Official Title: A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Safety and Efficacy of MSTT1041A or UTTR1147A in Patients With Severe Covid-19 Pneumonia

NCT Number: NCT04386616

Document & Date: Informed Consent Form, Version 4: 16-September-2020

INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Genentech, Inc. / "A PHASE II, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MULTICENTER STUDY TO EVALUATE THE SAFETY AND EFFICACY OF MSTT1041A OR UTTR1147A IN PATIENTS WITH SEVERE COVID-19 PNEUMONIA"**
Protocol Number:	**GA42469**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

1.1 INTRODUCTION

- You are being asked to take part in this research study (also known as a clinical trial) because you have severe COVID-19 pneumonia. This study is testing two different experimental drugs: a drug called MSTT1041A (also known as astegolimab) and a drug called UTTR1147A.
- Genentech, Inc. (a member of the Roche Group) is the sponsor of this study and is paying the study site to cover the costs of this study.
- This consent form tells you what will happen if you take part. It also tells you about the possible benefits and risks of being in the study.
- Taking part in this study is your choice. Please read the information carefully and feel free to ask questions. It may be helpful for you to discuss this information with your family and friends.
- Instead of participating in this study, you may choose to do the following:
  - Get treatment for your COVID-19 pneumonia without being in this study
  - Join a different study
  - Get no treatment
- Talk to your study doctor about all of your choices, and the risks and benefits of each choice. If you choose not to take part, you will not lose the regular care that you receive from your regular doctors.
- If you decide to take part, you will be asked to sign and date this consent form. You will be given a copy of your signed and dated consent form.

1.2 WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to compare the effects, good or bad, of either MSTT1041A or UTTR1147A versus placebo in participants with severe COVID-19 pneumonia. In this study, you will get either MSTT1041A, UTTR1147A, or placebo. A placebo looks like the study drug, but has no active ingredients.

About 390 people will take part in this study: 130 people will receive MSTT1041A, 130 people will receive UTTR1147A, and 130 people will receive placebo.

MSTT1041A and UTTR1147A are experimental drugs, which means health authorities, such as the United States Food and Drug Administration (FDA), have not approved them for the treatment of COVID-19 pneumonia.

1.3 WHAT WILL HAPPEN IF I PARTICIPATE?

This study has three parts:

1. Screening (to see whether you are eligible for the study)
2. Study Treatment
3. Follow-up (to check on you after study treatment is finished)

You will be randomly placed in one of the following study treatment groups:

- Group 1 will receive MSTT1041A, given as an infusion into the vein.
- Group 2 will receive placebo for MSTT1041A, given as an infusion into the vein.
- Group 3 will receive UTTR1147A, given as an infusion into the vein.
- Group 4 will receive placebo for UTTR1147A, given as an infusion into the vein.

In all groups, a second infusion may be given 2 weeks later if you are still in the hospital for severe COVID-19.

Your group will be decided by chance (like tossing a coin). You will have a one in three chance of receiving MSTT1041A, UTTR1147A, or placebo.

Neither you nor your study doctor can choose or know the group you are in. However, your study doctor can find out which group you are in, if your safety is at risk. Your study doctor cannot find out which group you are in to help decide whether you should switch to an unproven treatment.

During this study, you will be hospitalized and have study procedures daily until you leave the hospital (based on your study doctor's decision). After you leave the hospital, you will be followed up by telephone or video chat (remote visit), and you are encouraged to come back to the hospital on the 28th day and the 60th day after you are first treated. If visiting the hospital is not possible, you will be followed up by telephone or video chat by your study doctor or study nurse.

Your total time in the study will be about 60 days.

The study procedures are described in detail in Section 2.2. Some procedures will be the same as your regular care for COVID-19 pneumonia, and some procedures will be just for this study.

1.4 ARE THERE ANY BENEFITS?

Your health may or may not improve in this study, but the information that is learned may help other people who have a similar medical condition in the future.

1.5 ARE THERE ANY RISKS?

You may have side effects from the study drugs or procedures used in this study, as described in Sections 2.1 and 2.2. Side effects can be mild to severe and even life-threatening, and they can vary from person to person. Talk to your study doctor right away if you have any of the following during the study:

- Symptoms that are new or have worsened
- Changes in your prescribed or over-the-counter medications (including herbal therapies)
- Visits to the doctor or hospital, including urgent care or emergency room visits (after you leave the hospital)

There may be a risk in exposing an unborn child to study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to study drug, as described in Section 1.6. If you are pregnant, become pregnant, or are currently breastfeeding, you cannot take part in this study.

