TITLE: MULTI-CENTER, RANDOMIZED, PLACEBO CONTROLLED, INTERVENTIONAL PHASE 2A CLINICAL TRIAL EVALUATING THE SAFETY AND POTENTIAL EFFICACY OF MULTIPLE DOSING OF MESENCHYMAL STROMAL CELLS IN PATIENTS WITH SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-Cov-2)

NOTE: In cases where the patient is too ill to consent to treatment the legally authorized representative may provide consent. Throughout this document, the term "you/your" also refers to the patient for whom the treatment is being considered. If the patient recovers sufficiently to provide consent at a later time, the patient will be asked whether he/she consents to continue on the study.

PRINCIPAL INVESTIGATOR:

David Ingbar, MD Mayo Mail Code 276 420 Delaware Street SE Minneapolis, MN 55455 USA 612-624-0999 (office phone) ingba001@umn.edu (email) Page Operator: 612-273-3211	**Emergency Contact Number (for after hours patient medical issues):** 651--232-2000 (24-Hour) M Health Fairview Bethesda Hospital 559 Capitol Blvd. Saint Paul, MN, 55103

If your doctor is also the person responsible for this research study, please note that he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another professional who is familiar with the study but not part of the research team before deciding whether to participate in the research.

SOURCE OF SUPPORT: This research is supported by institutional funding sources until the time other grant funding is secure.

FINANCIAL INTEREST DISCLOSURE: In some cases, the investigators may have financial disclosures that may affect your willingness to participate in this research study. However, none of the investigators on this study have any relevant financial disclosures.

KEY INFORMATION ABOUT THIS RESEARCH STUDY
The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?
Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you have the virus that causes COVID-19 which has injured your lungs resulting in a condition called "Acute Respiratory Distress Syndrome" or "ARDS". ARDS is a serious complication that limits the lungs' ability to get oxygen to the blood, resulting in the need for a machine called a ventilator to help the lungs get the oxygen into the blood stream. Some patients may need to on the breathing machine for weeks or longer and may recover. Some patients will not respond to the ventilator alone and may require the use of a heart-lung machine, referred to as ECMO. Despite our best efforts, about 40% of all patients with ARDS will die. However, previously healthy younger patients will likely do better than older patients, particularly if they have other pre-existing health issues. Patients with COVID-19 ARDS are at high risk of poor heart and kidney function and need medicines to control very low blood pressure or need dialysis for kidney failure. With this severe an illness complications often occur, including: pneumonia; bloodstream infection or sepsis, often with low blood pressure; kidney failure requiring dialysis; lung collapse (pneumothorax); neuromuscular weakness; failure of multiple organs (liver, etc.); and heart dysfunction or arrhythmias.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
The COVID-19 virus causes inflammation in your lungs. The experimental treatment in this study is the infusion of three doses of mesenchymal stromal cells (MSC). As MSC can control inflammation in some other types of diseases. The purpose of this study is to see if 3 doses of MSC can be given safely and reduce the inflammation that injures the lungs.

MSC come from the bone marrow obtained from a healthy adult person. The bone marrow is processed for several weeks after which time the MSC are collected and frozen until they are needed. The use of bone marrow-derived MSCs is not approved by the Food and Drug Administration (FDA) as a treatment for ARDS. However, the FDA does permit it to be used in experimental research studies like this, under strict regulations.

How long will the research last?
The treatment is given over one week but you will be followed for a year to see how the lungs recover. Close follow up for a year or more is typical for patients with ARDS. .

What will I need to do to participate?
The study will be explained to you by your care team as well as the research nurse. It is important for you to know that you will either get three doses of MSC through your IV or three doses of fluid alone without the MSC in it. You and your doctors will not know which treatment you received until the end of the study. Like the flip of a coin, the computer will decide who gets which treatment. Out of every three people, 2 will get the MSC and one will get the IV fluid only. Before you get any treatment, you will need to have a few tests - blood tests, chest xray or CT, tests to

evaluate your heart - to see if you fit the requirements to be on this study. Additionally you will be asked to give extra blood for research tests.

