**Informed Consent for Research Participation: Antibody Screening for Prospective Plasma Donors**

**Title: Evaluation of Coronavirus Disease 19 (COVID-19) Convalescent Plasma**

**IRB# 20204**

CITY OF HOPE COVID COORDINATING CENTER WEB PAGES

**Page 1: Welcome Page**

**KEY INFORMATION**

You are invited to participate in this research study because you have had a COVID-19 infection and have indicated an interest in being a donor of COVID-19 convalescent plasma. The purpose of this research study is to assist in finding plasma donors for the treatment of COVID-19 patients and to conduct research to learn more about antibodies in this plasma. The information we learn by doing this research study may help to lead to a treatment for COVID-19.

During your active participation in this study, you will be asked to provide personal information in the form of a questionnaire, and you will be asked to provide blood samples (approximately 4 teaspoons). The questionnaire is expected to take up to 15 minutes. Based on your questionnaire, a swab of your nose and throat may also be done to test for the presence of COVID-19 virus. The blood draw and the nose/throat swab (if needed) are expected to last approximately 15 minutes and will take place at a clinic near you.

The major risks associated with this study include temporary discomfort from the needle stick, bruising, dizziness, and very rarely, an infection where the needle was inserted. The nose/throat swab (if needed) can be painful, can cause your eyes to water, make you sneeze, cause irritation in your nose and can make you feel light-headed.

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

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**Page 2: Why are you being asked to take part in this study?**

You recovered from a COVID-19 infection and are willing to donate your plasma to treat COVID-19 patients and help learn more about COVID-19. People who recover from COVID-19 develop in their plasma substances called antibodies, which may help fight SARS-CoV-2, the virus that causes COVID-19. This plasma is called "**COVID-19 convalescent plasma"** or **"CCP"**, and little is known about the properties of the antibodies present in CCP.

**The purposes of the research study are to:**

1. Determine if you qualify to be a COVID-19 convalescent plasma (CCP) donor based on FDA recommendations.
2. Assist your physician/medical center which has contacted you because it would like to use CCP to treat a COVID-19 patient.

3. Study your immunity to SARS-CoV-2, the virus that causes COVID-19, so that we will know what type of antibodies are given to COVID-19 patients.
4. Determine if the amount and type of antibody in the CCP given to patients has an impact on their improvement/recovery or not.
5. Use the data from this study to guide development of a COVID-19 vaccine or treatment.

**Where will research be carried out?** The testing of your blood, and if necessary your nose and throat swab, is being carried out by the City of Hope ("COH"), in Duarte, California, and its affiliate center the Translational Genomics Research Institute ("TGen"), in Flagstaff, Arizona. This document will explain what will be done if you participate. If there are words or concepts that you do not understand, please let us know by calling the City of Hope COVID-19 Coordination Center at 626-218-1817, and a call will be returned to you.

*If you understand this so far, please continue.*

**Page 3: What will happen to you in this study?**

You will register online and complete a questionnaire that asks for personal information and the history of your COVID-19 illness. It will take approximately 15 minutes to answer these questions. Your questionnaire will be reviewed by a doctor who will determine if you can proceed to the next step.

If you are found eligible to proceed to the next step, you will then be scheduled to come to a clinic near you to give a small amount of blood (approximately 4 teaspoons) from a vein in your arm to see if you have anti-COVID-19 antibodies, using several antibody tests. Based on your questionnaire, a swab of your nose and throat may also be done to test for the presence of COVID-19 virus. **This ends your participation in the City of Hope study**.

**NOTE:** If the City of Hope study shows that you are eligible to donate plasma, we will contact you and your physician with these results. If you are still interested in donating plasma, your physician will direct you to go to a local FDA-registered blood establishment where you will donate plasma via a procedure called "plasmapheresis". This is not part of the City of Hope study, and you will be asked to sign a separate consent form for this procedure.

*If you understand this so far, please continue.*

**Page 4**: **Optional biobanking for possible future studies**

Researchers are trying to learn more about COVID-19 and other diseases. Much of this research can be done using samples from your blood. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems. The researchers ask your permission to store and use your leftover samples and related health information (for example, your results of study tests) for future medical research. The research that may be done is unknown at this time and could include analysis of your genetic information performed by investigators that are not part of City of Hope. No identifying information will be attached to your samples. Storing samples for future studies is called "biobanking". You can still participate in the study if you do not agree to biobanking.

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 to Continue in Participation*

*in Research Activities*" for IRB# 20204 – "Evaluation of Coronavirus Disease 19 (COVID-19) Convalescent Plasma." Please sign the section of this this withdrawal form named "Biological Specimen Withdrawal of Consent" 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.

**Samples for future research studies:**
My samples and related information may be kept in a Biorepository (Biobank) for use in future health research.

YES NO

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

*If you understand this so far, please continue.*

**Page 5**: **What are the possible risks and discomforts?**

The risks of participating in this study are related to the blood draw, the nose/throat swab (if needed) and your personal information. The blood draw can cause mild pain or discomfort, bruising and swelling around the puncture site; it can make you light-headed and faint, and can lead to a skin infection at the site of the needle stick (rare). The nose/throat swab can be painful, can cause your eyes to water, make you sneeze, cause irritation in your nose and can make you feel light-headed. These risks are minor and can be treated easily. There is a chance that confidentiality of your private information could be lost; however, procedures are in place to minimize this risk.

**Risks associated with highly sensitive information**: To determine whether you could be a plasma donor, you will be asked to provide sensitive and personal information about your lifestyle in a questionnaire. If people not connected with the study learn this information, you could have problems getting a new job, keeping your current job, finding housing, or getting insurance (health, disability, or life insurance).