1.6 ARE THERE ANY SPECIAL REQUIREMENTS?

While participating in this study, you must adhere to certain requirements, as listed below:

- You should not join another research study testing a drug.
- For women: If you can become pregnant, you must use a reliable birth control method during the study and for 95 days after your final dose of study drug. Talk with your study doctor about what method may be best for you. Tell your study doctor right away if you get pregnant during this period. If you get pregnant, the study doctor will want to follow up with you on the outcome of the pregnancy and collect information on the baby.
- For men: If your partner is pregnant or able to become pregnant, you must use a condom during the study and for 95 days after your final dose of study drug. You must not donate sperm during this same period. Tell your study doctor right away if your partner gets pregnant during this period. The study doctor may ask your partner for permission to collect information about the pregnancy and the baby. No matter what your partner decides, you can continue to take part in this study.
- You should not use certain medications during this study. Your study doctor will talk to you about these medications.

1.7 WILL I BE PAID TO PARTICIPATE?

«Compensation»

{If participants will not be paid, include the following:}
You will not be paid for taking part in this study.

{If participants will be paid a varying amount per visit, include the following text and a payment schedule (see sample schedule):}
You will be paid for each visit you complete, according to the following schedule:

{Sample payment schedule:}

Remote Visits (Phone or Video Chat) Post Discharge Days 3, 7, 14, 21, 28 (if remote), 35, 45, Day 60 or Early Discontinuation (if remote)	${amount} per visit
In-Person End of Study (Day 60 or Early Discontinuation) / Unscheduled Visit/ Day 28 (if in clinic)	${amount} per visit

{If reimbursement for travel expenses is allowed, include the following if reimbursement is dependent on distance traveled:}
If you are required to travel more than {XX} miles ({XX} kilometers) one way from your home to the study site, you will be reimbursed for your reasonable travel costs (for example, transportation, parking).

{If reimbursement for travel expenses is allowed, include the following if reimbursement is not dependent on distance traveled:}
You will be reimbursed for your reasonable costs (for example, transportation, parking) to travel from your home to the study site.

Information from this study, including information from research on your samples, may lead to discoveries, inventions, or development of commercial products. You and your family will not receive any benefits or payment if this happens.

1.8 WILL IT COST ME ANYTHING?

While participating in this study, you will not have to pay for study drugs or procedures that are required only for this study and are not part of your regular medical care. You or your health plan will have to pay for medicines and clinic, hospital, and doctors' services that are part of your regular medical care. Some health plans will not pay for medications or procedures for people participating in research studies. Your study doctor can find out what your health plan will pay for.

1.9 WHAT HAPPENS IF I AM INJURED?

If you get injured because you took part in this study, contact your study doctor as soon as possible at the phone number listed on the first page of this form. Your study doctor will explain your options and tell you where to get treatment.

Genentech will pay for reasonable costs of immediate care for any physical injury that results from the study drug but only if all of the following are true:

- Genentech and the study doctor agree that your injury resulted from the study drug and not from a preexisting medical condition
- The costs are not paid for by your medical insurance
- Your injury was not because you or the study team did not follow instructions

You will not receive any other kind of payment.

If a participant is eligible for Medicare, federal law requires Genentech to inform the Centers for Medicare & Medicaid Services (the agency responsible for the Medicare program) when Genentech is going to pay for a participant injury. Genentech may need to share information, such as your name, date of birth, sex, and Medicare ID number (if you have one), with the Centers for Medicare & Medicaid Services.

If you get injured in this study, you will not lose any of your legal rights to seek payment by signing and dating this form.

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a subject participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19. This includes the study drugs MSTT1041A and UTTR1147A used in this study. Subjects using MSTT1041A and UTTR1147A in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

1.10 CAN I STOP BEING IN THE STUDY?

You can leave this study at any time. Tell your study doctor if you are thinking about stopping, and your study doctor will tell you how to stop safely. If you leave this study, you will not lose access to any of your regular care.

If there are important new findings or changes in this study that may affect your health or willingness to continue, your study doctor will let you or your legally authorized representative know as soon as possible.