Any treatments that are discovered to be beneficial and are available for general use, will be permitted.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?
Patients with ARDS can be very ill and their condition unstable. It is possible that the treatment with MSC could make things worse. In prior studies in ARDS before COVID-19, MSC seemed to be well tolerated when given in one large dose. The most likely risks to receiving MSCs include a rise or fall in blood pressure, a fall in the oxygen level or an increase in the carbon dioxide level in your blood. The infusion of MSC might cause a transfusion reaction or an allergic reaction.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section***

Will being in this study help me in any way?
We cannot promise any benefits to you or others from your taking part in this research. Because early results in patients with COVID-19 ARDS appeared promising and because of the ability of MSC to control inflammation, it is hoped that giving MSC in three doses will help you. More detailed information about the benefits of this study can be found under "***Will being in this study help me in any way? (Detailed Benefits)"***

What happens if I do not want to be in this research?
You do not have to participate in this research. Instead of being in this research study, your choices may include:

- Getting standard treatment for your condition without being in a study
- Getting a different experimental treatment and taking part in another study
- Choosing no treatment at all and receiving comfort care/hospice

Please talk to your doctor and care team about your choices before deciding if you will take part in this study.

QUESTIONS ABOUT THE STUDY:

You can contact the study investigator if you have any questions about the study, concerns or complaints. The study contact numbers are at the top of this page.

Who is being asked to take part in this research study?

Approximately, 40 patients with COVID-19 ARDS will be asked to take part in this study at several major university medical centers with about 15-20 patients being enrolled at each site including MHealth-Fairview Hospitals. As some patients might not meet all the criteria for getting the treatment, it is expected that 30 patients will get the treatment.

RESEARCH ACTIVITIES:

What will happen if I say yes, I want to be in this research?

Before you begin the main part of the study:

You will need to have the following "screening" tests to determine if you can be on the study. Many tests will have already been done as part of your medical care and will not be repeated if recently done. Any tests not already done, will need to be done with 48 hours of the patient going onto the breathing machine.

- Medical chart review to evaluate your medical history and recent testing that might have been done.
- Echocardiogram (ECHO) and EKG to evaluate your heart function and the rhythm of your heart beat. An ECHO uses sound waves to create a moving picture of your heart. It can find problems with heart function. It will be done at your beside. A technician will glide a special device called a transducer across your chest to take pictures of your heart. A small amount of clear gel will be applied to your chest to help the transducer work better
- Chest CT or chest X-ray to verify that you have pneumonia.
- Blood testing**:** Blood will be obtained to evaluate your blood counts, blood chemicals that assess kidney and liver function, blood clotting function, and how well your body is making antibodies generally.
- Pregnancy testing**:** Blood will also be obtained for pregnancy testing. If blood is not available, a urine sample will be obtained before any treatment. If you are pregnant, you will not be eligible to be in the research study.

During the main part of the study:

If the screening exams and tests show that you can be treated, a computer will decide whether you get MSC or fluid alone without MSC.

You will have a 2-in-3 (67%) chance of being assigned to receive MSC; and 1-in-3 (33%) chance of being assigned to receive fluid without MSC. Which experimental study product you receive will be determined by chance and neither you nor your doctor will be able to decide which treatment you will get. If there is a medical emergency, the study doctor will be able to find out what study product you are receiving.

- Treatments: In addition to receiving the standard treatments of ARDS and COVID-19, you will receive three doses, about 2 days apart, of either MSC or fluid without cells. The study infusion will be given through an IV catheter (a thin plastic tube that is placed into a vein) you already have for your care. Prior to the treatment, you will receive Tylenol and Benadryl to reduce the chance of a reaction [Please tell your doctors if you have any known allergies or reactions to medicines]. The infusion will be given over approximately 30 minutes. The study team will monitor you closely for any side effects potentially related to the infusion and provide any treatments to help those side effects.

- Blood Tests for Research: We will draw extra blood at the time of other routine blood work as part of standard care. About 30 minutes before and sometime between 1 and 4 hours after treatment, a blood gas will be obtained from an artery in the wrist or groin. For all other research tests, no more than 2 tablespoons of blood from a vein will be obtained daily for the

1 week after you get the treatment, then at 2, 3 and 4 weeks, and 2, 3, 6 and 12 months afterward.

