PARTCIPANT INFORMATION SHEET AND INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: Efficacy of Mitochondrial directed therapy in prevention of cardiac surgery associated AKI. Prevent Cardiac Surgery Associated AKI trial (Prevent CSA-AKI trial)

PROTOCOL NO: IRB Number NCR224635

INVESTIGATOR: YOOSIF ABDALLA, MD
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DIVISON OF RENAL DISEASE
PHONE 202-203-8960

INTRODUCTION:
In this consent form the expressions "you" and "I" refers to the participant. If you are a legally authorized representative of a participant, please remember that "you" or "I" means the participant and not you as the representative except for circumstances where you act on behalf of the participant.

SUMMARY:

You are being invited to voluntary participate in a study which examines the protective effect of two dietary supplements, Coenzyme Q10 (CoQ10) and Glutathione given together as (Q10G), on the risk of worsening kidney function in patients undergoing cardiac surgery. CoQ10 and glutathione are natural nutrients that work as antioxidants protecting human cells from damage. You will be requested to either take the supplements or a placebo (inactive treatment) by mouth once daily for up to 7 days. We will collect blood and urine samples to measure markers of kidney injury. CoQ10 and glutathione levels will be measured at three time points- before surgery, 24 and 48 hours after taking the supplement or placebo. We will collect clinical information and laboratory values from the medical records for a period of 90 days.

Your participation may help to further our understanding one the mechanisms of kidney injury. It also may lower your risk of developing acute kidney damage and may help in the recovery of kidney cells after kidney injury. You may not choose to participate if you don't want the risk of developing minor side effects like nausea, vomiting, diarrhea, rash and loss of appetite.
This document tells you about the clinical trial and includes information about the reason why the clinical trial is being done, what will happen to you if you take part in the clinical trial, and the possible benefits and risks of participating in this clinical trial. Take time to read this document carefully and feel free to talk about it with your partner, family members, family doctor or others.

Your trial doctor or a member of the clinical trial team will also talk to you in detail about the information in this document. Ask your trial doctor or a member of the clinical trial team to explain anything that is not clear to you.

If you choose to take part in this clinical trial, you will be asked to sign this document. You will get a signed and dated copy of this consent form.

PURPOSE OF THIS TRIAL:

One of the risks of undergoing cardiac surgery is Cardiac Surgery Associated Acute Kidney Injury (CSA- AKI). Acute Kidney Injury is damage that may happens to the kidney cells due to changes in blood pressure and blood supply to the kidney during heart surgery. Currently, there is no drug approved for the prevention of the treatment of CSA-AKI.

CoQ10 and Glutathione (Q10G) supplements are safe and widely available as an over-the-counter. They may have a potential to reduce kidney damage during heart surgery.

Some of the procedures performed in this clinical trial will be in addition to your standard of care. If you have questions about any of the procedures, you should ask the trial doctor or a member of the clinical trial team. About 242 participants from George Washington University are expected to participate in this clinical trial.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you receive the study drug and it works for you, it may lower your risk of developing acute kidney injury and may help to recover the damaged kidney cells. For a complete description of benefits please refer to the detailed possible benefits section below.

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

If you do not want the risk of developing the minor side effects like nausea. For a complete description of risks please refer to the detailed side effect section below.

TRIAL PROCEDURES

If you are eligible and choose to participate in Prevent CSA-AKI, you will be randomly assigned (like the flip of a coin) to a treatment group by a computer. You will receive either Q10G or placebo (inactive treatment). You will have a 50% chance of receiving Q10G and a 50% chance of receiving placebo. A 'placebo' looks like Q10G but does not have any active substance in it. No matter which treatment group you are assigned to, you will still receive all standard treatments for CSA-AKI as directed by your treating trial doctor(s). No one among the people taking care of you or among the clinical trial team will know what treatment you received until after the entire clinical trial is over. This setup creates the best way to objectively measure the effect of Q10G. However, your trial doctor can find out the treatment if it is needed for your health.

All trial assessments done up to the time the trial drug is started is referred to as Screening or as Baseline. From the day the trial drug is started, each day is given a number beginning with Day -1 (see the table below)

The planned duration of your participation in the clinical trial will be approximately 90 days, 7 days of receiving medication and total 90 days of follow up.