You may be required to stop participating in the study, even if you wish to continue. Below are some of the reasons why you may be asked to stop:

- Your safety would be at risk if you continued
- You were unable to or did not follow study instructions or procedures
- You need medical care that is not allowed by this study
- This study has been stopped by Genentech or a health authority

{If the site does <u>not</u> prohibit testing of samples after participant discontinuation, include the following:} When your participation ends, no new information will be collected about you with one exception: Any laboratory samples collected prior to stopping may still be tested, unless you specifically ask for your samples to be destroyed.

{If the site prohibits testing of samples after participant discontinuation, include the following:} When your participation ends, no new information will be collected about you. Any laboratory samples collected prior to stopping will not be tested.

However, Genentech will still be able to use information that was collected prior to stopping, including information from samples that were tested prior to stopping.

2.1 STUDY TREATMENT RISKS

Risks Associated with MSTT1041A

MSTT1041A has had limited testing in humans. There are no known side effects of this study drug so far, and experience in people is limited. However, to date, the study drug has generally been well tolerated and no major safety concerns have been identified. So far, 109 healthy participants and approximately 375 participants with severe asthma, 32 participants with moderate to severe atopic dermatitis (eczema), and 40 participants with chronic obstructive lung disease have received MSTT1041A.

The potential side effects based on human and laboratory studies or knowledge of similar drugs are listed below. There may be additional side effects that are not known at this time.

Potential Side Effects
• Allergic reactions can occur when drugs are given intravenously (into the vein), and such reactions can cause affected people to have symptoms such as headache, dizziness, rash, itching, flushing, swelling, shortness of breath, nausea, and sometimes vomiting, crampy abdominal pain, or incontinence. Severe allergic reactions could cause loss of consciousness, severe skin reactions, difficulty breathing or swallowing, and/or a decrease in blood pressure and could be life threatening. • If you receive MSTT1041A, it is possible that your body may make antibodies (a special type of protein your body makes in response to substances that are not usually present in your body), this may cause the study drug not to work or could increase your chances of getting an allergic reaction to MSTT1041A. Blood tests may be used to check for antibodies during the study. It is not known whether these antibodies will cause side effects. • Decrease or change of your body's response to infections • Worsening of existing heart diseases

Risks Associated with UTTR1147A

UTTR1147A has had limited testing in humans. So far, about 50 healthy participants and 97 participants with inflammatory bowel disease have received UTTR1147A. The side effects that have been associated with UTTR1147A are listed below. In clinical studies of UTTR11147A, these known side effects have not been serious and have been fully reversible. There may be side effects that are not known at this time.

Known Side Effects
Very Common Side Effects (occurs in more than 10 out of 100 participants)
• Reddening of skin • Dry/scaly skin • Dry lips • Increase in substance produced by the liver (C-reactive protein) that can indicate the presence of inflammation in the body There have been no signs or symptoms of inflammation (such as fevers, chills, or fatigue) in participants who received UTTR1147A .

Common Side Effects (occurs in 1–10 out of 100 participants)
• Itchy skin • Painful skin • Slight increase in levels of protein in the blood that helps in the formation of blood clots (fibrinogen) There have been no signs or symptoms of abnormal blood clots in participants who received UTTR1147A.

At high doses of UTTR1147A, the skin reactions have been severe in some participants and although they went away without needing treatment, it took between 1 and 4 months to get better.

Potential Side Effects
• Reaction that can occur during or after the study drug is given intravenously (into the vein). The reaction may include fever, chills, rash, low blood pressure, and difficulty breathing. • Infections because your body develops an immune substance that makes it harder for your body to control infections such as bacterial and fungal infections • Risk of growth of active cancer If you have any active cancer, signs of a potential-cancer, or a history of some specific types of cancer within the last 5 years, you may not be able to participate in the study. During the study treatment and follow-up periods, it is important that you tell your study doctor immediately about any new or enlarging growths that appear on your body, including changes in your skin.

2.2 STUDY PROCEDURES AND POTENTIAL RISKS

Procedures with Associated Risks		
Procedure	**Approximate Timing**	**Potential Risks**
Blood sample (about ½ –2½ tablespoons at each assessment)	• Screening • While in hospital: at regular visits and as needed until Day 60 • After you leave the hospital: at Day 28 and at your last study visit/Day 60, if you return to the clinic	Drawing blood can cause pain, bruising, or infection where the needle is inserted. Some people experience dizziness, fainting, or upset stomach when their blood is drawn.