- Data collection from your medical record: If you agree to be on the study, this also authorizes the study team to access your medical records to collect information on your condition and results of any tests and procedures performed for your clinical care, such as your blood pressure, heart rate, temperature, your medications, and whether there is any evidence of infection. We will also record measurements from your breathing machine as well as other treatments used to support your blood pressure or improve the oxygen levels in your blood stream.

- Central storage and future use of blood specimens: Blood samples obtained from a vein will be collected and stored for future evaluations to determine how levels of inflammation and immune response changed over time after receiving the treatment. All samples will be processed and frozen at the institution the patient is at but ultimately transported to a central laboratory at the University of Minnesota. All samples will be marked by a study number to protect your identity and maintain your privacy to the best of our ability. Only the study team will be able to link the study number with your identity, which will be kept here in a locked file. The stored samples will not contain your name or identifying information. Some of these samples may be released to other investigators, but they will have no way to identify you. In some instances, samples may have potential commercial value although not anticipated at this time. However, should this occur, you would not receive any payment or financial benefit from any products, tests or discoveries. If consent is subsequently withdrawn, unprocessed samples will be destroyed upon your request and additional testing will not be performed. At any time you may contact the principal investigator at 612-624-0999 for Dr. Ingbar.

  By signing this consent form, you authorize the Coordinating Center at the University of Minnesota and members of its professional staff and other investigators to use your biological samples for these purposes.

Clinical Care Procedures Performed To Check Your Health:

The following are standard of care procedures that would normally be performed whether or not you were enrolled on a research study. These procedures are performed to monitor your health and would occur during the year you are in this study.

- Blood Tests to check your health: Blood will be drawn through a catheter you already have in your vein. Blood tests will include blood counts, chemistries, and measures of inflammation and clotting function that are often abnormal in patients with COVID-19.

- EKG and Echocardiogram: We will perform follow-up EKG and Echocardiogram at Day 28. If the EKG or Echocardiogram is abnormal at day 28, additional tests will be done until normal at 2, 3 and 12 months after the initial infusion.

- Pulmonary Follow-up: The pulmonary team will check your lung health at the following time points: Day 28, month 2, month 3, month 6 and 1 year, and at additional time points, depending on the procedure. These checks will include the following tests:

    - Lung Function testor PFTs. PFTs measure how well your lungs can move air in and how fast you can breathe out. You will wear a nose clip and be asked to blow as hard and as fast as you can into a tube three or more separate times. We will

perform PFTs when you are off the breathing machine and strong enough to do the test. When appropriate, you would be tested at 3, 6 and 12 months.

- Chest CT or Chest X-ray: A chest CT (computed tomography) scan is an imaging method that uses x-rays to create cross-sectional pictures of the chest and upper abdomen. We will perform follow-up chest CT at 6 and 12 months
- Questionnaire: You will be asked questions about your breathing and energy level, and how that affects your daily activities.
- Six Minute Walk Test: You will be asked to walk back and forth at a comfortably quick pace in order to go as far as you can in 6 minutes. Your heart rate will be monitored during the test.

STUDY RISKS:

What side effects or risks can I expect from being in this research study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. Previously it was shown that giving a large single infusion dose of cells was safe in patients with ARDS (not due to COVID-19). However, given your severe underlying illness, it is not known whether giving you three doses of MSC may be riskier than giving a larger single dose of cells.

Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. In some cases, side effects can be serious, long lasting, or may never go away. There is also a risk that very serious side effects may lead to death.

