

# Partners HealthCare System Research Consent Form

Subject Identification
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General Consent Form Template  
Version Date: January 2019

Protocol Title: ESCAPE (Evaluation of SARS-CoV-2 Antibody-containing Plasma thERapy): A Prospective, Randomized, Double-Masked, Placebo-Controlled Trial of High-Titer COVID-19 Convalescent Plasma (HT-CCP) for the Treatment of Hospitalized Patients with COVID-19 of Moderate Severity.

Principal Investigator: Richard Kaufman, MD

Site Principal Investigator: Richard Kaufman, MD

Description of Subject Population: Patients who are hospitalized with COVID-19 but who have not yet developed moderate or severe ARDS.

## About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Some of the people who are eligible to take part in this study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s) to give permission for them to take part in the study and will ask them to agree (give their assent) to take part. Throughout the consent form, “you” always refers to the person who takes part in the study.

Some of the people who are eligible to take part in this study may not be able to give consent to take part because of their medical condition. Instead we will ask the person’s authorized representative to give consent. Throughout the consent form, “you” always refers to the person who takes part in the study.

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## **Key Information**

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

### **Why is this research study being done?**

In this research study we want to learn more about high-titer COVID-19 convalescent plasma (HT-CCP) transfusion as a possible treatment for people who have COVID-19, the coronavirus infection that you are now fighting. This study is being done to determine whether HT-CCP will help people with COVID-19 recover from their infection more quickly and lower their risk of having to go on a ventilator.

### **How long will you take part in this research study?**

If you decide to join this research study, it will take you about one year to complete the study. During this time, we will ask you to make 2-3 study visits to Brigham and Women's Hospital after you get better and are discharged from the hospital.

### **What will happen if you take part in this research study?**

If you decide to join this research study, we will draw blood samples, take nasopharyngeal swab samples, and you will receive a transfusion of two bags of either the investigational plasma or placebo plasma, depending on what arm you are randomized to.

### **Why might you choose to take part in this study?**

We cannot promise any benefits to you from taking part in this research study. If you receive the study treatment (HT-CCP), it is possible that you may have an improved outcome. Others with COVID-19 may benefit in the future from what we learn in this study.

### **Why might you choose NOT to take part in this study?**

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Taking part in this research study has some risks and requirements that you should consider carefully.

Important risks and possible discomforts to know about include: allergic reaction (e.g. difficulty breathing, drop in blood pressure, stomach upset, diarrhea, and/or rash), lung injury (difficulty breathing), circulatory overload (difficulty breathing), and non-infectious fever.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called “What are the risks and possible discomforts from being in this research study?”

## **What other treatments or procedures are available for your condition?**

There are currently no FDA-approved treatments for COVID-19. There may be other investigational therapy options (aka clinical trials) for which you may be eligible, and if so you will be notified of these options prior to enrolling in this study.

## **If you have questions or concerns about this research study, whom can you call?**

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Richard Kaufman is the person in charge of this research study. You can call him at 617-732-5232. You can also call Dr. Lindsey Baden (617-732-5885) or Dr. Clifton Mo (617-582-7969) with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Karina Oganezova at 617-525-4250.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

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## Detailed Information

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.

### Why is this research study being done?

We are doing this research to learn more about high-titer COVID-19 convalescent plasma (HT-CCP) transfusion as a possible treatment for people who have COVID-19, the coronavirus infection that you are now fighting. “Plasma” is the liquid portion of the blood that contains antibodies (immune proteins that are meant to fight off infection) and not blood cells. “HT-CCP” is plasma that contains a high amount of antibodies that were made to fight off COVID-19 because it is donated by another person who has also been infected with coronavirus but has recovered, so their immune system has had enough time to make these antibodies. “Transfusion” means that HT-CCP from a donor will be given to you through your vein.

This study is being done to determine whether HT-CCP will help people with COVID-19 recover from their infection more quickly and lower their risk of having to go on a ventilator or reduce the time they need to stay on a ventilator. It is not yet known whether HT-CCP helps people with COVID-19, which is why the study needs to be randomized, meaning some subjects will be randomly selected to receive HT-CCP while others will be randomly selected not to receive it.

HT-CCP is regulated as an investigational product by the U.S. Food and Drug Administration to treat COVID-19.

### Who will take part in this research?

We are asking you to take part in this research study because you have been diagnosed with COVID-19 and because your infection is severe enough to warrant hospitalization. About 220 people will take part in this research study. Up to 150 people will participate at Partners hospitals.