Chest X-ray or computed tomography (CT) scan: X-ray test that gives off radiation	• Screening • While in hospital: as needed during the study • After you leave the hospital: at your last study visit/Day 60, if you return to the clinic	Although there are no proven harmful effects from the radiation, no one can say for certain that there are no long-term harmful effects of radiation exposure. You may feel some discomfort or anxiety when lying inside of the CT scanner. The contrast material (dye) that is injected into your body may cause you to get a metallic taste in your mouth and to feel warm. Rarely, it causes nausea and vomiting. The dye can also cause damage to the kidneys, which may lead to kidney failure. This is a concern if you have poor kidney function. Rarely, the dye can cause a life-threatening reaction.
Nasopharyngeal swab: a study doctor or study nurse will take two swabs (like a long Q-tip or cotton swab) and wipe the inside of the back of your nose with each swab	• Screening • Day 1, Day 15, Day 21, Day 28 and as needed during the study	The nasal swab may be uncomfortable.

Non-Invasive Procedures with Minimal Risks	
Procedure	**Approximate Timing**
Review of medical history, including medications	• Screening
Recording of demographic information, such as age, sex, race/ethnicity (research purposes only)	• Screening
Vital signs while in hospital and at a return visit: temperature, pulse rate, blood pressure, breathing rate, oxygen level in your circulating blood	• Screening • While in hospital: Every day on a regular basis to monitor you • Day 28 and at your last study visit/Day 60 (if you come back for a return visit)
Limited vital signs: oxygen level and pulse rate may be taken during the telephone/video chats after you leave the hospital	• Every telephone/video chat up to and including your last study visit/Day 60
Complete physical examination	• Screening, and if your study doctor decides it is necessary during the study
Weight	• Prior to dosing on Day 1 and Day 15
Review changes in your health or medications	• Every visit
Electrocardiogram: measures electrical activity of your heart	• Screening • Day 14, and as needed while in hospital • Day 28, and at your last study visit/Day 60
Echocardiogram: ultrasound of your heart to see how well your heart is working	• Only if your study doctor decides it is necessary
Urine sample (for pregnancy testing for females only)	• Screening • As needed during study

Lung images and imaging reports collected by computed tomography (CT) scan may be performed during the screening visit to determine eligibility for the trial, and may be repeated during the study as needed.

Lung CT images collected at screening and throughout the study may be used for future research related to COVID-19 pneumonia or other infectious diseases, common pathways (links) among diseases, the use of experimental drugs in disease therapy, and/or the development of tests or tools that help with detecting or understanding COVID-19 pneumonia.

2.3 ACCESS TO STUDY DRUG AFTER COMPLETING THE STUDY

Currently, Genentech does not have any plans to provide the Genentech study drugs (MSTT1041A or UTTR1147A) or any other study treatments to you after you complete the study.

2.4 USE AND HANDLING OF LABORATORY SAMPLES

Sample Use

Blood, urine, and nasopharyngeal samples will be collected for reasons such as the following:

• Check your health through standard laboratory tests • Find out if you have COVID-19 pneumonia • Find out if you are pregnant • Check for any infection other than COVID-19 • Measure levels of COVID-19 virus • Find out how study drug is processed by your body (pharmacokinetics) • Find out if your body is making antibodies to study drug (immunogenicity) • Find out how your body reacts to the study drug	• Perform additional analyses related to processing of study drug or development of antibodies to study drug (if needed) • Find out how variations in biomarkers (such as disease-specific proteins or genes) affect your disease or your response to study drug, and develop biomarker tests

Sample Storage

Samples will be securely stored for a defined period (as described below) and will then be destroyed.

Samples will be stored for up to 5 years after the final study results have been reported, with the following exception:

- Samples for pharmacokinetics, immunogenicity, and biomarker testing will be stored for up to 15 years after the final study results have been reported.

