Informed Consent Form

Protocol Title: Antibody Enriched Plasma Donation for Future Treatment Opportunities

NCT#: NCT04376034

Document Date:23May2019

Key Information for:

Antibody Enriched Plasma Donation for Future Treatment Opportunities

You are being asked to participate in the research described below. This page provides key information that may help you to make this decision; more detailed information can be found after this section.

Why is this research being done and what is involved?

The purpose of this study is to determine if the use of convalescent plasma will help those with COVID-19 in critical condition recover. Participation in this study involves receiving plasma (what is left over when red and white blood cells are removed from your blood) from someone else that has recently recovered from COVID-19. It is estimated that it will take 2 to 6 hours to receive the plasma. You will be followed for 30 days after receiving the plasma therapy.

Do I have to participate and what are the risks?

Participation in this research study is completely voluntary and you are free to withdraw from the research at any time. If you do not want to participate, please discuss alternatives with the researcher or your doctor. You can also refer to the "Alternatives" section in this consent form.

You may or may not directly benefit as a result of participating in this study. Benefits may include the improvement of your health, but since it is not known whether plasma therapy will be effective in your case this cannot be promised or guaranteed.

Risks from participation in this study include potential allergic reactions such as: anaphylaxis and in rare cases transmission of viral illness or prion disease.

Who can I talk to if I have questions or concerns?

If you have any questions or concerns about this research or would want to withdrawal from the study, you can contact Brian P. Peppers, DO, PhD by phone at 304-594-4312 during normal working hours (Monday - Friday 9:00 A.M. to 4:00 P.M.). in the Department of Pediatrics at West Virginia University.

For more information, please see the Informed Consent Form.

Informed Consent for Research | More than Minimal Risk

Principal Investigator (PI) |	Brian P. Peppers, DO, PhD
PI Department |	Department of Pediatrics, Division of Allergy and Immunology
Co-Investigator(s) |	Pete Perrotta, MD, Aaron Shmookler, MD, Sunil Sharma, MD, David Skoner, MD, Lisa Giblin Sutton, PharmD, Theodore Kieffer, MD, Stacey Mahady, DO, Callum Lewandrowski, DO, and Trey Vanek, MD
Sponsor or Funding Source |	WVU Medicine
WVU IRB Protocol # |	2004965705
Study Title |	**Antibody Enriched Plasma Donation for Future Treatment Opportunities**

Introduction

You,_____, have been asked to participate in this research study, which has been explained to you by..... This study is being conducted by Brian P. Peppers, DO, PhD in the Department of Pediatrics, Division of Allergy and Immunology at West Virginia University, along with Pete Perrotta, MD, Aaron Shmookler, MD, Sunil Sharma, MD, Lisa Giblin Sutton, PharmD, David Skoner, MD, Theodore Kieffer, MD, Stacey Mahady, MD, Callum Lewandrowski, MD, and Trey Vanek, MD.

Purpose

You are being asked to join in this study because you have COVID-19 and are in critical condition. It has been explained to you that you have COVID-19 which is resistant to standard therapy.

The reason for doing this study is to determine if the use of convalescent plasma will help those with COVID-19 in critical condition recover. The purpose of this study is to evaluate the effectiveness and side effects of convalescent plasma and to learn more about your condition.

You have been invited to participate in this research study which involves an investigational agent, convalescent plasma, which has not yet been approved by the Food and Drug Administration (FDA) for treating COVID-19.

WVU expects to enroll between up to 240 subjects.

Description of Procedures

This study involves receiving an investigational agent called convalescent plasma for one (1) treatment that will take approximately 2-6 hours to give. This is available after an initial blood draw is used to type and screen the blood to see if there is a match with available stored plasma. Convalescent plasma is a new experimental therapy. Supportive care is the current therapy for your disease that includes IV fluids, nutrition, breathing assistance (such as a ventilator), and respiratory therapy. Other investigational medications such as antivirals, immunomodulators and antibiotics are available to potentially help treat your illness.

The use of any standard and/or investigational drug does not exclude you from being eligible to receive convalescent

plasma. The use of convalescent plasma may exclude you from using other investigational medications currently available or in the future.

Patients who require a ventilator (breathing machine) may receive a higher dose (2 units) of experimental plasma depending on availability. Depending on your overall health status you may be given 2 units over two days (1 unit on day 1 and then they second unit on the second day. Patients with less severe breathing problems with COVID-19 will receive a lower dose (1 unit) of plasma. If you were treated with the experimental plasma and still worsening after 3 days, then you would be eligible for repeat treatment with the study plasma, if more doses are available.

