Consent Form to Take Part in a Clinical Research Study and Authorization to Disclose Health Information

Sponsor / Study Title:	**Emergent BioSolutions Canada Inc. / "A Phase 1, Open-Label, Randomized Study to Evaluate Safety and Pharmacokinetics of Anti-SARS-CoV-2 Immunoglobulin (Human) Investigational Product (COVID-HIG) Administered through Intramuscular, Subcutaneous or Intravenous Routes as a Single Dose Regimen to SARS-CoV-2 Uninfected Adults"**
Protocol Number:	**EBS-CVH-006**
Principal Investigator: (Study Doctor)	**«PiFullName»**
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Address:	**«PiLocations»**

What is a Clinical Research Study?
The purpose of a research study is to gather information about how safe a study drug is and how well it works. Participating in a research study is not the same as getting regular medical care. Being in this study does not replace your regular medical care.

You are being asked to take part in a research study. This consent form will tell you:
- Details about the study and what will happen to you as a research participant
- Possible benefits and risks to you if you choose to take part in the study
- Your rights as a research participant

Before you give your consent to take part in the study, please read this form carefully and ask as many questions as you need to be sure that you understand what taking part in this study means. If you agree to participate in this study, you must sign and date this Consent Form before you start anything having to do with this study. You will be given a signed and dated copy of this Consent Form to keep. It is your choice to take part in this study because it is voluntary. There will be no penalty or changes to your medical treatment if you choose not to take part in the study. No promises can be made about the outcome of this study.

Any time you have questions about the study you may contact the study doctor at the phone number listed above.

You may change your mind about participating at any time during the study. You may leave the study at any time, even if you have signed and dated this form. You do not have to give a reason.

1. WHAT YOU SHOULD KNOW ABOUT THIS STUDY

This is a research study of a study product called COVID-HIG. The use of this study drug is investigational, meaning the drug has not been approved by the US Food and Drug Administration (FDA). This study has been reviewed by the FDA and Advarra Institutional Review Board (IRB). An IRB is a group independent from Emergent BioSolutions which reviews the study and ensures your right, safety and well-being as a study participant are protected at the hospital/research site where you will be receiving the study treatment. Although Advarra IRB has reviewed the information provided in this informed consent form and has granted approval for the study doctor to conduct the study, this does not mean Advarra IRB has approved your participation in the study. This study is funded by Department of Defense, which will be called "DoD" throughout the rest of this document.

The purpose of the study is to evaluate the safety and how the study product is being adsorbed, distributed, metabolized, and excreted in the body, which is also known as pharmacokinetic testing (PK testing), when it is administered intramuscularly (IM) or through your muscle, subcutaneously (SC) or through your fat and intravenously (IV) or through your vein. This information will help determine what COVID-HIG administration route tested in this study could be used to potentially prevent and/or treat COVID-19, the disease caused by SARS-CoV-2 virus.

If you choose to participate, you will receive one dose of study product (COVID-HIG) through your muscle (IM), fat (SC) or vein (IV). Since this is a randomized study (study product assigned by chance), there is a potential that you might get either IM, SC or IV of the study product with the same volume.

Up to 36 people may be taking part in this study at two research sites in the United States. You will be expected to participate in the study for about 2 months after you have been assigned to separate groups that compare different study treatments (Randomization).

The main risks to you if you choose to participate are the side effects of the study product including infusion and injection reactions, and the risk of loss of private information. There is also a theoretical risk of severe COVID-19 in persons who have received COVID-HIG who are exposed to the SARS-CoV-2 virus.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve or monitor your health. The purpose of a research study is to gather information about how safe the study product is and how well it works. Being in this study does not replace your regular medical care.

IMPORTANT GUIDELINES IN PROTECTING YOURSELF FROM CONTRACTING COVID-19:

- Stay home as much as possible and avoid close contact with others
- Practice social distancing (about 6 feet or two arm lengths)
- Wear a mask that covers your nose and mouth in public settings
- Wash your hands often with soap and water for at least 20 seconds, or use an alcohol-based hand sanitizer that contains at least 60% alcohol
- Clean and disinfect frequently touched surfaces

A new public health declaration, called the Public Readiness and Emergency Preparedness Declaration (PREP), was issued by the Department of Health and Human Services on March 10, 2020. This declaration limits the legal rights of a subject participating in a COVID-19 clinical study that uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19. This includes the study drug COVID-HIG used in this study. Participants using COVID-HIG in this study will have limits on their right to sue the manufacturers, the study sponsor, healthcare providers and others for significant injuries and adverse reactions.

a. What is the study drug?

COVID-HIG is prepared from pools of human plasma which may contain chemical agents or infectious diseases. The risk of getting an infection from COVID-HIG has been reduced by screening plasma donors for previous exposure to certain viruses, by testing for the existence of certain viruses and by inactivating and removing certain viruses during the making of COVID-HIG. Despite these measures, there is still a potential risk of infection from this product.

There is a theoretical risk that people who have low levels of ineffective antibodies against SARS-CoV-2 could have severe COVID-19 if they are subsequently exposed to the virus. This risk has not been observed so far in people who have received COVID-19 immune globulin products or vaccines being studied to prevent COVID-19. If any new information becomes available about this risk, your study doctor will discuss that information with you and obtain your consent to continue to participate in the study. To reduce this risk, your study doctor will counsel you on how to prevent getting COVID-19. If you do develop COVID-19, your study doctor will provide you with instructions on how to seek medical care.