Risks of MSCs:

Many patients have received MSC for the treatment of various diseases with few side effects. However, in very ill patients who are on a ventilator because of COVID-19 ARDS, there may be a higher frequency of known risks and there may be unknown risks. Potentially serious risks include**:**

- During the infusions, you may have symptoms like a rise in heart rate or a fall in blood pressure. This may or may not require treatment depending on its severity.
- During the infusions, you may have a fall in the oxygen level or an increase in the carbon dioxide level in your blood. This change is expected to be mild and the level to is expected to return to normal with additional oxygen therapy and adjustments to the ventilator.
- Possible reactions to the infusions may include temporary fever or chills.
- You may have an allergic reaction. An allergic reaction could result in hives, rash, difficulty breathing, low blood pressure, or severe blood circulation and breathing problems. None of the animals or human subjects in the mesenchymal stem cell studies for other diseases has demonstrated an immune response to the mesenchymal stem cell product, but such a response could occur.

- The cell product is prepared under sterile conditions; rarely, however, these products can become contaminated with bacteria and you can have a serious bacterial infection from the cell product.

We will do the following to decrease the risks of the infusion:

- Medications will be available to treat low blood pressure if they are needed. Your blood pressure and heart rate will be continuously monitored during the procedure.
- If you have a fall in the oxygen level in your blood and the oxygen level remains low, the doctor may temporarily stop the study infusion to allow for recovery. Your oxygen level will be continuously monitored during the procedure.
- Members of your care team will be at your bedside during the infusion to monitor you closely. The study infusion will be stopped at least temporarily if there are any concerns related to the infusion, such as low blood pressure or an allergic reaction related to the infusion. The care team will treat any possible side effects.

Risks of blood gas from an artery: Once before and once after treatment, a blood gas will be obtained. While blood gases are often obtained in patients who are on a ventilator, these two blood gases will be obtained to make sure the treatment was tolerated. Many patients will already have a catheter in the artery for management of the ventilator but if not, blood can be obtained from a needle temporarily paced in the artery in your wrist or groin. Common side effects include pain and discomfort when the needle is put through the skin into the artery. Afterward pressure will be put over the site for a several minutes after the blood gas is obtained; however, it may continue to bleed and cause significant bruising. The site will be closely monitored. In some cases, infection may occur although rare. Also, there may be reduced blood flow to the hand or leg where the blood gas was obtained resulting in pain and even more rarely, damage to skin and muscles which is also rare. Very rarely, an abnormal communication between the artery and nearby vein or tear in the artery may occur that may require surgery.

Risk of Breach of Confidentiality (right of privacy): In very rare cases people not associated with this research study may mistakenly see your identifiable research results. We will do everything in our power to prevent this from happening by keeping research records in locked files, and identify all specimens and medical information by a research record number, rather than your name or social security number. The information linking the number with your identity will be kept in a secure separate location by the study coordinator.

Reproductive Risks: If you are pregnant or nursing a child while receiving the study treatment, there may be risks to your unborn baby or nursing child. Nobody knows what these risks are right now. If you are a woman who can have children, you will have a pregnancy test done before your study drug assignment. The result of the pregnancy test must be negative in order for you to be in this research study.

Unknown risks: The experimental treatments may have side effects that no one knows about yet and this is the reason for a follow up medical visits at 2 months, 3 months and 1 year after study treatment. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

Will being in this study help me in any way? (Detailed Benefits):

Taking part in this study may or may not make your health better. While doctors hope MSCs will be more safe and effective, there is no proof of this.

NEW INFORMATION:
You will be promptly notified if any new information we learn during this research study may cause you to change your mind about continuing to participate in the study.

Will my medical information be kept private?

HIPAA:

We are committed to respecting your privacy and keeping your personal information confidential. When choosing to take part in this study, you are giving us permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule or what you may know as "HIPAA") to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the separate HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

Will my medical information be kept private?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance (such as the Quality Assurance Program of the Human Research Protection Program (HRPP))

Your identifiable information will be made available to members of the research team for an indefinite period of time. That medical information, as well as information obtained during this research study, may be shared with the following groups for the purpose of monitoring the study:

- Government agencies, e.g., the Food and Drug Administration (FDA), involved in keeping research safe for people.

- Members of the Data Safety Monitoring Board who will review all the data and determine whether there are any safety issues impacting study continuation.
- Authorized representatives of The University of Minnesota and its affiliates.
- The study doctors and study staff may share your information with representatives of the University of Minnesota and M Health. These people may use your information to provide oversight and administrative support for the research, conduct evaluations and reviews, and perform other activities related to the conduct of the research.

