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Department/Division: Center for Gene Therapy, Department of Hematology and HCT
Telephone number: 626 218 1817

City of Hope

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

IRB# 20204: Evaluation of Coronavirus Disease 19 (COVID-19) Convalescent Plasma

Patient Consent

KEY INFORMATION

You are invited to participate in this research study because you have COVID-19 infection and you have agreed to your doctor's recommendation to be treated with COVID-19 convalescent plasma as part of a separate trial. "COVID-19 convalescent plasma" means that the plasma is coming from someone who has recovered from a COVID-19 infection. The purpose of this research study is to learn more about COVID-19 convalescent plasma and the effect it has in treating COVID-19 infection. The information we learn by doing this research study may help to lead to a treatment for COVID-19.

The major risks associated with study are described below and include those associated with a blood draw (pain, bruising, possible local infection) and those associated with data collection of the results (potential loss of confidentiality and privacy).

You do not have to join this research study. If you are interested in learning more about this study, please continue to read below.

I. **PURPOSE OF THIS RESEARCH STUDY**: You have been asked to participate in this research study because you have COVID-19 infection and will be treated with COVID-19 convalescent plasma (also called "CCP"). Your treatment is part of a separate trial for which you will be asked to sign a separate consent form. The purpose of this study is to analyze in the convalescent plasma you will receive and in your blood the antibodies (created by the body's immune system to help stop infections like viruses and bacteria from harming the body) targeting SARS-CoV-2, which is the virus responsible for COVID-19 infection. The effect of these antibodies on your recovery will then be determined. Your participation on this study is expected to last for up to 28 days after you receive CCP or at your discharge from the hospital, whichever comes last. During this time, you may be asked to provide 3 to 4 blood samples and medical information about your health before and after treatment. There are several other centers taking part in this study.

II. **BACKGROUND**: There are no approved treatments for COVID-19 infection, but there are approved programs for the use of CCP in persons with COVID-19 infection. The early results indicate that CCP could improve the time to recovery from COVID-19 infection, but this is not known for sure. One concern is that each unit of CCP is from a different donor, and therefore the material can have different treatment properties and different levels of anti- SARS-CoV-2 antibodies. The goal of this study is to evaluate the types of antibodies in the CCP you receive and in your blood, and determine if these have an effect on your time to recovery.

III. **WHAT WILL BE DONE**: On the day of your COVID-19 convalescent plasma infusion, we will remove a small amount from the plasma unit (10 to 20 drops, which is less than 1% of the total CCP unit) before it is given to you. Then, we will collect information on how you are doing from your doctor, and a small blood sample (approximately 2.5 teaspoons) from your vein (or from a catheter in your vein) at each of the following timepoints: before you receive your CCP infusion, 12-24h after each CCP unit infusion (if you receive more than one CCP unit), and 7 days (+/- 3 days) after your last CCP infusion. The total collection of blood samples will not exceed 10 teaspoons. These blood samples will help us learn more about the antibodies present in your body.

Blood tests for research purposes will test the amount of antibody targeting SARS-CoV-2 in the CCP unit you receive and in your body overtime, and their ability to prevent COVID-19 infection. We will also identify what parts of the SARS-CoV-2 virus are being targeted by these antibodies. In addition, your response to the CCP will be determined by using genetic tests for genes that are activated or de-activate by the treatment. The samples collected will be shipped to an institution called TGen (the Translational Genetics Research Institute) in Flagstaff, Arizona and to the City of Hope in Duarte, California.
Your specimens will be coded with a number and your name will not be released to others outside of this study, and the location of this code will be located on a secured online portal.

The scientific, diagnostic and/or medical significance of the research to be done is not known. Therefore, neither you nor your doctors will be informed of your individual results, and they will not affect your treatment in any way. Some of this research may result in new inventions or discoveries that may be of potential commercial value and may be patented and licensed for the development of new products. Donors of blood, tissue and other biological materials do not retain any property rights to the materials. Therefore, you would not share in any money or other benefits that any entity might receive for these inventions or discoveries.

Tissue banking: With your permission, specimens left over after the research tests are done may be stored and used for future research purposes that have not yet been determined. The scientific, diagnostic and/or medical significance of the research to be done is not known. The testing that will be performed on your samples may involve whole genome sequencing which is an analysis of your DNA. Through this testing investigators are able to obtain information on all of a person's DNA or unique genetic makeup. Therefore, neither you nor your doctors will be

informed of your individual results, and they will not affect your treatment in any way. Your decision not to allow storage or future use of your tissue or specimens will not affect your ability to participate in this study.