To monitor the safety of the study participants, a committee of experts will review the safety information from this study. If there are any concerns, they may temporarily pause the study to give them the opportunity to assess the information in more detail to decide whether it is safe to continue or not.

Talk to the study doctor about any side effects that concern you.

b. Why am I being asked to participate in this study?

You expressed interest in participating in this research study. To be able to take part in this study you must meet all inclusion criteria while not meeting any of the exclusion criteria during screening. Your study doctor will determine if you are eligible for the study as part of the screening visit (as outlined in this consent form).

c. Who can participate in this study?

To be in this study, you must meet the following requirements:

- Sign and date this Informed Consent Form
- Be female or male 18-59 years of age and in good health
- Have a body mass index (BMI) less than or equal to 35.0 kg/m2 (the study doctor will measure your height and weight to determine your BMI)
- Be healthy as determined by the study doctor based on your medical history (no chronic disease, no chronic therapy and no ongoing acute condition within 4 weeks prior to

dosing), normal physical exam, vital signs, urine test & blood test results at your first visit

- Have no evidence of current COVID-19 infection based on test results, and no symptoms related to COVID-19 infection.
- Have no intention to become pregnant at any time while participating in the study
- For women who are not able to have children, you must be:
    - Surgically sterile (at least six weeks post bilateral salpingectomy, bilateral oophorectomy, or hysterectomy) or
    - Post-menopausal (defined as a history of more than 12 months without a period in the absence of other causes).
- For women who can have children you must:
    - Have negative pregnancy tests before enrolling in the study and before getting your study dose
    - Use a highly effective form of birth control to prevent pregnancy during the study such as one of the following (The study doctor or study staff will ask you about your preferred birth control method and review it with you at every study visit or phone call (if applicable):
        - Hormonal contraceptives (for example, implants, pills, patches) that have been started at least 30 days before the start of the study
        - Intrauterine device (IUD) that has been inserted at least 30 days before the start of the study
- Understand and agree to comply with all planned study procedures
- Not participate in any other research study in which you receive an investigational product (meaning it is not FDA-approved) within 30 days prior to your first study visit or plan to participate in another clinical study during the study follow up period
- Not have used any SARS-CoV-2 monoclonal antibodies, or COVID-19 convalescent plasma within 90 days prior to your first study visit, or plan to during the study follow up period
- Not have received any COVID-19 vaccinations within 60 days prior to your first study visit, or plan to during the study follow up period
- IgG antibody levels against the SARS-CoV-2 virus will be measured and must be below a defined threshold to participate.
- Have no history of reaction to blood or plasma products or to COVID-HIGIV excipients (proline, PS80)
- Have no history of allergy to latex or rubber
- Have no history of hemolytic anemia
- Have no history of IgA deficiency
- Have not received any blood product within the past 12 months
- Have not donated plasma within 7 days prior to dosing with the product or have not had significant blood loss or given a blood donation (greater than 450 mL, or about 2 cups) within 56 days prior to dosing with the product
- Have no history of known inherited or developed immunodeficiency or receipt of immunosuppressive therapy (for example, prednisone or equivalent for more than two consecutive weeks within the past three months)
- Have no history of / blood clotting issues

- Have not received a live vaccine within 30 days prior to screening or expected receipt of a live vaccine during the study period
- Not currently pregnant, breastfeeding, or planning to become pregnant during the study.
- No history of or suspected current drug or alcohol abuse problem.
- Have no other medical condition which may place you at increased risk due to participation in this study as determined by the study doctor
- Have no planned elective surgery or procedure during the follow-up period that impacts study compliance.

Tell the study doctor if you don't meet one or more of these study requirements. Before you can be enrolled in the study, the study doctor will perform a physical examination, run some laboratory tests, and ask you questions about your health and medical history (refer to Section 7 of this Informed Consent Form for further details on the privacy of the information collected). Based on the results, the study doctor will decide if you qualify for participation in the study.

d. How long will I be in the study?

It is expected that you will be participating in this study for 2 months (approximately 8 weeks).

e. How many people will be in the study?

You will be one of up to 36 people taking part in this study at 2 research sites in the US.

f. Why is this study being done?

The purpose of this study is to evaluate the safety of COVID-HIG and determine the best way to administer the product. It will also be used to determine how the study product is being absorbed, distributed, metabolized, and excreted in the body which is also known as pharmacokinetic testing (PK Testing). This information will help determine the best way to administer COVID-HIG to potentially prevent and/or treat COVID-19, the disease caused by the SARS-CoV-2 virus.

2. WHAT ARE THE ALTERNATIVES TO BEING IN THE STUDY?

You may not have any direct benefits from participating in this study. As this is a healthy volunteer study, there are no alternative courses of treatment, however you can choose not to participate in the study (for example, to not receive the study treatment).

3. WHAT ARE MY RESPONSIBILITIES DURING THE STUDY?

You will be expected to attend all planned visits and accept all study-related phone calls as listed in the study treatment schedule described in Section 4 of this Informed Consent Form. You must additionally:

- Show up on time for all scheduled study visits. Alert the study doctor/study staff as soon as possible if you must reschedule a visit for any reason.
- Allow the study doctor/study staff to draw blood and take urine samples on the study days listed in this consent form.
- Tell the study doctor/study staff about all past and current medical conditions for which you have received medical care or treatment.
- Tell the study doctor/study staff about any medications you started taking at least 30 days before your first study visit. Follow the study doctor's instructions between visits

- Report to the study doctor or study staff as soon as possible if you are hospitalized, have an emergency room visit, or become pregnant
- Tell the study doctor/study staff if you do not feel well or notice unusual changes in your mind or body while in the study. Also, let the study doctor know if you think you have been exposed to SARS-CoV-2 at any time during the study.