If you have had 2 units and your condition worsens or fails to improve, you will be eligible to have 1 additional unit every 3 days for a maximum of 8 units of convalescent plasma, if more doses are available.

Should you at any point through your routine care have plasma electrophoresis (your plasma is removed and replaced with fresh donor plasma that is not necessarily enriched in COVID19 antibodies), you will be eligible for 2 additional units of convalescent plasma per electrophoresis treatment and up to 8 units total after electrophoresis series is completed, if more doses are available.

It is not clear at this time which of the therapies is better for you. For this reason, the therapy offered will be based on you meeting the Federal Drug Administrations (FDA) Investigational New Drug (IND) guidelines for you receiving convalescent plasma. Receiving the convalescent plasma is determined based on you meeting the criteria, consenting to the treatment and the availability of the convalescent plasma.

You will be given plasma, the clear and pale yellow/amber, liquid portion of the blood, from a person who has recovered from COVID-19 that is compatible with your blood type. If receiving the convalescent plasma, it will be given through your IV or other advanced venous access. If you do not have one, an IV will be placed. Based on your medical records, you may be given an antihistamine such as diphenhydramine prior to the infusion, as well as a steroids and acetaminophen. You will then have the convalescent plasma infused through your veins. This process can take up to 2-6 hours. At times, the infusion can take more or less than the given time period.

We will monitor your progress by collecting up to 5mL of blood before each transfusion. We will then collect up to 5mL of blood within 24 hours after each transfusion (no sooner than 2 hours after transfusion) to examine improvements based on plasma infusion. Part or all of your blood sample(s) collected may be stored for future laboratory testing.

Treatment will be stopped if you have an adverse reaction or if your doctor determines that this treatment is not in your best interest. Any adverse reaction will be treated immediately in accordance with the standard of care, such as if you develop hives, you will be given more antihistamines.

In some circumstances, you doctor may end your participation in this study without your consent. This would occur in the event that your condition has improved and you no longer meet the criteria receiving the convalescent plasma, or you have a severe reaction(s) to the treatment and it is no longer safe for you to continue with the infusion even if you recover from the reaction.

You will be followed for 30 days after receiving the plasma therapy. You will be monitored for 30 days post infusion for return hospitalization or complications. If you are no longer in the hospital at the end of the 30 days, you will be contacted by phone for an update about your condition.

Risks and Discomforts

Drugs often have side effects. The drugs used in this program may cause all, some, or none of the side effects

listed. In addition, there is always the risk of uncommon or previously unknown side effects.

More common:

- Headaches
- Pruritus (itchy skin)
- Hives
- Nausea
- Muscle cramp

Less common:

- Vomiting
- Shortness of breath
- Anaphylaxis (severe allergic reaction, that is life-threatening)
- Tachycardia (fast heart rate)

Rare:

- Blood clots
- Hypertension (very high blood pressure)
- Seizures
- Transmission of viral illness
- Prion diseases - Prion diseases occur when normal prion protein, found on the surface of many cells, becomes abnormal and clump in the brain, causing brain damage. This abnormal accumulation of protein in the brain can cause memory impairment, personality changes, and difficulties with movement.

There may be other interactions that the researchers cannot predict with the use of convalescent plasma in addition to other medications. For instance, plasma infusion may increase the likelihood of increased volume overload. In addition, there is always the risk of uncommon or previously unknown side effect(s) or event(s). You may have other side effects that are hard to predict or unknown at this time; disability, serious injury, and death may be included among these side effects.

Your doctor(s), nurse(s) and medical staff will be checking you closely to see if any of these side effects or problems are occurring.

This study may involve risks to an unborn child. However, given the criteria of critical condition required for the use of convalescent plasma for the treatment of COVID-19, there may be potential benefit in the treatment for both the mother and the unborn child. For this reason, pregnant women will be eligible to receive convalescent plasma if they meet the criteria.

Men who are able to father a child should never have unprotected sex with a woman while in this study because it is not known if the drug is present in semen or sperm. Convalescent plasma will not prevent contracting or spreading a sexually transmitted disease.

Alternatives

You do not have to participate in this study.

