# Research Subject Informed Consent Form

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| **Title of Study:** | *Convalescent Plasma To Limit Coronavirus Associated Complications: A Randomized Blinded Phase 2 Study Comparing The Efficacy And Safety Of Anti-Sars-Cov-2 Plasma To Placebo In Covid-19 Hospitalized Patients (CONTAIN COVID-19)* ***s20-00541*** |
| **Principal Investigator:** | *Mila Ortigoza, MD/PhD*<br>*Department of Internal Medicine*<br>*Division of Infectious Diseases*<br>*NYU Langone Health*<br>*646-634-7803* |
| **Emergency Contact:** | *Mila Ortigoza, MD/PhD*<br>*646-634-7803* |

## About volunteering for this research study

You are being asked to join a research study, which will take place at NYU Langone Health affiliated centers. This form tells important information about the research. A member of the research team will also speak with you about taking part in this study. People who take part in research studies are called “participants”. This term will be used throughout the consent form.

You should ask questions of the person who is explaining this form to you. After you feel that you understand the research, if you want to be part of the study, you will be asked to sign the form. You can always ask more questions and can later change your mind about staying in the study. You will receive a copy of this form for your keeping.

You are a potential participant in this study because you have been diagnosed with a disease caused by the SARS-Co V-2 also known as coronavirus disease 2019 (COVID-19) and you are currently hospitalized. Overall, this study will enroll 1000 participants.

## What is the purpose of this study and how much time will it take?

The purpose of the study is to find out if convalescent plasma (the liquid portion of blood of patients who recover from COVID-19) can prevent the development or reduce the severity of respiratory progression in people with COVID-19. This plasma will have substances that could improve your chances of recovery.

The study will determine if this plasma therapy increases the level of oxygen in your blood, which means your lung function is better and decreases your need for additional oxygen and your need for mechanical ventilation or to go to the intensive care unit. Other purposes of the study are to determine if convalescent plasma therapy reduces the level of the virus in your nose and throat or improves laboratory measures of your immunity and your blood cell functions such as how your blood clots. At the present time, we don't have any approved medicines or vaccines to treat or prevent COVID-19.

This study is a randomized study. This means, like flipping a coin, you will be assigned to one of the treatment groups and receive either the convalescent plasma or the placebo (saline solution). There are no special requirements or criteria to be in either group. You will have an 50% chance of receiving convalescent plasma or placebo.

Your participation in this research study will last 3 months from the time you receive the treatment.

**What will I be asked to do in the study?**

This study will be both an in-patient and an out-patient study. This means some of the study will happen while you are in the hospital. Other study visits will either be by telephone or video, or will require in-person visits for follow-up blood work. If in-person visits are required, it will be at a NYU Langone Health facility.
If you take part in this study, you will have the following tests and procedures:

**Day 1: Your Screening/Baseline assessments**
If you choose to take part in the study, we will ask you to sign this consent form before you have any procedures with the study staff that are part of the study.
This visit takes about 30 to 45 minutes. During this visit, we will do some tests and procedures to see if you meet the requirements to take part in the study. The study doctor will review the results of these tests and procedures. If you do not meet the requirements, the study doctor will tell you why.
At this visit, we will:

- Ask you about your medical history
- Ask you what medications you take – including over-the-counter and prescription medications, vitamins or herbal supplements and any allergies to medication you may have
- Ask about your current symptoms such as fever, cough, shortness of breath. The time these symptoms started.
- Ask about the potential source of the COVID-19 infection

- Take your “vital signs” (blood pressure, temperature, heart and breathing rates)
- Take a blood sample. We will insert a needle into your arm and take a small tube or vial of your blood (about 5 teaspoons).
  - Blood type, blood count and chemistry will be checked.
  - Part of the blood samples will be used to check if your blood contains substances called antibodies, which are capable of fighting the virus that causes the illness.
  - We may also store a sample of your blood for future research.
- We will collect nose and throat swabs to measure for the amount of SARS-CoV-2, bronchoalveolar lavage (fluid collected from your lungs)
- Perform an ECG (electrocardiogram) to check the electrical activity of your heart.
- We will review your imaging of your lungs (chest x-ray or chest CT scans) that are being done as part of your ongoing care
- If you are a female of childbearing potential we will ask you for a urine or blood sample. We will test your urine or blood to see if you are pregnant

**Day 0: Transfusion/treatment day**
This assessment will take about 1 hour.
At this visit, we will:

- You will receive 10-20 ounces of plasma that is compatible with your blood type. The plasma will be obtained from the New York Blood Center or the American Red Cross and transferred to NYU Langone Health. You will either receive plasma containing antibodies to SARS-CoV-2 (convalescent plasma from blood donors) or standard fluid (saline solution).
- The plasma infusion takes about one to two hours. The first step is that we will obtain a blood sample. We will wipe the skin on your arm with alcohol to clean it. Then, we will administer the plasma through your intravenous line. We will monitor your vital signs (temperature, blood pressure, heart rate and breathing rate) and clinical condition throughout the infusion.
- Ask about your current symptoms such as fever, cough, shortness of breath.
- Ask you about your health, any medication you are taking and any new symptoms you may have
- Give you a Physical Exam
- Collect nose swabs to measure for the amount of SARS-CoV-2
- Blood samples to check if your blood contains antibodies
- We will also store a sample of your blood for future research.