4. WHAT WILL HAPPEN IF I JOIN THE STUDY?

The following details below summarizes what will take place if you are eligible and agree to be in the study.

If it is determined you are eligible, able and choose to participate in this study than the approximate length of time you will be involved will be approximately 12 weeks.

4.1 Screening (less than or equal to 14 days prior to Day 1)

If you agree to participate in this study, you will sign and date this Informed Consent Form before any study procedures are done. Once you have signed and dated this form a screening visit will occur. During this visit the study doctor and/or study staff will collect some information about you and do some tests to find out if you can be in the study.

They will:

- Assign you a participant code number that will identify you for the study purposes so that information collected about you is kept private (also see Section 7).
- Ask questions about you (age, gender, race/ethnicity) and your medical history, including medicines you take. You will need to tell study staff if you take any over-the-counter or prescription medicines and any vitamins or herbs.
- Two types of SARS-CoV-2 rapid tests will be performed to test if you are currently infectious with COVID-19. If you are determined to be infectious based on these tests, this will disqualify enrollment in the study. Review the conditions for being in the study with you.
- Perform a complete physical examination.
- The study doctor will discuss your method of birth control with you as women who are not using an acceptable form of birth control cannot be in the study.
    - If you are a woman who is not able to have children a test will be performed to confirm this.
- Collect blood sample to test if you are pregnant.
- Measure your height, weight, BMI and vital signs (temperature, blood pressure (seated), pulse, blood oxygen level and breathing rate.
- Draw blood (about 5 teaspoons will be collected) to check your general health (Hematology and Chemistry). You will also be tested for signs of illness or infection, including for HIV (human immunodeficiency virus), hepatitis B and hepatitis C. If you test positive for HIV, hepatitis B, hepatitis C or certain other illnesses or infections, you cannot be in the study. Depending on state law, you may have to sign and date a separate Informed Consent Form before this testing can start. The study doctor or study staff will tell you if the test results are positive. If required by state law, the study doctor or study staff may report a positive test result to the local health department.
- Collect urine samples for analysis (including urine drug test).

- Collect a nasopharyngeal swab sample test for COVID-19. The study doctor may be required by law to report the result of these tests to the local health authority.
- Collect a blood sample to test for SARS-CoV-2 antibodies.
- Provide counselling to you on precautions/measures to prevent contracting SARS-CoV-2 infection.
- Assess you for any COVID-19 symptoms or SARS-CoV-2 exposure.
- Assess any adverse events/side effects related to any study procedures.

If you meet the conditions to be in the study, your first study treatment will be given within 14 days after this screening visit. The study doctor/study staff will tell you when to come back for your second visit.

Re-Screening
If you are unable to meet the conditions to be in the study but the study doctor thinks that you would still be eligible, the study doctor in consultation with the sponsor's Medical Monitor may re-screen you. Re-screened participants will be assigned a new participant identification number if this occurs outside the initial screening period.

Pre-dosing (Day -1) – In-patient overnight assessment
- If needed, they will update medical history and ongoing medications.
- Assess if you had a suspected or confirmed exposure to SARS-CoV-2 or developed COVID-19 symptoms in the period of Screening visit to Day 1.
- A SARS-CoV-2 rapid test will be performed to test if you recently had COVID-19. If you are determined to have had COVID-19 recently based on this test, this will disqualify enrollment in the study.
- If you are a woman able to have children, you must have a negative urine pregnancy test for you to be in the study.
- The study doctor will discuss your method of birth control with you as women who are not using an acceptable form of birth control cannot be in the study.
- Review the conditions for being in the study with you.
- Alcohol breath test will be taken.
- Collect a blood sample to test for SARS-CoV-2 antibodies.
- Collect a nasopharyngeal swab sample test for COVID-19.
- Assess you for any COVID-19 symptoms or SARS-CoV-2 exposure.
- Assess any adverse events/side effects related to any study procedures.

4.2 Baseline (Visit 1, Day 1) Assessments – Randomization and Dosing
The study doctor will review with you the conditions for being in the study.

Additionally, the following procedures will be done:
- Collect a blood sample (about 1 teaspoon) before you receive the study drug (within 2 hours prior to dosing) to test for SARS-CoV-2 antibodies.
- Measure your vital signs (temperature, blood pressure (seated), pulse, blood oxygen level and breathing rate).

If you meet all requirements, you will be able to participate in the study. The study doctor will enroll up to a total of 36 participants for this study. You will be assigned to a study treatment arm on a random basis, meaning you could just as easily be assigned to one of three routes of administration. Details are described below:

- You will receive one study administration by one of the three routes of administration of COVID-HIG: Intramuscular (IM), Subcutaneous (SC) or Intravenous (IV)
- You will have an overnight in-clinic stay for 2 nights and 8 subsequent in clinic or telemedicine follow-up visits.

The following will be collected after the administration of the study drug:

- Assess any adverse events/side effects during injection and post-administration in the clinic overnight.
- Measure your vital signs (temperature, blood pressure (seated), pulse, blood oxygen level and breathing rate at 30 minutes and 1 hour after receiving the study drug.
- Collect a blood sample (about 1 teaspoon) after receiving the study drug at 1 hour, 2 hours, 4 hours, 8 hours and 12 hours to test for SARS-CoV-2 antibodies.
- Provide counseling to participants on precautions/measures to prevent contracting SARS-CoV-2 infection.
- Any medications given will be documented.