Alternatives that could be considered in your case include standard of care for the treatment of COVID-19 as well as any other investigational medications, as described above, that you meet the criteria for its use.

Benefits

Possible benefits that may result from your participation include the improvement of your health, but since it is not known whether plasma therapy will be effective in your case, you may not receive any benefit, or your condition may worsen. The knowledge gained from this study may eventually benefit others.

Financial Considerations

You will not need to pay for the convalescent plasma. You may wish to consult your insurance carrier prior to entering this study. There are no special fees for participating in this study, but any expense associated with current therapy or treatment of side effects will be billed to you and to your insurance company. You will not be paid for participating in this research.

Your data, health information, research results, specimens, or any and all other information related to this research study used in this research study may contribute to a new discovery or treatment. In some instances, your data, your health information, your research results, your specimens, these discoveries or treatments, or any other information related to this research study, even if identifiers are removed, may be of commercial value and may be sold, patented, or licensed by the investigators and West Virginia University for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money or commercial profit that the investigators, West Virginia University, or their agents may realize.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities, including the Food and Drug Administration (FDA), without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you or to others, such as suicide, child abuse, etc.

HIPAA Authorization

We know that information about your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patient/ West Virginia University Hospitals/ WVU Medicine/ WVUHS

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliates, WVU, WVU Hospitals, West Virginia University Health System (WVUHS). It also includes each site's research and medical staff.
- Health care providers who provide services to you as part of this research study.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- American Red Cross or other donation site

- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- WVU Medicine and the people and companies that they use to oversee, manage, or conduct the research.
- The members and staff of any institutional review board that oversees this research study.
- The West Virginia University Office of Human Research Protections and the Office of Sponsored Programs.

The Following Information Will Be Used

Information from your existing medical records, and new information about you that is created or collected during this study, such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, EKG results, demographic data, pulmonary tests, imaging scans, and study forms.

The Information is Being Disclosed for the Following Reasons

- Review of your data for quality assurance purposes and to determine your status of eligibility for this study.
- Publication of study results (without identifying you).
- Other research purposes such as reviewing the safety or effectiveness of the study drug and other products or therapies; evaluating other products or therapies for patients; developing a better understanding of the condition; and improving the design of future clinical trials.

You May Cancel This Authorization at Any Time by Writing to the Principal Investigator

Brian P. Peppers, DO, PhD
WVU Medicine - Department of Pediatrics
1 Campus Drive, Morgantown, WV 26505
Phone: 304-594-1313

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time, you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time.

ClinicalTrials.gov

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.

Voluntary Compensation

There is no money set aside to help treat you if you get hurt or sick in this study. The study doctor and WVU or its partners do not have special funds to pay for research related injuries if they occur.

If you injured as a result of this research, treatment will be available. This care will be billed to you or your insurance company. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Dr. Brian Peppers at 304-594-1313 if you are injured or for further information.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time prior to receiving the plasma serum at no penalty to you.

If you choose to withdraw your participation from the study, the data collected on you up until that time remains a part of the study database and may not be removed. No additional information will be added to the study database after your withdrawal.

Refusal to participate or your decision to stop participating will not affect your future care at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue participating in this study.

Contact Persons

If you have any questions, concerns, or complaints about this research, you can contact Brian P. Peppers, DO, PhD by phone at 304-594-1313 during normal business hours (Monday - Friday 9:00 A.M. to 4:00 P.M.). Additionally, you can contact Dr. Charles Mullet or Dr. Pete Arrotta at (304) 598-4000 and ask for them to be paged.

If you are hurt from being in this research, you should contact Brian P. Peppers, DO, PhD by phone at 304-594- 1313 during normal business hours (Monday - Friday 9:00 A.M. to 4:00 P.M.). If injury occurs outside of business hours and is related to your participation in this research, please contact Brian P. Peppers, DO, PhD through WVU Medicine's main phone line: 304-598-4000, inform them of your participation in a medical research study and ask for Dr. Peppers to be paged or call (800) 982-6277.

For information regarding your rights as a participant in research or to talk about the research, contact the WVU Office of Human Research Protections (OHRP) at (304) 293-7073 or by email at IRB@mail.wvu.edu.

Future Contact

Future research may be conducted for which you are eligible. If you are interested in being contacted for future research, please indicate so by completing this section.

- ☐ Yes, I want to be contacted if future research studies, for which I may be qualified, become available.
- ☐ No, I **do not** want to be contacted if future research studies, for which I may be qualified.