### What will happen in this research study?

If you decide to join this research study, the following things will happen:

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- You will have a 1 out of 2 chance of being randomized to arm A of the study and a 1 out of 2 chance of being randomized to arm B.
- If you are randomized to arm A, you will receive a transfusion of two bags of HT-CCP (about 250 milliliters of plasma in each bag [about 8 ounces]) that was collected from either one or two donors who have already recovered from COVID-19. You will receive this transfusion as soon as possible after study enrollment, and you will receive both bags in sequence within a 24-hour period. You will also continue to receive standard medical care from your hospital care team.
- If you are randomized to arm B, you will receive a transfusion of two bags of standard plasma (about 250 milliliters of plasma in each bag [about 8 ounces]) that was collected from either one or two donors who have not had COVID-19 and whose plasma most likely does not contain antibodies against SARS-CoV-2 (the virus that causes COVID-19). You will also continue to receive standard medical care from your hospital care team.
- The bags of plasma that you will receive will only be identified as “Thawed Plasma”, so neither you nor your team of doctors and nurses will know whether they contain HT-CCP or regular plasma.
- A research blood sample (no more than 50 milliliters, about 3 tablespoons) will be taken from your vein before you receive the study agent on day 1 of the study. An additional sample (no more than 50 milliliters) will be taken from your vein approximately 6 to 12 hours after you receive your second transfusion (on day 1 or day 2 of the study). An additional research blood samples (no more than 50 milliliters, about 3 tablespoons) will be taken from your vein on day 7 of the study, and every seven days thereafter until you are discharged from the hospital.
- Starting on day 0-1 after enrollment, you will have a nasopharyngeal (NP) swab (the same test that you had done to diagnose you with COVID-19) once weekly until you test negative. However, you will retain the right to refuse a swab at any time.
- If you are intubated (on a ventilator), you may also undergo a tracheal aspirate once weekly starting on day 7 until you either test negative or come off of the ventilator. A tracheal aspirate is a procedure where a respiratory therapist inserts a suction catheter into your endotracheal tube (breathing tube), with or without an injection of a small amount of normal saline into the tube, to collect a sample of your respiratory secretions. These tracheal aspirate samples will only be obtained if a tracheal suction by a respiratory therapist is clinically indicated on the day of intended sampling.

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- If you get better and leave the hospital before day 28 of the study, a member of the study staff will either see you in the outpatient clinic or call you on the telephone once a week until day 28 to see how you are feeling and to make sure you are not having any problems. If you have not yet tested negative on your NP swab, you may also be asked to undergo additional NP swabs at a weekly interval until you test negative. If you come into the clinic, study staff may also ask you to submit a research blood sample.
- After day 28 of the study, you may be asked to return to the outpatient infectious disease clinic approximately three times over the course of the next year for a visit and research blood draw.

You may or may not receive HT-CCP before you leave the hospital.

This study is randomized and double-masked. “Randomized” means that the study arm into which you are placed is chosen by chance. “Double-masked” means that neither you nor your team of doctors and nurses in the hospital will know which study arm you are on and whether you have received HT-CCP or regular plasma.

You will not need to stop any of your current medications to enroll in this study. You will not need to fast before your research tests are performed.

After you leave the hospital, Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

Reasons for early withdrawal from the study include:

- you withdraw your consent to participate in the study.
- you fail to make your follow-up clinic appointments after you leave the hospital

You are free to withdraw from the study at any time by notifying a member of the study team of your desire to withdraw.

Your de-identified research specimens may be sent to collaborative institutions outside of the Partners system.

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital

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labs). Please ask your study doctor if you have any questions about what information will be included in your electronic medical record.

We may also perform a whole genome analysis on your DNA sample. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome analyses, all or most of your genes are looked at and used by researchers to study links to your immune response to COVID-19.

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of whole genome studies. These banks may also analyze and store DNA samples, as well. These central banks will store your genetic information and samples and give them to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks. However, we cannot predict how genetic information will be used in the future. The samples and data will be sent with only your code number attached. Your name or other directly identifiable information will not be given to central banks. There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

Research using your samples and whole genome information is important for the study of virtually all diseases and conditions. Therefore, the sample/data banks will provide study data for researchers working on any disease.

## **How may we use and share your samples and health information for other research?**

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

At the completion of this research study, we would like to store and be able to use and share your identifiable samples and health information with researchers at Partners for other research related to COVID-19. If we share your samples and/or health information with other researchers outside of Partners, we will label the samples and information with a code instead of your name or other directly identifying information. The key to the code connects your name or other identifiers to

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your sample and/or information. We will keep the code in a password-protected computer or locked file.

Because these samples and/or health information are identifiable, we are asking your permission to store, use and share them for other research. You can still take part in the research study whether or not you give permission for the storage, use, and sharing of the samples and health information for other research.

Do you agree to let us store and use your samples and health information for other research related to COVID-19.

YES  NO Initial \_\_\_\_\_

## Will you get the results of this research study?

You and your doctor should not expect to get information about the results of the research study or the results of your individual participation in the research study. We and the researchers involved in the study will study samples and information from many people. It could take many years before anyone knows whether the results have any meaning. There is a small chance that we or the researchers could find out something from the study that might be important to your health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your health, we cannot guarantee that you will be contacted.