Study-related procedures

- Total amount of blood to be collected per patient during the entire study will be 15 ml (5 ml each collection)
- Total amount of urine to be collected per patient during the entire study will be 120 ml of urine (40 ml each collection)

Schedule of Activities:

Study Activities	**Any day of the week prior to surgery Day D0**	**Day -1**	**Day 0**	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Days 7-90**
Screening and baseline	x								
Q10G/Placebo intake		X	X	X	X	X	X	X	
Blood collection	X		X	X					
Urine collection	X		X	X					
Review of medical information	x		X	X	X	X	X	X	X
Review of daily labs	x	X	X	X	X	X	X	X	X
Review of support systems (ventilation, therapy, BP meds)		X	X	X	X	X	X	X	X
Current hospitalization status			X	X	X	X	X	X	X

Screening and Baseline:

If you agree to take part in this clinical trial, you or your legal representative will need to sign this consent form. You may have some tests to check if you can start the trial supplements and information about your health status before the start of the trial supplements will be collected:

- Demographic information (age, gender, race, etc.) and information about whether you were living at home, at a rehabilitation site or nursing facility before you were admitted to the hospital will be collected.
- Information will be collected about your current health, vital signs, medical history, medications and treatments you have received, and your weight and height will be measured or estimated.
- If you are a woman able to have children, you will have a pregnancy test. If you are pregnant, you cannot participate in the trial.
- If not already done as part of standard care, blood will be collected for standard safety tests and to see how your kidneys are functioning. In addition, a blood sample will be taken to check levels of CoQ10, and for biomarker testing. Biomarkers are substances that may provide information about how Q10G works, or the causes of disease and its individual course. Biomarkers may also help identify participants who may benefit from Q10G, or identify participant at increased risk for side effects.
- A urine sample will be collected for biomarkers.
- You will be randomized to receive trial supplement (either Q10G or placebo).

The trial supplements will be administered orally starting the day before surgery then daily while admitted for maximum 7 days, if discharged home prior to finishing the 7-day course no further doses required.

Study medication and labs draw timing

- The first supplements or placebo dose will be taken the day before surgery
- 1st samples collection of 5 mL of blood and 40 ml of urine will happen any day in the week prior to surgery, only if the collection didn't happen as outpatient then it will happen in hospital the day prior to surgery Day-1.
- 2nd samples collection will be on the Day of surgery (Day 0), 3rd and last collection will happen 1 day after surgery (Day 1) (preferable 2nd & 3rd collections should happen about 24 & 48 hours from the first doses of the supplements).

Procedures that are to be performed Day -1 to Day 2

- Information will be collected about your current health, any side effects you may have, and medications and treatments you receive.
- As outlined above Blood and Urine samples will be collected to evaluate the blood levels of supplements and for biomarker testing. This is the only biospecimen collections and tests that are separate from the standard of care.
- You will be administered the trial supplements by mouth if possible, if not then we will use the temporary feeding tube you have.
- Review the daily regular labs including hemoglobin, renal and liver functions, blood sugar and coagulation profile
- Review the needs and duration of mechanical ventilation, renal replacement therapy & blood pressure medication support

Procedures that are to be performed Days 3 through 5

- Information will be collected about your current health, any side effects you may have, and medications and treatments you receive.
- You will be administered the trial supplements by mouth if possible, if not then we will use the temporary feeding tube you have.
- Review the labs including hemoglobin, liver function, blood sugar and coagulation profile
- Review the needs and duration of machine assisted breathing, dialysis (the process of filtering the blood when the kidneys are not able to cleanse it) & blood pressure medication support
- If Participant left the hospital prior to their 7 days of treatment, they will not undergo the blood monitoring that they would have experienced in the hospital sitting.

Day 5 through Day 90

- Information will be collected about whether you have been in the hospital since you were discharged and whether you are living at home, are in the hospital or living in another facility.
- Available medical information will be reviewed to evaluate the effects of the supplements on the clinical outcomes.
- Review the labs including hemoglobin, liver function, blood sugar and coagulation profile

- Review the needs and duration of mechanical ventilation, renal replacement therapy & blood pressure medication support

Early Termination Visit:

If you are withdrawn or choose to withdraw from the trial, or contact with you is lost, your trial doctor will contact you (your family or caregiver) or may access your medical records or publicly available records, to determine your health/survival status.