If you agree to allow your specimens to be used for future research, you can change your mind later. If you change your mind, please ask for the *"Withdrawal of Informed Consent for Use of Specimens for Future Research"* for IRB # 20204–Evaluation of Coronavirus Disease 19 (COVID-19) Convalescent Plasma." Please sign this withdrawal form and send it to the principal investigator of this study at City of Hope (Dr. John Zaia). Once City of Hope processes your signed withdrawal of informed consent, your specimens will not be used in any new research. At that time, any of your existing specimens will be destroyed.

I agree to have tissue stored for future research:

Yes ☐ No ☐ Initials: _____

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

Yes ☐ No ☐ Initials: _____

IV. **POSSIBLE BENEFITS**: You will not benefit directly from participation in this study. Potential benefit to others may result from the knowledge gained from your participation in this research study.

V. **POSSIBLE RISKS AND DISCOMFORTS**:
Blood draw: The risks of drawing blood include temporary discomfort from the needle stick, bruising, dizziness, and very rarely, an infection where the needle was inserted. All specimens requested for this study will be collected at the time of routine procedures. Doing this will make the procedure take a little longer but will not involve an extra needle stick.

Risks associated with genetic research: Study of your genes may be performed in the future. Results of any genetic research will not be used in your medical care. The results will not be given to you, the study doctor, or your personal doctor. Some people may find it upsetting to learn that they have certain mutations or errors in genes that could lead to future health problems for themselves or their children.

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health, and may prevent discrimination by health insurers and employers based on genetic information. GINA is intended to ease concerns about discrimination that might keep some people from getting genetic tests that could benefit their health, and enable people to take part in research studies such as this without fear that their DNA information might be used against

them by health insurers or their workplace. This protection does not extend to disability or life insurance. Additional information can be found at http://www.genome.gov/10002328.

Who else will have access to my genetic information?

The researchers may decide to share data gathered from your samples to help further research into COVID-19 and other diseases. One way to do this is by putting information into scientific databases where it is stored along with information from participants in other studies. Researchers can then study the combined information to learn even more about science and health. If you agree to take part in the study, some of your genetic and health information might be placed into a public (open access) scientific database or a controlled database and shared with other researchers. Public or Open access means some of this information, without your identification, may be made available over the internet and will be freely available to anyone who is interested. Controlled access means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information.

Your name and other information that could directly identify you will never be placed into a scientific database. However, because your genetic and health information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. There are many safeguards in place to protect your information while is it stored in data repositories and used for research.

VI. **ALTERNATIVES TO PARTICIPATION**: Your alternative is to not participate in this study. Choosing not to participate will not affect your ability to be treated with CCP or any present or future relationship that you might have with City of Hope.

VII. **CONFIDENTIALITY OF INFORMATION**: Any information learned from this study in which you might be identified will be confidential and disclosed only with your permission. Every effort will be made to keep any information collected about you confidential. However, it is impossible to guarantee that information about you will not be mistakenly released. If, despite our best efforts, identifying information about you is released, it could negatively impact you or your family members. This risk is small.

By signing this form, however, you allow the researchers to make your information available to the City of Hope Institutional Review Board (IRB) Office, the City of Hope Protocol Review and Monitoring Committee (PRMC), the Office for Human Research Protections (OHRP), the TGen Institutional Review Board Office, or the California Institute for Regenerative Medicine (CIRM) which is the sponsor of this study, and other regulatory agencies as required by law. If information learned from this study is published, you will not be identified by name.

VIII. **OFFER TO ANSWER QUESTIONS AND RESEARCH INJURY NOTIFICATION**: The principal investigator, Dr. John A. Zaia, or the physician responsible for your CCP treatment and for your

COVID-19 care or treatment, has offered to answer any and all questions regarding your participation in this research study. If you have any further questions, or in the event of a research related injury, you can contact Dr. Zaia at (626) 256-HOPE (4673) ext. 82817.

IX. **SPONSOR OF THIS RESEARCH**: This study is supported by a grant from the California Institute for Regenerative Medicine (CIRM) and by funds from the City of Hope**.**

X. **COST TO THE RESEARCH PARTICIPANT FOR PARTICIPATION**: Neither you nor your insurance carrier will be charged for participation in this research study.

XI. **PAYMENT TO THE RESEARCH PARTICIPANT FOR PARTICIPATION**: You will not be paid for taking part in this research study.

XII. **EXPLANATION OF TREATMENT AND COMPENSATION FOR INJURY**: If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form. City of Hope will offer you the care needed to treat injuries directly resulting from taking part in this research. This care will be billed to you or your insurance company. You will be responsible for deductible and co-payments, or any costs not paid by your insurer. There are no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

XIII. **VOLUNTARY PARTICIPATION WITH RIGHT OF REFUSAL**: Your participation in this research study is voluntary. You are free to withdraw your consent for participation in this study without any loss of benefits, penalty, or interference with any future treatment at City of Hope.

