data retention schedule.

Please be aware that because Regeneron 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 Regeneron'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 or genetic 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 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 Master Protocol Assessing the Safety, Tolerability, and Efficacy of Anti-Spike (S) SARS-CoV-2 Monoclonal Antibodies for the Treatment of Ambulatory Patients with COVID-19
Protocol Number:	R10933-10987-COV-2067
Sponsor:	Regeneron Pharmaceuticals, Inc.
Research Site:	[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.

Name of Study Participant (Print Name)	Signature	Date (DDMMMYYYY)

Study Investigator or Person Obtaining Consent

I have fully informed the participant about the study:

Name of Study Investigator or Person Obtaining Consent (Print Name)	Signature	Date (DDMMMYYYY)

Witness Signature

☐ 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 (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 <u>may</u> 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	**Date**