2.5 PROTECTION, USE, AND SHARING OF INFORMATION

During this study, health and personal information (“information”) about you will be collected. This section describes the protection, use, and sharing of your information, which consists of the following:

- Information in your medical record, which is held by the study site

- Information (including imaging data) that is collected or produced during this study ("study data"), which is held by the study site, Genentech, other Roche affiliates, and Genentech's representatives (people and companies who work for Genentech)

Your privacy is very important, and Genentech uses many safeguards to protect your privacy, in accordance with applicable data privacy laws and laws related to the conduct of clinical trials. Your study data and samples will be labeled with a participant identification (ID) number that is unique to you and not related to or derived from information that identifies you (such as your name, your picture, or any other personally identifying information). Genentech, other Roche affiliates, and Genentech's representatives will only have access to study data and samples labeled with a participant ID number, except when accessing your medical record under certain circumstances, as described below:

Your information (including your medical record, which contains personal information that can identify you) may need to be reviewed to make sure the study is being done properly or to check the quality of the information. This information will be kept private. The following people and groups of people may review and/or copy this information:

- Authorized individuals (such as study monitors and auditors) representing Genentech and Genentech's collaborators and licensees (people and companies who partner with Genentech)
- The Institutional Review Board or Ethics Committee (people responsible for protecting the rights and safety of people who take part in research studies)
- Regulatory authorities (government agencies involved in keeping research safe for people, such as the FDA)

Genentech, other Roche affiliates, and Genentech's collaborators and licensees may use study data labeled with your participant ID number. Your study data may also be shared with independent researchers or government agencies, but only after personal information that can identify you has been removed. Your study data may be combined with other people's data and/or linked to other data collected from you. Your study data may be used to help better understand why people get diseases and how to best prevent, diagnose, and treat diseases, and to develop and provide access to new medicines, medical devices, and health care solutions.

Your information will not be given to your insurance company or employer, unless required by law. If the results from this study are published in a medical journal or presented at a scientific meeting, you will not be identified.

Information from this study will be retained by the study site for 15 years after the end of the study or for the length of time required by applicable laws, whichever is longer. In addition, Genentech will retain the study data for 25 years after the final study results have been reported or for the length of time required by applicable laws, whichever is longer.

2.6 STUDY RESULTS

Results from exploratory biomarker tests will not be shared with you or your doctor, unless required by law. Information from these tests will not be part of your medical record.

A clinical study report containing the results of this trial will be made available to anyone who requests a copy. Before this report is provided, additional steps will be taken to protect your information from being linked to you.

A reader-friendly summary of the results of this study will be available within 2 months after the final clinical study report has been completed; contact your study doctor about the timing of these reports. The summary will not include any information that could identify people who took part in the study. Once the summary is available, you can view the study results by entering the study number (GA42469) in the search bar at the following site: https://forpatients.roche.com/

A description of this clinical trial will be available at 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.

2.7 WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

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

- By mail: [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser: [redacted].

Signature

I confirm that I have read this consent form, or it has been read to me. I understand the information presented and have had my questions answered. I understand that I will be given a copy of all pages of this form after it has been signed and dated. I agree to take part in this research study as described above and authorize the study site to use and share my information as described in this form.

Participant name (print)

If applicable – Name of participant's legally authorized representative (print) | Relationship to participant

Participant signature or signature of participant's legally authorized representative | Date

I, the undersigned, have fully explained this informed consent to the participant named above and/or the participant's legally authorized representative.

Name of person conducting informed consent discussion (print)

Signature of person conducting informed consent discussion | Date

Witness name [a] (print)

Witness signature [a] | Date

[a] If the investigator or Institutional Review Board or Ethics Committee deems a witness signature is necessary (as per ICH Guidelines, Good Clinical Practice [E6], 4.8.9, or local regulations).

SECTION 3: CONSENT FOR OPTIONAL WHOLE GENOME SEQUENCING

You are being asked to undergo an optional blood draw to collect a sample for whole genome sequencing (WGS) as part of study GA42469.

WGS is an analysis of your genetic material (DNA and RNA). Your genetic material serves as an “instruction book” for the cells that make up your body. WGS data from large numbers of participants may help researchers learn how variations in the sequence of genes might affect a disease or response to study treatment. This information might also identify possible links among diseases and may provide new avenues for drug development and personalized therapies. Toward this goal, Genentech would like to perform WGS on your blood sample. This will allow for exploration of broad health research questions across disease areas.

Taking part in WGS is entirely voluntary. No matter what you decide, it will not affect your participation in the main study or your medical care.