XIV. **IRB REVIEW AND IMPARTIAL THIRD PARTY**: This study has been reviewed and approved by the City of Hope Institutional Review Board (IRB). A representative of that Board, from the Office of Human Research Subjects Protection, is available to discuss the review process or your rights as a research participant. The telephone number of the Office of Human Research Subjects Protection is (626) 256-HOPE (4673) ext. 62700.

XV. **FINDINGS RELATING TO WILLINGNESS TO CONTINUE PARTICIPATION**: You will be informed of any significant new findings related to this study which might affect your willingness to continue to participate.

EXPERIMENTAL SUBJECT'S
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject, you have the following rights:

1. To be told what the research study is trying to find out,
2. To be told what will happen to you and whether any of the procedures, drugs, or devices to be used are different from what would be used in standard practice,
3. To be told about the risks, side effects, or discomforts of the things that will happen to you as part of the research study,
4. To be told if you can expect any benefit from participating in the research study, and, if so, what the benefit might be,
5. To be told of the other choices you have and how they may be better or worse than being in the research study,
6. To be allowed to ask any questions concerning the research study, both before agreeing to be in the study and during the course of the study,
7. To be told what medical treatment is available if any complications arise,
8. To refuse to participate in the research study or to change your mind about participation after the study is started. To be informed that this decision will not affect your right to receive the care you would receive if you were not in the study,
9. To receive a copy of the signed and dated research study consent form,
10. To be free of pressure when considering whether you wish to agree to be in the research study.

SIGNATURE FOR CONSENT: By signing this consent form, you are making a decision to participate in this research study. Your signature on this informed consent form indicates that you:

1. Have read and understood the information in this form.
2. Have had the information in this form explained to you.
3. Have had a chance to ask questions and these questions were answered to your satisfaction.
4. Have been informed that you will receive a copy of this signed consent form, which includes the "Experimental Subject's Bill of Rights."

I hereby agree to be a research participant in this research study:

_____ _____ _____

Research Participant's Signature Date Time

(date and time must be in research participant's handwriting)

_____

Print Research Participant's Name

LEGALLY AUTHORIZED REPRESENTATIVE (LAR) SIGNATURE

_____ _____ _____

LAR's Signature (if applicable) Date Time

(date and time must be in LAR's handwriting)

_____

Print LAR's Name and indicate relationship to participant

INDIVIDUAL OBTAINING CONSENT SIGNATURE

_____ _____ _____

Signature of Individual Obtaining Consent Date Time

_____

Print Name of Individual Obtaining Consent

FOR USE WITH IRB APPROVED TRANSLATED SHORT/LONG CONSENT FORMS FOR NON ENGLISH SPEAKING PARTICIPANTS ONLY

NOTE: To determine who should sign below, review the guidance document, *Consenting Non English Speaking Research Participants (Pediatric or Adult) – Who Signs What?*

Interpreter: By signing here, I attest that I have acted as interpreter and facilitated this consent process.

_____ _____ _____

Interpreter's Signature Date Time

_____

Print Interpreter's Name

Witness: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name

IRB# 20204: EVALUATION OF COVID-19 CONVALESCENT PLASMA

Patient Consent

AUTHORIZATION TO USE AND DISCLOSURE OF YOUR PROTECTED HEALTH INFORMATION (PHI) FOR PURPOSES OF THIS STUDY:

I. **Purpose of this Authorization**: The information about your health is something that is protected by law and cannot, except for certain purposes, be disclosed (shared) without your permission. As part of this research, you are agreeing to allow City of Hope, its affiliated research doctors, healthcare providers, and physician network to use and share with others your protected health information ("PHI"), as needed for the research. If you agree to participate in the study named above (called the "Study"), you must sign this authorization in addition to the *Study Consent Form*.

II. **The Information About You that is Covered By this Authorization**: PHI refers to information that we maintain about you that identifies you and includes the information contained in your medical record. Your medical record consists of information related to your health and the treatment we provide to you, such as your medical history, the results of physical exams, blood tests, x-rays and other diagnostic and medical procedures. If you sign this authorization, you are allowing City of Hope and the individuals indicated below to use and share any PHI we maintain about you that is required for your participation in the Study.

Certain information about you that is highly confidential is needed for the Study. If you sign this form, you are allowing City of Hope and the individuals indicated below to use and disclose the following highly confidential PHI about you: information about HIV/AIDS testing or treatment (including the fact that an HIV test was ordered, performed or reported, regardless of whether the results of such tests were positive or negative).