Signatures and Authorization

You have been given the opportunity to ask questions about the research and your authorization of HIPAA, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy.

Participant Signature

I willingly consent to my participation in this research and authorization of HIPAA.

Signature of Subject or Subject's Legal Representative

Printed Name | Date

Consenting Individual Signature

The participant or legal representative has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Person Obtaining Informed Consent

Printed Name | Date

Impartial Witness Signature (if applicable)

The participant or legal representative has had the opportunity to have questions addressed. As the impartial witness, I confirm that the participant willingly agrees to be in the study.

Signature of Impartial Witness

Printed Name | Date

Key Information for:

Antibody Enriched Plasma Donation for Future Treatment Opportunities

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Informed Consent for Research | More than Minimal Risk

Principal Investigator (PI) |	Brian P. Peppers, DO, PhD
PI Department |	Department of Pediatrics, Division of Allergy and Immunology
Co-Investigator(s) |	Pete Perrotta, MD, Aaron Shmookler, MD, Sunil Sharma, MD, David Skoner, MD, Lisa Giblin Sutton, PharmD, Theodore Kieffer, MD, Stacey Mahady, DO, Callum Lewandrowski, DO, and Trey Vanek, MD
Sponsor or Funding Source |	WVU Medicine
WVU IRB Protocol # |	2004965705
Study Title |	**Antibody Enriched Plasma Donation for Future Treatment Opportunities**

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If you have had 2 units and your condition worsens or fails to improve, you will be eligible to have 1 additional unit every 3 days for a maximum of 8 units of convalescent plasma, if more doses are available.

Should you at any point through your routine care have plasma electrophoresis (your plasma is removed and replaced with fresh donor plasma that is not necessarily enriched in COVID19 antibodies), you will be eligible for 2 additional units of convalescent plasma per electrophoresis treatment and up to 8 units total after electrophoresis series is completed, if more doses are available.

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You will be followed for 30 days after receiving the plasma therapy. You will be monitored for 30 days post infusion for return hospitalization or complications. If you are no longer in the hospital at the end of the 30 days, you will be contacted by phone for an update about your condition.

Risks and Discomforts

Drugs often have side effects. The drugs used in this program may cause all, some, or none of the side effects

listed. In addition, there is always the risk of uncommon or previously unknown side effects.

More common:

- Headaches
- Pruritus (itchy skin)
- Hives
- Nausea
- Muscle cramp

Less common:

- Vomiting
- Shortness of breath
- Anaphylaxis (severe allergic reaction, that is life-threatening)
- Tachycardia (fast heart rate)

Rare:

- Blood clots
- Hypertension (very high blood pressure)
- Seizures
- Transmission of viral illness
- Prion diseases - Prion diseases occur when normal prion protein, found on the surface of many cells, becomes abnormal and clump in the brain, causing brain damage. This abnormal accumulation of protein in the brain can cause memory impairment, personality changes, and difficulties with movement.

There may be other interactions that the researchers cannot predict with the use of convalescent plasma in addition to other medications. For instance, plasma infusion may increase the likelihood of increased volume overload. In addition, there is always the risk of uncommon or previously unknown side effect(s) or event(s). You may have other side effects that are hard to predict or unknown at this time; disability, serious injury, and death may be included among these side effects.

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This study may involve risks to an unborn child. However, given the criteria of critical condition required for the use of convalescent plasma for the treatment of COVID-19, there may be potential benefit in the treatment for both the mother and the unborn child. For this reason, pregnant women will be eligible to receive convalescent plasma if they meet the criteria.

Men who are able to father a child should never have unprotected sex with a woman while in this study because it is not known if the drug is present in semen or sperm. Convalescent plasma will not prevent contracting or spreading a sexually transmitted disease.

Alternatives

You do not have to participate in this study.

Alternatives that could be considered in your case include standard of care for the treatment of COVID-19 as well as any other investigational medications, as described above, that you meet the criteria for its use.

Benefits

Possible benefits that may result from your participation include the improvement of your health, but since it is not known whether plasma therapy will be effective in your case, you may not receive any benefit, or your condition may worsen. The knowledge gained from this study may eventually benefit others.

Financial Considerations

You will not need to pay for the convalescent plasma. You may wish to consult your insurance carrier prior to entering this study. There are no special fees for participating in this study, but any expense associated with current therapy or treatment of side effects will be billed to you and to your insurance company. You will not be paid for participating in this research.