If you wish/decide you do not/no longer want to be contacted or allow access to your medical records for follow-up information, tell your trial doctor.

Human Biological Samples

While you are in this clinical trial, you will have biological samples taken. A total of 15 mL of blood and 120 ml of urine will be collected. These samples are necessary to evaluate your health and the effects of Q10G and may provide new information to help better understand your disease and how Q10G works. Samples will be analyzed at either the institution where you are being treated or sent to a central laboratory for analysis. Samples will be discarded after results have been obtained. The below section refers to the use of your samples.

WHAT SAMPLES MAY BE USED FOR:

- Your samples will be used for the research purposes explained in the procedures section of this form.
- Your samples will not be sold or used directly for the production of commercial products.
- In case of any commercial gain based on research results from your samples, GWUH will have the ownership of the research results and may file patents. The research done with your samples may help develop new products, new medical tests or treatments in the future that have commercial value. There will be no financial benefit to you for any commercial findings or products as a result of your sample use. By agreeing to take part in this clinical trial, you agree to give up your rights for any commercial value resulting from your samples and data.
- Your samples may be provided to a laboratory for testing and research use and storage purposes done for and on behalf of GWUH and its third party collaborators. Some samples being collected will be sent to NIH during the course of the clinical trial or following completion of the clinical trial.
- All identifiable samples will be handled in a manner to maintain your confidentiality and will be labelled with a code number and kept in locked storage. Only your clinical trial team will

be able to link your samples with your identity. No one outside the trial hospital working with your samples will know your identity.

- Your samples will be stored for up to six years after the clinical trial is published.
- Your samples may be stored for longer than these specified periods if this is required by a regulatory or government agency, such as the FDA.
- If additional tests are to be performed with your samples that are not associated with this trial biomarker research related to the effects of Q10G or for better understanding your disease, we will inform you of those details. You can decide not to give consent for these additional tests using your samples. You have the right to be told about such new tests that use your samples for a new purpose not described in this document and you have the right to refuse these new tests on those samples.

Some reports from laboratory tests done for the clinical trial at central laboratories will not be put in your health/medical record and will be kept confidential to the best of our ability within the law. You will not be provided with the results of these laboratory tests.

YOUR RESPONSIBILITIES FOR THIS TRIAL

If you decide to take part in this clinical trial, it is important that you agree to:

- Follow the instructions provided by your trial doctor or the clinical trial team;
- Go to your trial visits. As soon as you know that you will not be able to go to a clinical trial visit, please contact your trial doctor or a member of the clinical trial team to schedule a new visit.
- Truthfully answer any questions from your trial doctor or the clinical trial team when asked about any changes in your health, visits to other doctors or hospital admissions, or changes in your medication, including prescribed medications, over the counter medications, herbal remedies, and vitamins.
- If you are or are planning to take part in other clinical trials, please inform your trial doctor. Do not take part in any other clinical trials without the consent of your trial doctor while you are taking part in this clinical trial.
- Tell the trial doctor if you believe you are pregnant.
- Tell your trial doctor or a member of the clinical trial team if you change your mind about taking part in the clinical trial.

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS / STUDY POSSIBLE RISKS?

All supplements and drugs may cause side effects. Safety of CoQ10 and Glutathione were shown in many clinical trial data, most commonly reported side effects were mild digestive side effects like abdominal discomfort, nausea, vomiting, diarrhea, rash and appetite loss.
Patients using warfarin (blood thinner) may need more frequent blood checks and higher doses to achieve the medication target.
Diabetic patients may require more blood sugar checks and less medication to lower the blood sugar because of the effect of CoQ10.

Long term use of Glutathione may lower zinc level.

Allergic Reaction:

Sometimes people have allergic reactions to drugs. If you have a very bad allergic reaction, you could die. Some signs that you may be having an allergic reaction are:

- Rash or hives
- Having a hard time breathing
- Wheezing when you breathe
- Sudden change in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat or eyes
- Fast pulse
- Sweating

You should get medical help and contact the study doctor or staff if you have any of these or any other side effects during the study.