**Follow ups Day 1 – 7 (in-patient):**

- Ask you about your *current symptoms* general health and well-being
- Ask about symptoms such as fever, cough, shortness of breath.
- Ask you about your health, any medication you are taking and any new symptoms you may have
- Blood work and ongoing medical care will continue for the duration of the study and in follow-up visits by study team
- Take your "vital signs" (blood pressure, temperature, heart and breathing rates)
- We will monitor your oxygen levels
- Collect nose and throat swabs to measure for the amount of SARS-CoV-2 (Day 7 only)
- View imaging of your lungs and monitor other laboratory studies that are being done as part of your ongoing care
- Perform an ECG (electrocardiogram)

**Follow up Day 14 (if still hospitalized or as outpatient):**

- Ask you about your *current symptoms* general health and well-being
- Ask about symptoms such as fever, cough, shortness of breath.
- Ask you about your health, any medication you are taking and any new symptoms you may have
- Blood work and ongoing medical care will continue for the duration of the study and in follow-up visits by study team.
- Give you a Physical Exam
- Collect nose and throat swabs to measure for the amount of SARS-CoV-2

**Follow up 28 (if still hospitalized or as outpatient):**

- Ask you about your *current symptoms* general health and well-being
- Ask about symptoms such as fever, cough, shortness of breath.
- Ask you about your health, any medication you are taking and any new symptoms you may have
- Collect nose and throat swabs to measure for the amount of SARS-CoV-2
- Collect blood work to learn how you are recovering from the infection
- After this visit, you will be notified whether you received convalescent plasma or placebo and given recommendations for COVID-19 vaccination timing based on the latest federal guidelines.

**Follow up 60 (outpatient):**

- Ask you about your *current symptoms* general health and well-being
- Ask about symptoms such as fever, cough, shortness of breath.
- Ask you about your health, any medication you are taking and any new symptoms you may have

**Follow up 90 (outpatient):**

- Ask about your current symptoms such as fever, cough, shortness of breath.
- Ask about symptoms such as fever, cough, shortness of breath.
- Ask you about your health, any medication you are taking and any new symptoms you may have
- Collect nose and throat swabs to measure for the amount of SARS-CoV-2
- Collect blood work to learn how you are recovering from the infection

**What are the possible risks or discomforts?**

Participation in this study may involve some added risks or discomforts. These may include those from study procedures and/or side effects of medications that are part of this study. In addition to the risks listed below, there may be risks that have not appeared before. You must contact the study doctor if you are concerned about anything during the course of your participation.

The risks and/or discomforts include the following:

**Blood Draw**
Rarely, the vein where we inserted the needle will become sore or red. Sometimes, a temporary harmless “black and blue” may develop. Very rarely, fainting may occur.

**Risks of Treatment Plasma and blood transfusion:**

1. Risk of receiving transmitted viruses (e.g. HIV, West Nile Virus, Zika, Hepatitis B, Hepatitis C) and/or allergic/adverse reactions that may affect your throat, lungs, and/or your heart.
2. There is a possible risk of the treatment plasma worsening your disease and causing inflammation in your lungs.
3. Transfusion reaction which may cause you to have fever, dark colored urine, back pain, itching, chills or shortness of breath
4. Another potential risk is that the treatment plasma may make it more difficult for your infection fighting (immune system) to fight new infections.
5. Based on available information and the use of convalescent plasma in other diseases like influenza and SARS, these risks are none to minimal. There were no immediate adverse effects observed with convalescent plasma use in 80 individuals with SARS in 2005 and in 20 individuals with Influenza A (H1N1) in 2009. The risks can be further reduced by standard screening for blood transfusions, monitoring of your vital signs and clinical status, and routine patient care techniques that are standard for all hospitalized patients.
6. Risk of thrombosis (blood clot deep inside a vein)

**Pregnancy Risks:**

**Females:** If you are part of this study while pregnant or breast-feeding an infant, it is possible that you may expose the unborn child or infant to risks. The effect of Convalescent Plasma on an embryo or fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful.

If you are a menopausal woman and have not had a menstrual period for the past 12 months or more, you will not need to have a pregnancy test. Also, you will not need to have a pregnancy test if you have had a hysterectomy (surgical removal of your uterus and/or ovaries). All other female participants must have a pregnancy test before starting the study drug.

### New Findings

If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

### Unknown Risks

We have described all the risks we know. However, because this is research, there a possibility that you will have a reaction that we do not know about yet and is not expected.