4.3 Day 2, 3, 4, 6, 8, 15, 29, and 43,

Visits are conducted as in-clinic or telemedicine/home healthcare follow-ups. If randomly selected to IV group (Arm 3), omit visits on Day 3 and Day 6. The study doctor will review with you the conditions for being in the study.

Additionally, the following procedures will be done:

- Adverse events: Review how you have been feeling after the study infusion. Any side effects will be recorded by the study doctor.
- Targeted physical exam only if the study doctor thinks it is necessary based on their assessment of your health.
- If you are a woman able to have children, the study doctor or study staff will ask you about your preferred birth control method and review it with you at every study visit or phone call (as applicable)
- Collect a blood sample (about 1 teaspoon) to test for SARS-CoV-2 antibodies.
- Provide counselling to you on precautions/measures to prevent contracting SARS-CoV-2 infection.
- Draw blood sample (about 5 teaspoons) to check your general health (Hematology and Chemistry). This is only required on Day 2 and Day 4. For days 3, 6, 8, 15, 29, 43, and 57 samples will be collected if the study doctor thinks it is necessary based on their assessment of your health.
- Collect urine sample to check your health. This is only required on Day 2 and Day 4. For days 3, 6, 8, 15, 29, 43, and 57 sample will be collected if the study doctor thinks it is necessary based on their assessment of your health.
- Measure your vital signs (temperature, blood pressure (seated), pulse, blood oxygen level and breathing rate only required on Day 2 and Day 4. For days 3, 6, 8, 15, 29, 43, and 57

sample will be collected if the study doctor thinks it is necessary based on their assessment of your health.
- Collect a nasopharyngeal swab sample for COVID-19 (for days 2, 3, 4 and 6 sample will be collected if the study doctor thinks it is necessary based on their assessment of your health).

If deemed necessary by the study doctor, you can be evaluated during an unscheduled visit to further follow up on your safety. The following assessments may be performed during this time:
- Adverse events: Review how you have been feeling after the study infusion. Any side effects will be recorded by the study doctor.
- Any medications you are taking will be documented.
- Targeted physical exam if the study doctor thinks it is necessary based on their assessment of your health.
- Collect a nasopharyngeal swab sample for COVID-19 if the study doctor thinks it is necessary based on their assessment of your health.
- Draw blood (about 5 teaspoon) and/or collect urine sample to check your health if the study doctor thinks it is necessary based on their assessment of your health.
- Measure your vital signs (temperature, blood pressure (seated), pulse, blood oxygen level and breathing rate) if the study doctor thinks it is necessary based on their assessment of your health.
- If you are a woman that if able to have children, the study doctor or study staff will ask you about your preferred birth control method and review it with you.
- If you are a woman able to have children, the study doctor may draw blood to check for pregnancy if they think it is necessary based on their assessment of your health.
- Provide counselling to you on precautions/measures to prevent contracting SARS-CoV-2 infection.

If you become positive for COVID-19 during the study period, you will be assessed based on your COVID-19 symptoms. This can be performed over the phone if needed. No further serum samples for SARS-CoV-2 antibodies will be collected from you (PK testing). Therefore, all remaining study visits (except the last study visit on Day 57) can be performed over the phone for the study doctor to monitor your safety. If you test positive for COVID-19 at Day 57, you will be followed up on until your symptoms resolve or up to 30 days after study completion if your symptoms are ongoing. You may be asked to attend an in-person safety assessment if the study doctor determines it to be necessary.

4.4 Day 57 (End of Study)

Visit will be conducted in-clinic or by home healthcare at your home and by telemedicine. The in-clinic or telemedicine study team will call and /or video chat with you to perform the following:
- Adverse events: Review how you have been feeling after the study infusion. Any side effects will be recorded by the study doctor.
- Any medications you are taking will be documented.

- Based on your study doctor's assessment of how you are feeling and medications you are taking an unscheduled in-clinic visit may be scheduled, or you could be referred to your primary healthcare provide if immediate medical attention was required.
- If you become positive for COVID-19 you will be assessed based on your COVID-19 symptoms. This can be performed over the phone if needed.
- You will be reminded of precautions/measures to prevent contracting SAR-CoV-2 infection.
- Complete a nasopharyngeal swab test for COVID-19.
- Draw blood (about 1 teaspoon) to test for SARS-CoV-2 antibodies.
- Targeted physical exam only if the study doctor thinks it is necessary based on their assessment of your health.
- If you are a woman able to have children, the study doctor or study staff will confirm the method of birth control you are currently using.
- Draw blood (about 2 teaspoons), to check your general health (Hematology and Chemistry), only, if the study doctor thinks it is medically necessary to draw blood.
- Collect a urine sample, only if the study doctor thinks it is medically necessary.
- Draw blood (about 2 and ½ teaspoons), to test for illness or infection (HIV (human immunodeficiency virus), hepatitis B and hepatitis C.
- Vital signs (temperature, blood pressure (seated), pulse, blood oxygen, level and breathing rate) will be performed if medically necessary.

4.5 Withdrawal Visit

Your participation in this study is completely voluntary. You may drop out of this study at any time without giving a reason. Your choice to drop out of this study will not in any way affect your medical treatment.