**Incidental findings:** It is possible the research procedures could find a medical problem unrelated to the purpose of this study that you did not know about before. If during the research procedures we learn information that may be important for you to know about, such as the possibility of a previously unknown medical condition, we will tell you. You may authorize the release and communication of the findings to your personal doctor, but evaluation of this would be determined by you and your doctor without further involvement by City of Hope.

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.

**What are the benefits?** There is no benefit to you for participating in this study. However, we believe that the research you are contributing to, may lead to a treatment for COVID-19.

**What are the costs to you?** There will be no costs to you for participating in this study.

**Will I get paid for my participations?** You will not be paid for taking part in this study. You may be eligible for reimbursement for up to $50 for travel expenses.

The scientific, diagnostic and/or medical significance of the research to be done is not known. 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.

**What if I am injured or if there is a breach of privacy?** If you think you have been hurt as a result of taking part in the donor screening 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.

**Who do I contact with questions?** If you feel that your questions are not being answered, the City of Hope COVID-19 Coordination Center can be contacted at 626-218-1817.

This study has been reviewed and approved by the Institutional Review Board (IRB). A representative of that Board, from the Office of Human Research Subjects Protection, is available to discuss the review process, your rights as a research participant, or any concerns or complaints you might have. The telephone number of the Office of Human Research Subjects Protection is (626) 256-HOPE (4673) ext. 62700 or toll free at 1-866-680-2906. You can also write to the City of Hope IRB, 1500 E. Duarte Road, Duarte, CA 91010.

*If you understand this so far, please continue.*

**Page 6: What are my rights in California as a Research Subject?**

**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.

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**Page 7. Alternatives, Voluntary Participation, Findings related to Participation, and Acknowledgement of Consent to Participate**

If you have questions or are unsure whether you would like to participate please, contact the City of Hope COVID-19 Coordination Center at 626-218-1817. Your alternative is not to participate. Please understand your participation is voluntary and you have the right to discontinue participation at any time without any loss of benefits, penalty, or interference. Saying no to this study or withdrawing at any time will not affect your care in any way. You will be informed if there are any significant protocol changes or other new information related to this study that might affect your willingness to continue to participate. You can withdraw consent at any time by contacting the City of Hope COVID-19 Coordination Center at 626-218-1817. By pressing “I agree” at the bottom of this page you consent to participate.

[I agree]-button leading to HIPAA Authorization.

**Page 8: Authorization to use and disclosure of your Protected Health Information (PHI) for purposes of this study**

- **Purpose of this Authorization and Who May Disclose Your Personal Health Information**: As part of this research, you are agreeing to allow City of Hope National Medical Center (City of Hope) to use and share with others your protected health information (PHI), as needed for the research study referenced above (the "Study"). You are also agreeing to allow other health care providers to disclose your health information to City of Hope for purposes of the research.
- **Information About You that is Covered By this Authorization:** PHI refers to information that we maintain about you that identifies you, including information in your medical record related to your health, treatment, your medical history, exam and test results and other diagnostic and medical procedures. While this study is not targeting highly confidential information, information about the existence of genetically handicapping conditions may be collected if patients with genetically handicapping conditions agree to participate. If you sign this form, you are allowing City of Hope and the individuals indicated below to use and disclose any PHI we maintain about you, including information about the existence of genetically handicapping conditions for purposes of this study. Additionally, you are authorizing your other health care providers to provide copies of your complete medical record, including information regarding genetically handicapping conditions, to City of Hope for purposes of the research.
- **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.
- The people authorized to use and disclose your PHI for purposes of the Study include the Principal Investigator and research staff supporting the Study; your City of Hope physicians and health care team; and the Health Information Management Services Department. This also includes any agents or contractors used by these individuals or groups for purposes of conducting or managing this Study. At City of Hope, the Institutional Review Board, Data & Safety Monitoring Committee and other research oversight committees will have access to your PHI to monitor research. You are also allowing your PHI to be shared with regulatory agencies, such as the Office for Human Research Protections, the National Cancer Institute, the California Institute for Regenerative Medicine (CIRM), and with any person or agency as required by law.
- This study involves tissue banking (storing your specimens such as blood or tumor tissue). The banked tissue will be stored indefinitely at the City of Hope, Duarte, California, and at TGen, Arizona. No other additional uses and disclosures other than for the purposes of the Study are covered by this authorization. City of Hope's Notice of Privacy Practices will continue to govern the use and disclosure of your PHI for non-Study purposes. If necessary, another separate permission will be obtained from you for any non-Study uses or disclosures of your PHI.
- **Expiration of this Authorization**: One hundred (100) years from the date of your signature.
- **Further Sharing of 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. Information from this Study may be published in scientific journals or presented at scientific meetings but your identity will be kept confidential.

- **Your Rights Under this Authorization**: You may cancel or revoke this Authorization at any time by contacting City of Hope's Privacy Officer at (626) 256-HOPE (4673) ext. 64025. Ask for the **Revocation (Cancellation) of Authorization for Use of Protected Health Information for Research** form. Fill this form out and return it as the form instructs. If you cancel this Authorization, your PHI will no longer be used or disclosed for this Study, and you will no longer be able to participate in the Study. However, PHI shared about you prior to receiving your cancellation cannot be taken back. As a result, PHI already shared prior to the revocation of your authorization will continue to be used as necessary for the integrity of the Study.
- **Signing this Authorization is Your Choice:** Your ability to obtain care at 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 understand this so far, please continue.*

[I agree]- button leading to the questionnaire. I agree to the use and sharing of my PHI. You will be given a copy of this authorization form.