You will not receive any direct benefit from undergoing the optional blood draw. However, information from these procedures may benefit other people with COVID-19 pneumonia or a similar condition in the future. You will not be paid for undergoing the optional blood draw.

The procedure and its potential risks are described below.

If you agree to donate a sample of blood for WGS, the sample (about 0.2 tablespoons) will be collected at the same time as one of your scheduled blood draws. So, you will not have to undergo any additional procedures.

The risks associated with drawing blood are described earlier in this consent form in Section 2.2.

Some genetic differences can help to predict future health problems experienced by you or your blood relatives. So, this information might be of interest to health providers, life insurance companies, and others. It is possible that your genetic information could be used in ways that would cause you or your family distress. For example, this information could reveal that you (or a blood relative) carry a genetic disease.

Your samples and information related to the WGS will be kept under the same level of privacy used for the main study. Samples will be stored for up to 15 years after the final study results have been reported.

Biomarker testing may involve analysis of your genome (DNA), an "instruction book" for the cells in your body. Your blood samples may be tested for inherited genome variations associated with COVID-19 pneumonia. Testing may include analysis of all of your DNA (whole genome sequencing) or analysis of all of your DNA that codes for proteins (whole exome sequencing. Analyses of samples from a large number of people may help researchers learn more about MSTT1041A, UTTR1147A, and similar drugs, COVID-19 pneumonia and other diseases, possible links among diseases, genome variations and how they might affect a disease or a person's response to study treatment, and new avenues for drug development and personalized therapies.

Testing of your samples may provide information related to your genome ("genetic information"), including information about inherited characteristics.

Your samples and genetic information will not be labeled with your name, your picture, or any other personally identifying information. Genentech uses many safeguards to protect your privacy.

The Genetic Information Nondiscrimination Act generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you on the basis of your genetic information. This act generally will protect you in the following ways:

- Health insurance companies and group health plans cannot request your genetic information from this research
- Health insurance companies and group health plans cannot use your genetic information when making decisions regarding your eligibility or premiums
- Employers with 15 or more employees cannot use your genetic information from this research when setting the terms of your employment

This federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

You can change your mind about participating. If you want to withdraw your consent for the optional blood draw, tell your study doctor that you no longer want to participate.

Signature

I willingly consent to undergo optional blood draw to collect a sample for whole genome sequencing (WGS)

Participant name (print)

If applicable – Name of participant's legally authorized representative (print) | Relationship to participant

Participant signature or signature of participant's legally authorized representative | Date

I, the undersigned, have fully explained this informed consent to the participant named above and/or the participant's legally authorized representative.

Name of person conducting informed consent discussion (print)

Signature of person conducting informed consent discussion | Date

Witness name [a] (print)

Witness signature [a] | Date

[a] If the investigator or Institutional Review Board or Ethics Committee deems a witness signature is necessary (as per ICH Guidelines, Good Clinical Practice [E6], 4.8.9, or local regulations).

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

If you decide to be in this study, the study doctor and study staff will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Genentech, Inc.
- Representatives of PPD.
- Representatives of [redacted] IRB (an Institutional Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study.
- A data safety monitoring board which oversees this study.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study drugs work and are safe.
- For other research activities related to the study drugs.

Your health information may be used or shared for the purposes of this research study and for research related to COVID-19 pneumonia or other infectious diseases, common pathways (links) among diseases, the use of experimental drugs in disease therapy, and/or the development of tests or tools that help with detecting or understanding COVID-19 pneumonia. Your health information may be used by and/or shared with Genentech, other Roche affiliates, Genentech's collaborators and licensees, the Institutional Review Board or Ethics Committee, and regulatory authorities

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study doctor at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign and date this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

Participant name (print)	
If applicable – Name of participant's legally authorized representative (print)	Relationship to participant
Participant signature or signature of participant's legally authorized representative	Date

I, the undersigned, have fully explained this authorization to the participant named above and/or the participant's legally authorized representative.

Name of person conducting authorization discussion (print)	
Signature of person conducting authorization discussion	Date
Witness name [a] (print)	
Witness signature [a]	Date

[a] If the investigator or Institutional Review Board or Ethics Committee deems a witness signature is necessary (as per ICH Guidelines, Good Clinical Practice [E6], 4.8.9, or local regulations).