Please ask questions about any and every part of this study you do not understand before you sign and date this Consent Form. If you drop out of the study you cannot re-enter, but this will not affect you in any other way.

If you decide to leave this study after you receive the study product, or are asked to leave by your study doctor, you will be asked to have a final visit for your safety. This can be done either by coming back to the study doctor's office or through telemedicine and a home visit, if needed. These tests are to identify any unexpected side effects.

Additionally, if you decide to leave this study after randomization, whether you receive the study product or not, you will be asked to choose one of the following options:

1. I am withdrawing <u>PARTIAL</u> participation in any study-related procedures but agree to be contacted by phone every four weeks for follow-up related to COVID-19status up to Day 57 (Day 29, and Day 56).
2. I am withdrawing <u>FULL</u> consent and decline to be contacted for any safety follow-up for the purpose of this study.

Your study doctor will record your decision within your chart and your condition at the time you leave the study.

Early withdrawal visit procedures will be performed for participants who received study treatment and who withdrew from the study prior to Day 57. As much of the following information as possible will be collected from you at this visit for your safety:

- Adverse events: Review how you have been feeling after the study infusion. Any side effects will be recorded by the study doctor.
- Targeted physical exam only if the study doctor thinks it is necessary based on their assessment of your health.
- Collect a blood sample (about 1 teaspoon) to test for SARS-CoV-2 antibodies
- Draw blood (about 5 teaspoons) will be collected to check your general health (Hematology and Chemistry) if the study doctor thinks it is necessary based on their assessment of your health.
- Collect a urine sample to test for signs of illness, only if the study doctor thinks it is medically necessary.
- Draw blood (about 2 and ½ teaspoons), to test for illness or infection (HIV (human immunodeficiency virus), hepatitis B and hepatitis C.
- Vital signs (temperature, blood pressure (seated), pulse, blood oxygen, level and breathing rate) will be performed if the study doctor thinks this is necessary.
- If you are woman of childbearing potential, the study doctor will confirm use of contraceptives.
- Provide counseling on precautions/measures to prevent contracting SARS-CoV-2 infection.
- If you become positive for COVID-19, you will be assessed based on your COVID-19 symptoms. This can be performed over the phone if needed.
- Complete a nasopharyngeal swab test for COVID-19 if the study doctor thinks it is medically necessary.

Use of your Data and/or Specimens

The researchers would like to ask your permission to keep the data and specimens (like blood) collected from you during this study to use them in future research studies. Please tell us how we may use this material in future research studies.

Will you allow the researchers to store your information and/or specimens to use in future research studies?

Yes_____(initials) **OR** No_____ (please initial)

Identifiers might be removed from your identifiable private information or identifiable biospecimens collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

You should also know that it is possible that products may someday be developed with the help of your specimens and data, and there are no plans to share any profits from such products with you, regardless of whether your identifiable information is removed.

5. WHAT ARE THE POTENTIAL RISKS, SIDE EFFECTS, AND DISCOMFORTS?

The risk of being in this study are listed in sections 5.1 - 5.6 below. All drugs may cause side effects. There may be side effects of COVID-HIG that are not yet known.

5.1 Risks and Side Effects of COVID-HIG

All drugs may cause side effects. Tell the study staff right away if you have any problems or if you notice anything different about your emotional or physical health.

Known side effects of COVID-HIG and risks associated with study participation are:

Intravenous (IV, into the vein)

- Common side effects (greater than or equal to 1/100 and less than 1/10) of immunoglobulin intravenous products are infusion reactions including the following:
    - Abdominal (stomach) or back pain
    - Nausea and vomiting within 30 minutes of IV infusion
    - Fever
    - Headache
    - Chills
    - Fatigue (feeling tired)
    - Myalgia (muscle pain)

  These reactions may start at the end of IV infusion and last for several hours after the infusion.
- Rare side effects (greater than or equal to 1/10000 and less than 1/1000) of immunoglobulin products including those administered intravenously:
    - Hypersensitivity: undesirable reactions produced by the normal immune system, including allergies and autoimmunity (a group of symptoms that may include hay fever, pink eye, hives, skin itching, skin flushing, swelling of the skin, difficulty with breathing, abnormal heart rate/blood pressure).
    - Renal failure: impaired kidney function where the kidneys fail to filter wastes from the blood.
    - Aseptic Meningitis Syndrome (AMS): the layers lining the brain become inflamed (swollen).
    - Hemolysis: abnormal breakdown of red blood cells.
    - Thrombotic Events: blood clot/obstruction of blood flow.
    - Transfusion-Related Acute Lung Injury (TRALI): fluid accumulation in the lungs, normally caused by blood transfusions.

Intramuscular (into the muscle)

- Common side effects
    - Tenderness
    - Pain
    - Bruising
    - Soreness or stiffness of the muscles at the injection site that may persist for several hours after the injection.
    - Fever

  - Headache
  - Chills
  - Rash
  - Fatigue
  - Nausea
- Rare side effects
  - Hypersensitivity: undesirable reactions produced by the normal immune system, including allergies and autoimmunity (a group of symptoms that may include hay fever, pink eye, hives, skin itching, skin flushing, swelling of the skin, difficulty with breathing, abnormal heart rate/blood pressure).
  - Thrombotic Events: blood clot/obstruction of blood flow.
  - Risk of local tissue injury such as nerve damage

Subcutaneous (under the skin)

- Common side effects
  - Redness, itching, and swelling may occur at the injection site
  - Fever
  - Headache
  - Chills
  - Rash
  - Fatigue
  - Nausea
- Rare side effects
  - Hypersensitivity: undesirable reactions produced by the normal immune system, including allergies and autoimmunity (a group of symptoms that may include hay fever, pink eye, hives, skin itching, skin flushing, swelling of the skin, difficulty with breathing, abnormal heart rate/blood pressure).