Blood draws:

Most of the blood tests will be taken from catheters (tubes) that are already in one of your veins so you should not experience additional discomfort. When a sample of your blood is drawn by using a needle, you may experience some temporary discomfort, bruising, swelling or, in rare circumstances, infection at the needle site. You may feel dizzy or you may faint. Tell the trial doctor or a member of the clinical trial if you do not feel well after having your blood drawn.

Pregnancy risks

The safety of Q10G during pregnancy and breast-feeding has not been tested previously in human studies. Therefore, if you are pregnant or breast-feeding, you will not participate in this clinical trial.

For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse and donating eggs) or use contraceptive measures as defined below:

- Women must remain abstinent or use contraceptive methods with a failure rate of < 1% per year during the treatment period. Women must refrain from breastfeeding and donating eggs during this same period of time.

- Examples of contraceptive methods with a failure rate of < 1% per year include bilateral tubal ligation, male sterilization, hormonal contraceptives that inhibit ovulation, hormone-releasing intrauterine devices, and copper intrauterine devices.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY / POSSIBLE BENEFITS?

Possible benefits from taking part in this clinical trial may include:

- If you receive the study drug and it works for you, your health problem may get better from taking part in this clinical trial. In this clinical trial you may get placebo which means you will not receive the active drug during the clinical trial.
- Taking part in this clinical trial will help doctors learn more about CSA-AKI. This may help others with your health problem in the future.

We cannot promise that you will get any benefits from this clinical trial.

ALTERNATIVE TREATMENTS

The only alternative treatment for CoQ10 & Glutathione is supportive care. Regardless of whether you decide to take part in this clinical trial, you will receive all standard medical care including supportive care as clinically indicated. This is also the case if the trial supplements are prematurely stopped. Your trial doctor can talk with you about the risks and benefits of supportive care.

COSTS

The trial drug will be made available to you at no charge and you will not be required to pay for any trial procedures. You or your insurance company will have to pay for routine care you would receive whether or not you are in the study. You may talk to the study staff and your insurance company about what is covered.

PAYMENT

You will not receive any payment or compensation for participating in this clinical trial.

COMPENSATION FOR INJURY

You may have medical problems or side effects from taking part in this research study. If you have any side effects from administration of Q10G or are injured during the study, tell your

study doctor right away. Once you tell your study doctor, he will either provide you with or refer to your proper medical treatment.

If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away. This can be done through:

- George Washington University Hospital (GWUH) and/or the George Washington University Medical Faculty Associates ("GW MFA"); or
- Your physician; or
- A treatment center of your choice.
- The cost of any medical treatments or procedures required for any illness, injury or complication or acute kidney injury, or any other medical problem will remain your responsibility or the responsibility of your health insurance company.

There are no plans for GW Hospital and/or the GW MFA to pay you for any injuries or illnesses. There are no plans to pay you for lost pay or other losses.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Access to your study records will be limited to those who need the information for purposes of this study, as well as your health care providers if they need access to the information. All records will be kept in a secure location and access will be limited to research study personnel.

Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed, unless you give the appropriate authorization.

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of health information that identifies you. This kind of information is known as "protected health information" or "PHI." This section tells you your rights about your protected health information in the study. This section also lists who you let use, release, and get your protected health information. You are free to not allow these uses and releases by not signing this form. However, if you do that that, you cannot participate in the study.

Protected health information that may be used and released (disclosed) in this study includes information such as:

- This consent form;
- Information about your medical history from your medical records and your doctor's office;
- Information obtained from you to be used in the Study as a result of tests or procedures;
- Results of physical examinations
- Laboratory results obtained on specimens collected from you (like blood, urine, tissue);

- Medical images like x-rays, CT scans, and MRIs;
- Admissions information;
- Interviews with you conducted by members of the Research Team;
- Your race and ethnicity will be collected to assess whether race and ethnicity influence the effects of Q10G.

By signing this form, you allow the use, sharing, copying, and release of your protected health information to carry out the study by:

- Medical Faculty Associates
- George Washington University Hospital
- Your healthcare providers (like doctors and hospitals) which are not part of the study,
- The study doctor and his or her research team, and
- Other healthcare providers such as labs which are part of the study.