### Loss of Confidentiality:

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

## What if new information becomes available?

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

## What are the possible benefits of the study?

Because of the nature of research, it is possible that you may receive no benefit at all and others may benefit in the future. If you are assigned to the control group, then it is unlikely you will have any benefit. It is also possible that participating in the research study may make your condition worse.

Although we don't know how convalescent plasma will benefit your symptoms of COVID-19, we are doing this study to find out. If it does have benefit, those benefits might include a faster recovery time, or decreased need for intensive care and/or oxygen therapy.

It is also possible that convalescent plasma will not have a beneficial effect. If this is the case, the information from your response to the plasma will help the researchers learn more about this disease and may help people with COVID-19 in the future. If you are assigned to the control group, then it is unlikely you will have any benefit. You will be notified whether you received convalescent plasma or placebo after the Day 28 visit.

**What other choices do I have if I do not participate?**

Taking part in this study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with NYU Langone Health.

**At the present time, there is one approved drug, called Remdesivir, that may reduce the amount of SARS-CoV-2 virus. Remdesivir is given to all patients with Covid-19 who qualify to receive it. If you qualify to receive it, it will be given to you regardless of whether you participate in this study and regardless of what study product you receive. Besides Remdesivir, the researchers do not know of any other procedures or treatments that may eliminate or reduce the amount of SARS-CoV-2 virus for people with Covid-19 who require hospitalization.Will I have to pay for anything?**

There will be no costs to you for participating in this research study. Procedures and tests that are part of the research will not have any costs associated with them. However, if you receive tests and/procedures that would have been done as part of your healthcare, these procedures will be billed to your insurance carrier as standard of care.

**What happens if I am injured from being in the study?**

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form**.**

There are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

*Due to the coronavirus public health crisis (COVID-19), the federal government has issued an order that may limit your right to bring a claim if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies to this study, it limits your right to bring a claim against the researchers, healthcare providers, and any*

*study sponsor, manufacturer, and/or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html* or call 1-855-266-2427.

**When is the study over? Can I leave the Study before it ends?**

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.
If you decide to withdraw your consent to participate in this study, you should notify Dr. Mila Ortigoza at *646-634-7803*.

The Principal Investigator may also withdraw you from the study *and the study medication may be stopped [if applicable],* without your consent for one or more of the following reasons

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

**If I take part in this research study, how will you protect my privacy?**

Your privacy is very important to us. The study doctors will make every effort to protect it.

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are

exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- The research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The IRB that oversees the research and the research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your

information is shared outside this institution, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Your de-identified information also will be shared with other studies. This means identifying features like your name or date of birth will be removed first so that information shared with other studies cannot be traced back to you. Key codes used to identify you will not be shared with members of other studies. The information will be used to better understand COVID-19 and its treatment.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

## What are your Rights?

You have the right not to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

## How does the Institutional Review Board (IRB) protect you?

The Institutional Review Board (IRB) reviews all human participant research before it can be implemented and then regularly as long as there is any research activity. The primary concern of the IRB is for the protection of human participants participating in research. For questions about your rights as a research participant, contact the NYU Grossman School of Medicine Institutional Review Board (IRB) Office at (212) 263-4110/ irb-info@nyulangone.org.

**Who can I call with questions, or if I'm concerned about my rights as a research participant?**

You can call the IRB with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want. Dr. Mila Ortigoza is the person in charge of this research study. If you want to speak with someone not directly involved in this research study, please contact The NYU Grossman School of Medicine IRB at (212) 263-4110.

- You can talk to them about:
- Your rights as a research participant
- Your concerns about the research
- A complaint about the research Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

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.

**When you sign this form**, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at (212) 263-4110. If you do, we will destroy remaining specimens and information but if these were already shared with other researchers, we cannot get them back.

**INITIAL ONE (1) OF THE FOLLOWING OPTIONS**

_____ I consent to have my specimens and information about me used for future research studies.

_____ I do NOT consent to have my specimens and information about me used for future research studies. Information about me will be kept as long as required by regulations and institutional policy but will not be used for future studies.

| Name of Participant (Print) | Signature of Participant | Date |
|---|---|---|

| Name of Person Obtaining Consent (Print) | Signature of Person Obtaining Consent | Date |
|---|---|---|

For participants unable to give consent, the consent for study participation and authorization to collect and use protected health information is given by the following authorized participant representative:

| Name of Authorized Participant Representative (Print) | Signature of Authorized Participant Representative | Date |
|---|---|---|

Select the category that best describes the above Authorized Participant Representative:

- ☐ Court-appointed guardian
- ☐ Health care proxy
- ☐ Durable power of attorney
- ☐ Family member/next of kin; for this category describe relationship below

**Witness to Consent Process for Non-English-Speaking Subjects (using a translated consent form OR "Short Form" in Subject's Spoken Language)**

Statement of Witness

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

| Name of Witness (Print) | Signature of Witness | Date |
|---|---|---|

**Witness to Consent of a Subject Who Cannot Read or Write**

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

| Name of Witness (Print) | Signature of Witness | Date |
|---|---|---|