During this study you will be observed for any bad or harmful effects. The study doctor will decide if it is safe for you to keep participating in the study.

Talk to the study doctor about any side effects that concern you. You can ask the study doctor for additional information about COVID-HIG that is available to healthcare professionals.

5.2 Possible risks to pregnancy and unborn baby (fetus or embryo), reproduction, or nursing infant

The risks to an unborn baby are not yet known for COVID-HIGIV; however, immunoglobulin products have been widely used during pregnancy for various medical conditions. If you become pregnant at any time during the study period, you must notify the study staff within 24 hours of becoming aware of the pregnancy. No additional doses of study product will be given to you, but you are still expected to return to the research site for follow-up and to continue with the study related test to ensure your safety.

If you become pregnant, the sponsor will follow your pregnancy until the outcome (and your baby up to 28 days post-birth. During this follow-up, only information regarding the pregnancy will be collected.

To prevent pregnancy, use of highly effective method of contraception throughout the study is required and may include any one of the following:

- Hormonal (combined estrogen and progesterone or progesterone only) contraceptives (for example, implants, pills, patches) that have been started at least 30 days before Study Day 1
- Intrauterine device (IUD) or hormone release intrauterine system (IUS) that has been inserted at least 30 days before Study Day 1

5.3 Risks from sample collections

Blood Sample

Some people have discomfort or pain when blood is collected. Some people feel faint or pass out during or shortly after blood is drawn. If you feel faint, lie down right away so you don't get hurt from a fall and tell the study staff or study doctor right away. There is a risk of infection, bleeding and/or bruising at the spot where blood was taken or a clot may form when blood is collected, but these are rare.

Nasopharyngeal Swab

A nasopharyngeal swab is a long, flexible swab that is used to absorb secretions from the area of the upper throat that lies behind the nose (nasopharynx). A person experienced in obtaining nasopharyngeal swabs will insert the swab into your nostril at a distance that is approximately equal to the distance from the nostrils to the outer opening of the ear. The swab may be left in place for several seconds and then slowly removed while it is rotated. You may gag or experience discomfort, eyes watering, sneezing, headache, earache, runny nose or bleeding from the nose. In most cases, these symptoms are mild and go away on their own. Rarely, people may experience leakage of cerebrospinal fluid (fluid that surrounds the brain) from the nose after a nasopharyngeal swab test. Your study doctor will speak to you to make sure you do not have any conditions that place you at increased risk for this complication.

5.4 Risks of physical injury resulting from participation

All forms of medical or mental health diagnosis and treatment, whether routine or experimental, involve some risk of injury. There may also be risks in this study that we do not know about. Even with all the care that is taken, you may still develop medical complications from participating in this study. If during the course of the study you get hurt or sick or experience any side effect to the study drug or study procedure, please contact the study doctor. If such complications arise, the study doctor will help you get the proper medical treatment.

In the event of an injury that occurs to you as a result of receiving COVID-HIG or undergoing study procedures, you will receive the necessary medical treatment. In the event that you suffer injury as a direct result of participating in this study, Emergent BioSolutions will cover the costs of reasonably necessary medical treatment not covered by your medical or hospital insurance or by third-party or governmental programs providing such coverage. Emergent BioSolutions or the study doctor will not cover costs for medical care for injuries or illnesses that are not a direct result of research activities. No other compensation is routinely available from Emergent BioSolutions or the study doctor.

You are not prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital/research site. By signing and dating this Consent Form, you do not give up your legal right to look for and receive required medical treatment. You also do not give up any rights to seek payment for personal injury by signing and dating this form.

5.5 Risks to confidentiality

Efforts will be made to keep the records as confidential as possible within the limits of the law. However, confidentiality cannot be assured as there is always some risk that an unauthorized person may view your records. In order to maintain confidentiality, your study records will be stored in a secure location such as a locked office and locked cabinet. Electronic data will be password-protected. Study records and samples taken from you will be coded with a number, not your name. Records will only be shared with authorized personnel and only in connection with carrying out the obligations relating to the study.

5.6 Risks related to COVID-19 pandemic

The Sponsor will monitor the situation related to other factors, for example, COVID-19 pandemic to ensure that potential risks to study participants and study staff are mitigated. The following strategies will be implemented:

- The conduct of the study will be in accordance with state and local travel limitations/restrictions.
- Study staff at the hospital/research site will take appropriate precautions to protect study participants.
- Safety assessments will be performed by telephone or home healthcare when appropriate.
- If travel restrictions or other factors, for example, COVID-19 pandemic related illnesses impact the conduct of the study, specific measures will be taken to mitigate risk to study staff and participants.

6. WHAT ARE THE POSSIBLE BENEFITS TO BEING IN THE STUDY?

Participation in this study may not provide you with any direct medical benefit. However, the information collected about you by taking part in this study may provide important information in treating future individuals at risk of SARS-CoV-2 infection with COVID-HIGIV.

7. PRIVACY AND CONFIDENTIALITY

7.1 What are my Privacy and Confidentiality rights?

Privacy rights of participants taking part in clinical research studies are being protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Your rights as a participant under this act include deciding who has access to your personal health information (called “Protected Health Information”).