Your data, health information, research results, specimens, or any and all other information related to this research study used in this research study may contribute to a new discovery or treatment. In some instances, your data, your health information, your research results, your specimens, these discoveries or treatments, or any other information related to this research study, even if identifiers are removed, may be of commercial value and may be sold, patented, or licensed by the investigators and West Virginia University for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money or commercial profit that the investigators, West Virginia University, or their agents may realize.

Confidentiality

Any information about you that is obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and test results, just like hospital records, may be subpoenaed by court order or may be inspected by the study sponsor or federal regulatory authorities, including the Food and Drug Administration (FDA), without your additional consent.

In addition, there are certain instances where the researcher is legally required to give information to the appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you or to others, such as suicide, child abuse, etc.

HIPAA Authorization

We know that information about your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

Persons/Organizations Providing the Information

Patient/ West Virginia University Hospitals/ WVU Medicine/ WVUHS

Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliates, WVU, WVU Hospitals, West Virginia University Health System (WVUHS). It also includes each site's research and medical staff.
- Health care providers who provide services to you as part of this research study.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- American Red Cross or other donation site

- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- WVU Medicine and the people and companies that they use to oversee, manage, or conduct the research.
- The members and staff of any institutional review board that oversees this research study.
- The West Virginia University Office of Human Research Protections and the Office of Sponsored Programs.

The Following Information Will Be Used

Information from your existing medical records, and new information about you that is created or collected during this study, such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, EKG results, demographic data, pulmonary tests, imaging scans, and study forms.

The Information is Being Disclosed for the Following Reasons

- Review of your data for quality assurance purposes and to determine your status of eligibility for this study.
- Publication of study results (without identifying you).
- Other research purposes such as reviewing the safety or effectiveness of the study drug and other products or therapies; evaluating other products or therapies for patients; developing a better understanding of the condition; and improving the design of future clinical trials.

You May Cancel This Authorization at Any Time by Writing to the Principal Investigator

Brian P. Peppers, DO, PhD
WVU Medicine - Department of Pediatrics
1 Campus Drive, Morgantown, WV 26505
Phone: 304-594-1313

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This authorization will expire at the end of the study unless you cancel it before that time.

ClinicalTrials.gov

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.

Voluntary Compensation

There is no money set aside to help treat you if you get hurt or sick in this study. The study doctor and WVU or its partners do not have special funds to pay for research related injuries if they occur.

If you injured as a result of this research, treatment will be available. This care will be billed to you or your insurance company. There is no commitment to provide any compensation for research-related injury. You should realize, however, that you have not released this institution from liability for negligence. Please contact the investigator, Dr. Brian Peppers at 304-594-1313 if you are injured or for further information.

Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time prior to receiving the plasma serum at no penalty to you.

If you choose to withdraw your participation from the study, the data collected on you up until that time remains a part of the study database and may not be removed. No additional information will be added to the study database after your withdrawal.

Refusal to participate or your decision to stop participating will not affect your future care at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue participating in this study.

Contact Persons

If you have any questions, concerns, or complaints about this research, you can contact Brian P. Peppers, DO, PhD by phone at 304-594-1313 during normal business hours (Monday - Friday 9:00 A.M. to 4:00 P.M.). Additionally, you can contact Dr. Charles Mullet or Dr. Pete Arrotta at (304) 598-4000 and ask for them to be paged.

If you are hurt from being in this research, you should contact Brian P. Peppers, DO, PhD by phone at 304-594- 1313 during normal business hours (Monday - Friday 9:00 A.M. to 4:00 P.M.). If injury occurs outside of business hours and is related to your participation in this research, please contact Brian P. Peppers, DO, PhD through WVU Medicine's main phone line: 304-598-4000, inform them of your participation in a medical research study and ask for Dr. Peppers to be paged or call (800) 982-6277.

For information regarding your rights as a participant in research or to talk about the research, contact the WVU Office of Human Research Protections (OHRP) at (304) 293-7073 or by email at IRB@mail.wvu.edu.

Future Contact

Future research may be conducted for which you are eligible. If you are interested in being contacted for future research, please indicate so by completing this section.

☐ Yes, I want to be contacted if future research studies, for which I may be qualified, become available.

☐ No, I **do not** want to be contacted if future research studies, for which I may be qualified.