You also allow the study doctor and the research team, and other healthcare providers which are part of the study to release your health information to:

- Research collaborators participating in this study at other institutions (NIH)
- Regulatory agencies such as the U.S. Food and Drug Administration (FDA) to review data on the safety and effectiveness of the product that is being tested in this study and other Federal and state agencies that regulate research
- Accrediting agencies and GWU legal counsel;
- Clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to your care; and
- GWU, GWU Hospital or GWU MFA workforce who are involved with the research;
- If you are transferred or readmitted to a hospital other than the trial hospital, your trial doctor or a member of the clinical trial team will continue collecting your personal data as if you stayed at the trial hospital, for the purpose of the clinical trial. The trial hospital will ensure that any collection and transfer of your personal data is done in accordance with applicable laws.

It is critical to the interpretation of the results of this study that you not know the treatment group in which you are participating. After the study is finished you may request to review your personal health information collected during this study and to have a copy of that information placed in your medical record. This right to review and copy your personal health information only extends to information that is placed in your medical record; it does not extend to information that is placed in your research record.

This permission does not end unless you cancel it, even if you leave the study. You can withdraw this permission at any time: you may withdraw from the clinical trial entirely or you may withdraw only from receiving trial drug and continue trial procedures and/or data collection. If you withdraw entirely, you will be asked to complete an end of trial visit. Such withdrawal (fully or partially) will not affect information a healthcare provider has already used in reliance on your permission to do so. Even if you cancel this authorization, the researchers may still use and disclose protected health information they already have obtained about you as necessary to maintain the integrity or reliability of the research and you may be asked to take part in a final visit or follow-up. However, no new PHI (unless you have a side effect related

to the study) or new biological specimens will be collected from you after you revoke your authorization. You can also request the destruction of collected samples that would otherwise remain in storage or request that no new analysis is done on your samples.
To cancel your authorization, you will need to send a letter to your study doctor. This letter must be signed and dated and sent to this address: Yoosif Abdalla, 2150 Pennsylvania Ave NW, Washington, DC, 20037. A copy of this revocation will be provided to the study doctor and his or her research team. Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits.
Your protected health information will be treated confidentially to the extent permitted by applicable laws and regulations. Federal law may allow someone who gets your health information from this study to use or release it in some way not discussed in this section and it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you authorize the study doctor and members of the research team to use and share with others (disclose) your PHI for the purpose of this study. If you do not wish to authorize the use or disclosure of your PHI, you cannot participate in this study because your PHI is necessary to conduct this study.

Publication

On completion of the clinical trial, results and data from the trial that will not include any personal identifiers may be published in accordance with regulatory requirements.
Although information about this clinical trial, including the results, may be published for scientific purposes, presented or posted electronically (for example, in a clinical studies registry database) or presented to scientific groups, your name and personal information will not be used and your identity will not be revealed.
A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Storage of Personal Data and Biological Samples

Your personal data and biological samples will be stored for up to 6 years after the clinical trial is published. Your samples may be stored for longer than these specified periods if this is required by a regulatory or government agency.

NEW INFORMATION

During the clinical trial, new information about the risks and benefits of the project may become known. Your trial doctor will talk with you about any important new information that is learned during the course of the clinical trial that may affect your willingness to continue to take part in the clinical trial. This new information may also mean that you can no longer take part in this clinical trial. In all cases, you will be offered all available care to suit your needs and/or medical condition.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Taking part in this clinical trial is entirely voluntary. You do not have to take part in this clinical trial and you are free to withdraw at any time. Your choice not to take part or to stop taking part in this clinical trial, will not affect your routine/regular treatment, your relationship with those treating you or your relationship with the place where you are getting treatment. There will not be any penalty and you will not lose any benefits to which you are otherwise entitled.

PREMATURE END OF THE CLINICAL TRIAL OR CLINICAL TRIAL TREATMENT

This clinical trial or the trial drug may be stopped without your consent by the study doctor or the sponsor at any time.
Reasons to stop the clinical trial or put the clinical trial on hold include:

- Q10G has been shown not to work.
- Q10G has been shown to work and there is no need for the clinical trial to continue.
- Q10G has been shown to cause serious side effects.
- Decisions made by the Regulatory Authorities, such as the FDA or IRB/EC.
- The study is stopped by the FDA

The trial doctor may also stop your treatment with trial drug if it is not in your best interest to continue.