III. **Purposes for Uses and Sharing of your PHI; Who Will Use, Share and Receive your PHI**: Your PHI will be used and shared with others for the purpose of doing this research as described in the *Study Consent Form*. Your PHI will also be used to keep the research sponsor informed about this Study, for reporting to those individuals and authorities responsible for overseeing our research activities to make sure that the activities are properly conducted, and to report to regulatory agencies as required by the Study.

The people authorized to use and share your PHI for purposes of the Study include the Principal Investigator and the research staff supporting the Study; your physicians and the health care team; the Health Information Management Services Department (i.e., Medical Records Department); and affiliated research doctors and other medical centers participating in the research, if applicable). This also includes any agents or contractors used by these individuals or groups for purposes of conducting or managing this Study. At the City of Hope, the

Institutional Review Board ("IRB"), and other City of Hope research regulatory committees will have access to your PHI as necessary to monitor research.

You are also allowing your PHI to be shared with the Office for Human Research Protections ("OHRP") and with any person or agency as required by law. In addition, certain other regulatory agencies, including, the Food and Drug Administration ("FDA"); will have access to your PHI.]

Your information will also be shared, with the California Institute of Regenerative Medicine (CIRM), the "Research Sponsor" and its employees, agents or contractors who are involved in the administration of the Study.

Also certain other groups and institutions, including, the Translational Genomics Research Institute (TGen) will also have access to your PHI as necessary for research purposes and to conduct the Study.

This study also involves tissue banking (storing your specimens such as blood or tumor tissue). The tissue banked as part of this study will be kept at City of Hope, California and TGen, Arizona. The banked tissue will be stored indefinitely.

This authorization will allow us to use and share your PHI for the Study. No other additional uses and disclosures other than for the purposes of the Study are included in this authorization. City of Hope's Notice of Privacy Practices will continue to protect your non-Study information. If necessary, another separate permission will be obtained from you for any non-Study uses or sharing of your PHI.

IV. **Expiration of this Authorization**: This authorization to use and share your PHI will expire twenty-five (25) years from the date that you sign this authorization.

V. **Further Sharing of Your PHI**: Your privacy is important and this is the reason for having rules which control who can use or see your PHI. City of Hope maintains control over your PHI at present, but once we share this information with a third party (for example, an individual or agency outside of the City of Hope), then it is no longer possible to maintain the same level of protection. The persons outside our control may not be governed by federal or state privacy laws and it is possible that they could share your PHI with others for whom you have not given permission.

The information from this Study may be published in scientific journals or presented at scientific meetings but your identity will be kept confidential.

VI. **Your Rights Under this Authorization**: You may cancel this permission to use and share your PHI at any time by contacting City of Hope's Privacy Officer at (626) 256-HOPE (4673) ext.

64025. You should ask for the form, *Revocation (Cancellation) of Authorization for Use of Protected Health Information for Research*. Fill this form out and return it as the form instructs. Your cancellation begins when the Health Information Management Department of City of Hope receives this form. If you cancel this authorization to use and share your PHI, you will no longer be able to participate in the Study. This is because the research under this Study cannot be conducted without your PHI.

Once you cancel your permission to use and share your PHI, the researchers and others involved in conducting the Study will no longer be able to use or share your PHI for this research. PHI already used and shared up to this point as part of this Study will continue to be used for purposes of this research. This means that any uses of your PHI and any PHI shared about you by City of Hope prior to receiving your cancellation (revocation) form cannot be taken back. While no further PHI about you will be shared for the Study, your PHI already shared will continue to be used in the overall Study.

VII. **<u>Signing this Authorization is Your Choice</u>:** Your ability to obtain care at the City of Hope will not be affected by your decision to sign this authorization form. You will be able to continue to receive health care at City of Hope if you choose not to sign this authorization form or if you sign this form and later cancel your permission to use and share your PHI.

If you agree to the use and sharing of your PHI, please sign below. You will be given a copy of this authorization form.

_____ _____ _____
Research Participant's Signature Date Time
(date and time must be in research participant's handwriting)

_____
Print Research Participant's Name

LEGALLY AUTHORIZED REPRESENTATIVE (LAR) SIGNATURE

_____ _____ _____
LAR's Signature (If applicable) Date Time

_____
Print Name of LAR and indicate relationship to participant

INDIVIDUAL OBTAINING CONSENT SIGNATURE

_____ _____ _____
Signature of Individual Obtaining Consent Date Time

_____
Print Name of Individual Obtaining Consent

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_____ _____ _____

Interpreter's Signature Date Time

_____

Print Interpreter's Name

Witness: By signing here, I attest that I witnessed the consent process and that the entire consent form was discussed.

_____ _____ _____

Witness' Signature Date Time

_____

Print Witness' Name