Signatures and Authorization

You have been given the opportunity to ask questions about the research and your authorization of HIPAA, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy.

Participant Signature

I willingly consent to my participation in this research and authorization of HIPAA.

Signature of Subject or Subject's Legal Representative

Printed Name | Date

Consenting Individual Signature

The participant or legal representative has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Person Obtaining Informed Consent

Printed Name | Date

Impartial Witness Signature (if applicable)

The participant or legal representative has had the opportunity to have questions addressed. As the impartial witness, I confirm that the participant willingly agrees to be in the study.

Signature of Impartial Witness

Printed Name | Date

Key Information for:
Antibody Enriched Plasma Donation for Future Treatment Opportunities

Principal Investigator: Brian Peppers, DO, PhD
Department: P.O. Box 9214, Department of Pediatrics, Morgantown, West Virginia, 26506 - 9214

Study Title: Antibody Enriched Plasma Donation for Future Treatment Opportunities

WVU IRB Protocol # | 2004965705

In the event you experience any side effects or injury related to this research, you should contact Brian Peppers, DO , PhD at (304) 594-1313. After hours contact WVU's main line at (304) 598-4000 and have Dr. Peppers Paged. For information regarding your rights as a research subject, and/or if you have any questions, concerns, or complaints about this research, you can contact the Office of Research Compliance at (304) 293-7073.

For more information about this research and about research-related risks or injury, you can contact Dr. Brian Peppers at (304) 594-1313.

In addition, if you would like to discuss problems, concerns, have suggestions related to research, or would like to offer input about the research, contact Office to Research Integrity and Compliance at 304-293-7073.

Note to Parent(s)/Legal Guardian(s):

Parent(s)/Legal Guardian(s) must sign the Patient Information and Informed Consent Form. This assent form should be read in parallel with the Patient and Parent Information and Informed Consent Form to obtain complete study information.

WHAT IS A RESEARCH STUDY?

A research study is something like a science project at school, but harder to do. When doctors and scientists want to learn more about a medicine, they have to test it on people to see if the medicine helps people and to make sure it does not hurt them.

WHY DO YOU WANT ME TO BE IN THIS STUDY?

The people who are running this study think your current illness with the coronavirus can be helped by giving you a medication. This medicine is new and it is not fully known if it will help you or not. The medicine has these things called antibodies in it. Antibodies act like suction cups and stick to things such as the coronavirus. When these suction cups stick to the things it tells your body to get rid of whatever it is stuck too, like the coronavirus. You do not have to be in the study if you do not want to be.

WHAT DO I HAVE TO DO?

If you choose to be in this study, the study doctor/nurse will:

- Take a small sample of your blood to see what type of the medicine is a good match for you
- You will then receive the medicine when it is ready through an IV in your arm. If an IV is not already placed in your arm this will be done, if possible at the same time a small sample of your blood is taken
- One (1) treatment will take approximately 2-6 hours. This is about the same time it takes to watch 1 to 3 movies
- Another small sample of your blood will be taken the day after you get the medicine
- If you have more than one treatment we will again collect a small blood sample before and after each transfusion

WHAT IF I DO NOT WANT TO BE IN THIS STUDY?

You do not have to be in this study. If you do not want to be in the study, the doctor will not force you to be in it. If you decide to be in the study, but change your mind, you can stop being in the study.

If you do not want to be in the study, or if you change your mind, just tell the doctor or nurse. You might need to have some more tests to make sure you are OK, but then you will not be in the study any more.

If the Study Doctor learns of any new important information about antibodies against COVID-19, she or he will tell you and your parents.

WILL I GET ANYTHING FOR BEING IN THE STUDY?

The medicine may or may not help you. Aside from maybe feeling better you will not get anything from being in the study.

COULD I BE HURT IF I AM IN THE STUDY?

The medicine could make you itchy, feel short of breath or have a headache. We will be watching you closely and will treat you for anything that may hurt you.

WILL ANYONE SEE MY MEDICAL INFORMATION FROM THIS STUDY?

People who are running this study will see your medical information; however, they will not keep any information that has your name on it. Your name will not be given out to anyone not working on this study.

Now I think I know about the study and what it means – Here is what I decided:

NO, I do not want to be in the study

OK, I will be in the study

Signature of Subject or Subject's Legal Representative

Printed Name | Date

Consenting Individual Signature

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Person Obtaining Informed Consent

Printed Name | Date