WHO TO CONTACT FOR MORE INFORMATION?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number(s) listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at
202-994-2715
GW Office of Human Research
1922 F Street NW, 4th Floor, Washington, DC 20052
E-mail: ohrirb@gwu.edu
if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Contacts in case of emergency and for questions about the clinical trial

You will receive a card indicating that you are participating in this trial. The card will include the name and phone number of the trial doctor. Please have this card with you at all times, as long as you remain in the trial.

INFORMED CONSENT FORM

Sign this form ONLY if all of the following statements are true:

- I have read (or someone has read to me) the information in this document in language that I understand.
- The content and meaning of this information have been explained to me.
- I have been given an opportunity to ask my questions in private as well as to meet with a member of the clinical trial team to discuss this clinical trial. I have had a chance to consider the information, including the risks and benefits of taking part in this clinical trial, to ask questions, and to discuss the clinical trial. My questions have been answered to my satisfaction.
- I have asked a member of the clinical trial team any questions I may have and have had enough time to decide if I want to take part in this clinical trial.
- I agree that biological samples may be collected from me as explicitly stated in this consent form.
- I have decided to take part in this clinical trial. I understand I will get a signed and dated copy of this document.

Please initial your choices below:

- I agree that my trial doctor/staff can access my medical records or publicly available records, to determine my health/survival status if contact with me is lost or I withdrew from the trial (initial on the appropriate line).

  ___ Yes ___ No

  By signing this form, I consent and provide my authorization to the processing and use of my personal data for the purposes of my participation in the clinical trial as described in this form. I agree to the use of my coded medical information for future medical or pharmaceutical research. I acknowledge that without my permission, my personal data and samples cannot be used and that I will not be able to take part in the clinical trial.

I am free to stop taking part in this clinical trial at any time for any reason and my choice to stop taking part will not affect my future medical care. I agree to follow the clinical trial doctor's instructions and will tell the doctor at once if I have any changes in my health. By signing this document, I am not giving up any of my legal rights.

Assenting Instructions for Adult Subjects Unable to Consent:

- All subjects unable to consent are required to assent, unless the investigator determines that the capability of the subject is so limited that the subject cannot reasonably be consulted.
- If assent is obtained, have the person obtaining assent document assent on the consent form.

_____
Printed Name of participant

_____ _____
Signature of participant Date and time of Signature

_____
Printed Name of Legally Authorized Representative (if participant *is incapacitated*)

_____ _____
Signature of Legally Authorized Representative Date and time of Signature

_____
Relationship of Legally Authorized Representative to the participants

In-person consent _____ *Telephone consent* _____ *Teleconference Consent*

Statement of the Witness (when applicable*)

The information in the informed consent form was accurately explained to, and appeared to be understood by the subject or the subject's representative. Informed consent was freely given.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness
(if *consent obtained remotely*)

Date and time of Signature

*Impartial Witness: If the subject or the subject's legally authorized representative cannot read, the signature of an Impartial Witness is needed.

An impartial witness is:

- a person who is independent of the trial,
- who cannot be unfairly influenced by people involved with the trial
- who attends the informed consent process
- who reads the informed consent form and any other written information supplied to the subject or the subject's legally authorized representative.

Person Obtaining Consent

I, the undersigned, trial doctor/investigator/ clinical trial personnel, confirm that I have verbally given the necessary information about the clinical trial, that I answered any additional questions, and that I did not exert any pressure on the subject or the subject's legally authorized representative to participate in the clinical trial.

I declare that I acted in full accordance with the ethical principles described in GCP Guidelines and other national and international legislation in effect.

A copy of this form, signed by both parties, will be provided to the subject or the subject's legally authorized representative.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent | Date and time of Signature

Incapacitated participants enrolled in the clinical trial must sign the most recent ICF as soon as they are capable to do so.

Assent for Adult Subjects Unable to Consent:

Printed Name of Adult Subject

Signature of Adult Subject, as able | Date and time of Signature

Person Obtaining Assent

- ❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

- ❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Printed Name of Person Obtaining Assent

Signature of Person Obtaining Assent | Date and time of Signature

Consent for continued research participation:

I understand that I am currently participating in a research study. I further understand 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 understand 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 understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator.

Printed Name of participant

Signature of participants | Date and time of Signature

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent | Date and time of Signature