Protected Health Information is medical information about you that includes your entire historical medical records, all study doctor visits, evaluations, biospecimens (for example, blood samples), laboratory tests, diagnostic tests, procedures, treatments, medications taken, hospitalizations, etc. The study doctor may also get information about your past, present and/or future physical or mental health and/or condition from your primary care doctor. Protected

Health Information contains identifiers that can link your medical records specifically to you, such as:

- Your name and initials
- Your address
- Date of birth
- Social security/insurance number
- Dates and results of various tests and procedures
- Basic demographic information (such as age, gender, ethnicity/race)

Your written authorization is required before any information about you can be collected, shared, or stored.

7.2 What information will be collected for the study and why?

The study doctor and study staff will collect your medical history, blood samples, results from laboratory analyses and procedures, and results from physical examinations. Your study medical record will also contain personal information such as your name, address, telephone number, date of birth, social security/insurance number, or unique identifiers.

Information collected about you during this study will be used to determine the best way to administer this product and ensure your safety throughout your participation in the study.

The study information may also be published in a scientific or medical article. You will not be personally identified in these instances. In addition, the sponsor may re-analyze the results at a later date and combine them with results of other studies.

a. How will my information be shared, protected, and stored?

Any information learned about you in this study will be treated as confidential.

The study doctor, study sponsor (Emergent BioSolutions), the DoD, third parties working on behalf of the study sponsor (CRO), Advarra IRB and the proper national and international regulatory authorities such as US FDA may be able to see your health and research records and test results. They may copy information from your health record for the purpose of this research study and to confirm your safety. Your records will be protected and kept as private as possible under local/national/international regulations. Total privacy cannot be guaranteed.

Copies of your medical records that are related to the research may be collected by the study sponsor (Emergent BioSolutions) with your name or initials, address, telephone number, date of birth, social security/insurance number, or unique identifiers removed in order to review for your safety and to ensure the study data is recorded correctly. These copies may be transferred via encrypted email, secure fax line, or uploaded to a secure, password-protected website. These copies will be permanently destroyed at the end of the study unless required by law for safety reporting.

A description of this clinical study 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.

The study information sent to the sponsor and their representative(s) by your study doctor and/or institution (hospital/research site) will not include your name or initials, address, telephone number, date of birth, social security/insurance number, or unique identifiers. As a safety measure to help keep confidentiality, a participant code number will be used as an identifier.

The study doctor will keep this personal health information in your study-related medical records (that we will refer to as "your records") during the study and for up to 25 years after the study is completed.

Clinically Relevant Results
Research results that are clinically relevant, including individual research results, will not be disclosed to you.

b. Authorization to Use and Disclose Protected Health Information

By signing and dating this authorization, you are allowing the study doctor and/or research site) to have direct access to your Protected Health Information collected in this study, and to receive your Protected Health Information from either your physician or facilities where you have received health care.

Your signature and date on this authorization authorizes:

- The study staff, study doctors, and/or research site to have access to your Protected Health Information collected as part of this study
- The study doctor and/or research site to receive your Protected Health Information from your physician and/or facilities where you have received any health care
- Your Protected Health Information to be shared with other persons or organizations involved in the conduct or oversight of this research study, including but not limited to: U.S. Food and Drug Administration (FDA); Centers for Disease Control (CDC); the DoD, Advarra IRB; regulatory agencies in other countries; third parties working on behalf of the sponsor; and the laboratory(ies) handling the lab specimens for this study. The other persons and/or organizations need to see your personal health information so they can review the data and to make sure of the quality of the study conduct and/or the data collected. These other persons and/or organizations may or may not have the same obligations as the study doctor or research site to protect your Protected Health Information.

Your Protected Health Information will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study. Your Protected Health Information will be used for as long as the sponsor reports study information to the FDA or other countries' regulatory agencies. In California and any other state that requires an expiration date, the authorization will expire 50 years after you sign and date this authorization document.

You may cancel this authorization and request to withdraw your authorization in writing at any time by contacting the study doctor listed on the first page of this Consent Form. If you cancel the authorization, continued use is permitted for the Protected Health Information obtained

before the cancellation, if its use is necessary in completing the research, including samples collected for future research. However, if any Protected Health Information is collected after your cancellation it may not be used in the study.

If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study.

Finally, federal regulations allow you to obtain access to your Protected Health Information collected or used in this study. However, in order to complete the research study, your access to this Protected Health Information may be temporarily suspended while the research study is in progress. When the study is completed, your right of access to this information will be reinstated. This authorization will expire once there is no longer a need to review and analyze the information related to this study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

Signature of Participant	Date (dd.mmm. yyyy)	: Time (24hr clock)

Printed Name of Participant

8. WILL I RECEIVE ANY MONEY OR OTHER COMPENSATION FOR TAKING PART IN THIS RESEARCH STUDY?

«Compensation»

You will be paid up to a total of $xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***["following each completed visit", "monthly", "quarterly", "at the end of your participation in the research study", "following each completed visit or at the end of your participation in the research study, whichever you prefer"]***.

If you have any questions regarding your compensation for participation, please contact the study staff.

We will reimburse you for the cost of ***[describe: e.g., traveling to your study visits]***. You will be reimbursed approximately ***[e.g., 2 weeks, 1 month, etc.]*** after you submit your travel receipts to the study staff.