## What are the risks and possible discomforts from being in this research study?

Risks and possible discomforts of study treatment include:

- Allergic reaction, which can cause difficulty breathing, dizziness or lightheadedness, stomach upset, diarrhea, and/or rash; in severe cases, allergic reactions can be life-threatening.
- Transfusion-related acute lung injury (TRALI), which can cause difficulty breathing; in severe cases, TRALI can be life-threatening.
- transfusion-associated circulatory overload (TACO), which can cause difficulty breathing; in severe cases, TACO can be life-threatening.
- Febrile non-hemolytic transfusion reaction, which causes a non-infectious fever.



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- Transmission of a non-coronavirus infection (e.g. hepatitis virus, HIV) through the donated plasma; this is rare.
- Hypotensive transfusion reaction, which causes a drop in blood pressure; this is rare.
- Acute hemolytic transfusion reaction, which can cause fever, back pain, difficulty breathing, and blood in the urine and can be life-threatening; this is rare.
- Transmission of a different strain of novel coronavirus, which could worsen your infection; this is a potential, but not a proven, risk.
- an unintended effect of the donor antibodies on your immune system, which could worsen your infection or increase your chances of a second COVID-19 infection after you recover; this is a potential, but not a proven, risk.

Other things to consider are the possibility that HT-CCP could theoretically weaken your long-term immunity to SARS-CoV-2. For this reason, you will be asked to return to the outpatient infectious disease clinic at BWH periodically (between 2-3 times in total) during the first year after you are discharged from the hospital to see how you are doing and to test your blood for evidence of immunity to the virus.

If you are pregnant, the risks to you described above could also affect your fetus. A severe allergic transfusion reaction could cause your blood pressure to drop, which could be life-threatening to you or your fetus. Some types of transfusion reactions could cause you to have difficulty breathing (allergic reaction, TRALI, or TACO). In severe cases, these types of reactions could be life-threatening to you or your fetus. There is a low risk that you or your fetus could be infected with a virus such as HIV or viruses that cause hepatitis. Theoretically, HT-CCP could cause your SARS-CoV-2 infection to worsen; this could also affect the health of your fetus.

There may be other risks of the study treatment that are currently not known.

## **What are the possible benefits from being in this research study?**

We cannot promise any benefits to you from taking part in this research study. If you receive the study treatment (HT-CCP), it is possible that you may have an improved outcome. Others with COVID-19 may benefit in the future from what we learn in this study. If you are pregnant and receive the study treatment (HT-CCP), it is possible that your fetus may have an improved outcome.

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## What other treatments or procedures are available for your condition?

There are currently no FDA-approved treatments for COVID-19. There may be other investigational therapy options (a.k.a. clinical trials) for which you may be eligible, and if so you will be notified of these options prior to enrolling in this study.

## Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

## What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

## Will you be paid to take part in this research study?

You will not be paid for taking part of this study.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

## What will you have to pay for if you take part in this research study?

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Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

## **What happens if you are injured as a result of taking part in this research study?**

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Due to the coronavirus public health crisis, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies, it limits your right to sue the researchers, healthcare providers, any study sponsor or manufacturer 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

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

## **If you take part in this research study, how will we protect your privacy?**

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Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as “identifiable information.”

## **In this study, we may collect identifiable 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 information and why they may need to do so:**

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable 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 identifiable information to perform additional research on

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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 identifiable 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 identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

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 identifiable information **will not** be used for these purposes without your specific permission.

## Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable 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 identifiable 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, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable 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.

## Informed Consent and Authorization

### Statement of Person Giving Informed Consent and Authorization





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**Signature of Study Doctor or Person Obtaining Consent:**

**Statement of Study Doctor or Person Obtaining Consent**

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

\_\_\_\_\_  
Study Doctor or Person Obtaining Consent                      Date                      Time (optional)

**Subject Advocate**

In certain situations, the Partners Human Research Committee (PHRC) will require that a subject advocate also be involved in the consent process. The subject advocate is a person who looks out for the interests of the study subject. This person is not directly involved in carrying out the research. By signing and dating below, the subject advocate represents (or “says”) that the subject has given meaningful consent to take part in the research study.

**Statement of Subject Advocate**

I represent that the subject or authorized individual signing above has given meaningful consent.

\_\_\_\_\_  
Subject Advocate (when required)                      Date                      Time (optional)

**Consent of Non-English Speaking Subjects Using the “Short Form” in the Subject’s Spoken Language**

**Statement of Hospital Medical Interpreter**



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As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

\_\_\_\_\_  
Hospital Medical Interpreter

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time (optional)

**OR**

**Statement of Other Individual (Non-Interpreter)**

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

\_\_\_\_\_  
Date

\_\_\_\_\_  
Time (optional)

**Consent of Subjects Who Cannot Read or Write or are Physically Unable to Talk or Write**

The consent form was presented orally to the subject in the subject's own language, the subject was given the opportunity to ask questions, and the subject has indicated his/her consent and authorization for participation by (check one box as applicable):

Making his/her mark above

Other means \_\_\_\_\_  
(fill in above)

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