We will protect your privacy by removing your name and other personal information from your research records. Only the study team will know who you are and be able to tell which information and stored blood samples are yours.

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Some laboratory testing may be added to your medical record because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

We will do our best to keep your personal information private but confidentiality cannot be guaranteed. You will not be identified by name or other identifiable information in any publication or presentation at a scientific meeting unless you sign a separate form giving your permission.

Internet Transmission: We will do everything possible to protect your privacy and confidentiality but information transmitted over the internet is insecure and no method of electronic storage is perfectly secure therefore absolute confidentiality cannot be guaranteed

FDA Clinical Trial Registry [21 CFR 50.25]
A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WITHDRAWAL FROM STUDY PARTICIPATION:
You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely. If you leave the study, no more information about you will be collected in the study. However, all the information collected before you left the study will still be used for the study.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at the University of Minnesota, or affiliated health care provider or your current or future relationship with a health care insurance provider.

The study doctor may stop you from taking part in this study at any time if he/she believes it is your best interest, if you do not follow the study rules, or if the study is stopped.

If consent is subsequently withdrawn, unprocessed samples will be destroyed upon your request and additional testing will not be performed. However, any research use of your medical record information and testing prior to the date that you formally withdraw your permission will not be destroyed.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

What are the costs of taking part in this study?

The treatment with MSCs or fluid without MSC will be provided to you at no cost to you or your insurance company. Some of the services you will receive are being done only because you are participating in this research study. Examples of theses "research only" services include research blood testing. Those services will be paid by the study and will not be billed to you or your health insurance company.

In addition, some of the services you will receive during this research study are considered to be "routine clinical services" that you would have received even if you were not participating in the research study. Examples are routine lab tests, chest x-rays/CT scans, PFTs, and any procedures performed for your routine medical care. These services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

What happens if I am injured because I took part in this study?
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Due to the coronavirus public health crisis, the federal government has issued an order that may limit your ability to recover damages if you are injured or harmed while participating in this COVID-19 clinical study. If the order applies, it limits your ability to recover damages from the University, researchers, healthcare providers, study sponsor, manufacturer or distributor involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death due to this study. To find out more about this "Countermeasures Injury Compensation Program" go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

VOLUNTARY PARTICIPATION:

Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whom do I contact if I have questions, concerns or feedback about my experience?
This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

VOLUNTARY CONSENT

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

*The subject is unable to consent because: _____

I therefore, consent to participation for the subject.

Your signature documents your permission for the named participant to take part in this research.

_____
Printed Name of Participant

_____ _____
Signature of Legally Authorized Representative Date

_____ _____
Printed Name of Legally Authorized Representative Date

_____ _____
Signature of Person Obtaining Consent Date

_____ _____
Printed Name of Person Obtaining Consent Date

WITNESS STATEMENT:
The participant was unable to read or sign this consent form because of the following reason:

☐ The participant is unable to read the information

☐ The participant is visually impaired

☐ The participant is non-English speaking

☐ The participant is physically unable to sign the consent form. Please describe:

_____

☐ Other *(please specify)*:

_____

For the Consent of Non-English Speaking Participants when an Interpreter is Used:
A**s** someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Interpreter Date

_____
Printed Name of Interpreter

OR:

Statement from a Non-Interpreter:
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

_____ _____
Signature of Individual Date

_____
Printed Name of Individual

CONSENT FOR CONTINUED RESEARCH PARTICIPATION:

I have been informed that I am currently participating in a research study. I have been informed that consent for my participation in this research study was initially obtained from my authorized representative as a result of my inability to provide direct consent at the time that this initial consent was requested. I have now recovered to the point where it is felt that I am able to provide direct consent for continued participation in this research study.

The above information has been explained to me and all of my current questions have been answered. I have been informed that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I have been informed that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date and Time

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise.

Printed Name of Person Obtaining Consent	Role in Research Study
Signature of Person Obtaining Consent	Date and Time