There will be no expenses charged to you for taking part in the study. All tests, examinations, study drugs and medical care required as part of this study will be provided at no cost to you.

9. WHAT IF I WANT TO STOP THE STUDY EARLY?

Your participation in this study is completely voluntary. You may drop out of this study at any time without giving a reason. Your choice to drop out of this study will not in any way affect any necessary medical treatment.

Please ask questions about any and every part of this study you do not understand before you sign and date this Consent Form. If you drop out of the study you cannot re-enter, but this will not affect you in any other way.

If you decide to leave this study after taking the study drug, or are asked to leave by your study doctor, you will be asked to come back to the hospital/research site for tests for your safety. These tests are to identify any unexpected side effects. Your study doctor will make sure your medicines are working if you were on previous medicines. The study doctor will record your condition at the time you leave the study.

10. WHAT IF THERE ARE NEW FINDINGS?

You will be told in a timely manner by your study doctor of any new important information about this study, COVID-HIG, and other information that may affect your health, welfare, or willingness to stay in the study. You may be asked to sign and date a new (revised) Consent Form to show that you have been told of this new information. You may contact the study doctor at any time after your participation ends to find out if any new information about this study has become available.

11. YOU MAY BE TAKEN OUT OF THE STUDY BY THE STUDY DOCTOR OR THE SPONSOR AT ANY TIME WITHOUT YOUR CONSENT

The study doctor, the study sponsor (Emergent BioSolutions), or US FDA may decide to take you out of the study if:

- It is in your best interest
- The IRB/IEC/REB suspends/terminates study approval
- You are unable to meet or follow the study requirements
- The study is cancelled
- The study shows signs of causing medical harm to you

The study sponsor (Emergent BioSolutions) may decide to end the study at any time.

12. WHOM TO CONTACT ABOUT THIS STUDY?

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.
You may also contact the study coordinator with questions:
Study Coordinator: _____Telephone: _____

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser:
Pro00057674.

Study Number and Title: EBS-CVH-006 / A Phase 1, Open-Label, Randomized Study to Evaluate Safety and Pharmacokinetics of Anti-SARS-CoV-2 Immunoglobulin (Human) Investigational Product (COVID-HIG) Administered through Intramuscular, Subcutaneous or Intravenous Routes as a Single Dose Regimen to SARS-CoV-2 Uninfected Adults

This Consent Form contains important facts that will enable you to decide if you want to participate in this study. If you have any questions that are not answered in this form, please ask the study staff.

With your consent your primary physician will be told of your participation in the study.
I consent to having my family doctor or primary health care provider notified by the research team of my participation in this study and/or any significant findings related to my health (please check yes or no).

☐ Yes (please complete the information below) ☐ No

Name and address of family doctor or primary health care provider:

Name: _____

Address: _____

Telephone: _____

STATEMENT OF INFORMED CONSENT

NOTE: This informed consent with the "original" signatures and dates must be retained in the participant's file by the clinical study doctor. A signed and dated copy must be given to the participant/participant's legally authorized representative for their records.

Research Site Code:_____
Participant Identification Number: _____
Study Number: _____
Name of study doctor: _____

You (the participant) must complete the following:

Please Initial Boxes

1. I confirm that I have read and understand this consent form for the above study. _____(initials)
2. I confirm that the study has been explained to my satisfaction and I have had the time and opportunity to ask any questions. I know whom to contact if I think of more questions later. _____(initials)
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving reason, without my medical care or legal rights being affected. _____(initials)
4. I understand that sections of my medical notes may be looked at by responsible individuals appointed by Emergent BioSolutions, Advarra IRB and regulatory authorities where it is relevant to my taking part in the study. I give permission for these individuals to have direct access to my records. _____(initials)
5. By taking part in this study I agree to the transfer of my personal data within Emergent BioSolutions and to regulatory authorities, such as the US Food and Drug Administration (FDA), both within and outside North America. _____(initials)
6. I have been given the information about the use and disclosure of my protected health information from this research. _____(initials)
7. By signing and dating this consent and authorization form, I have not given up any of my legal rights. _____(initials)
8. I authorize the use and disclosures of my health information for the purposes described above to the parties listed in this consent form for this study. _____(initials)
9. I understand and agree to my primary physician being notified of my participation in the study (if appropriate). _____(initials)
10. All of my questions have been answered. _____(initials)
11. I agree to take part in the above study. _____(initials)

A copy of the signed and dated Consent Form will be given to you to keep.

Signature of Participant

Signature of Participant	Date (dd.mmm. yyyy)	: Time (24hr clock)

Printed Name of Participant

Signature of Person Explaining Consent

I have carefully explained to the person taking part in the study what they can expect from their participation, and I have made every effort to answer all questions to their satisfaction. I hereby certify that when this person signs this form, to the best of my knowledge, they understand:

- What the study is about
- What procedures/interventions/investigational drugs or devices will be used
- What the potential benefits might be
- What the known risks might be

I can confirm that this research participant speaks the language that was used to explain this research and is receiving an informed consent form in the appropriate language.

I have watched this person sign the Consent Form.

Signature of Person Explaining Consent	Date (dd.mmm.yyyy)	: Time (24hr clock)

Printed Name of Person Explaining Consent

Document Approvals

Approved Date: 22 Mar 2022

Approval Task Verdict: Approve	20:04:54 GMT+0000
Approval Task Verdict: Approve	12:58:04 GMT+0000
Approval Task Verdict: Approve	13:52:15 GMT+0000