NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Strategy for Improving Stroke Treatment Response (SISTER)

Sponsor/Protocol Principal Investigator: Eva A. Mistry, MBBS MSCI

Performance Site Principal Investigator: Yasmin Aziz, MD

Performance Site: University of Cincinnati

Participant Name: _____

Telephone Number: _____

If applicable,
Legally Authorized Representative Name: _____

Telephone Number: _____

KEY INFORMATION

Purpose of the Study:	The purpose is to test the effects of the study medication called TS23 on you and your recovery from a stroke caused by a blockage of a blood vessel. TS23 is designed to dissolve the blood clot causing a stroke. TS23 is not approved by the US Food and Drug Administration (FDA) to treat strokes. This study is research and participation is voluntary.
Length of the Study:	You will be in this research study for approximately 3 months. After you leave the hospital, you will be seen by the study team at day 30 and day 90 after your stroke. The study will involve 7 visits over this 3-month period of time. Five of these visits will be while you are in the hospital and 2 visits will be after you leave the hospital.
Risks:	The main potential risk of this study is serious bleeding into the brain or other parts of your body. Serious bleeding may be fatal. See section titled “What are the Risks and Discomforts of the Research Study? for additional risks related to the study.
Benefits of the Study:	You may or may not directly benefit from being in this study.
Alternative procedures:	You may choose not to participate in this study. Regardless of your decision you will receive standard medical care as per your clinical team.

INTRODUCTION

The study doctor wants to know if you would like to be part of a research study. This informed consent document contains important information about the research.

If you have any questions about or do not understand something in this document, you should ask the study doctor or study staff. You should also discuss your participation with anyone you choose in order to better understand this study and your options.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information.

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

If you are acting as a representative to give consent for another person to participate in this study, “you” throughout this consent document refers to that individual.

The obligation of a representative is to try to determine what the individual would do if competent, or if the subject's wishes cannot be determined, what the representative thinks is in the person's best interest. If possible, an attempt should be made to obtain permission from the individual. Some persons may resist participating in a research protocol that has been approved by their representatives. Under no circumstances may individuals be forced to participate.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to take part in this research study because you are at least 18 years of age and you have been diagnosed with an ischemic stroke. An ischemic stroke is a stroke caused by blockage of the blood flow to the brain. Your clinical team has determined that you are not a candidate for standard treatments for removal of this blockage.

WHY IS THIS RESEARCH BEING DONE?

We are trying to find out what effects, good or bad, TS23 has on you and your ischemic stroke.

The research is being done to determine if TS23 is safe and effective for the treatment of patients with an ischemic stroke that do not meet the criteria for standard treatments to remove the clot.

The study medication, TS23, has never been studied in stroke patients before. The use and doses of TS23 that are being tested have not been approved by the U.S. Food and Drug Administration (FDA).

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

You will be in the research study for approximately three months.

The researcher may decide to take you off this research study at any time. The reasons may be:

- You are not following the instructions by your study doctor,
- If the study doctor decides it would be in your best medical interest to stop your study participation

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to your study doctor and your regular doctor first so that stopping can be done safely. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful to you.

The information collected about you up until the point that you withdraw from the study will remain part of the study database and may not be removed.

If you are withdrawing from the study, the study team will ask you if you are willing to allow further medical information to be collected from your routine medical care.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is funded by the National Institutes of Neurological Disorders and Stroke (NINDS) and Translational Sciences, Inc.

Translational Sciences, Inc. was founded by Dr. Guy Reed at the University of Arizona. Dr. Reed has a limited role in this study. The company is testing TS23 to see if it works to treat life-threatening blood clots, acute inflammation, and severe bleeding. If TS23 is shown to help people in this study, he may benefit financially. This disclosure is made so that you can decide if this information will affect your willingness to participate in this study.

This study is conducted by Eva Mistry, MBBS, MSCI at the University of Cincinnati.

Medical supervision for the study is provided by Yasmin Aziz, MD.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 300 people will take part in this study at up to 50 sites in the United States. A total of 32 people will take part in this study at the University of Cincinnati.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

Screening
If you have not already undergone an imaging study called “perfusion scan”, you will get that scan as part of this study. Based on the results of this scan, the researchers will decide if you are eligible to participate in this study.

Randomization
If the imaging study shows that you can be in the study and you decide to participate, you will be “randomized” into one of the five study groups described below. Randomization means that you are put into one of the five groups by chance. It is like pulling a name out of a hat. You will have an equal chance if being put into any one of the groups. However, after a total of 50 subjects have been enrolled, if one study medication does not appear to be as effective or safe as the others, it may be given less frequently or not at all. You will not know which group you are in.

Study Medication or Placebo
The study treatment will depend on which group you are assigned to. There are five study medication groups.

One of the groups will receive placebo. A placebo is a solution that looks like the study medication solution but does not contain any active ingredients.

The other 4 groups will receive different amounts of TS23 based on how much they weight. The amount is described in milligram (mg) of TS23 per kilogram (kg) of body weight.

All the study treatments are given through a vein over 15 minutes.

Group 1: Placebo
Group 2: TS23 - 3 mg/kg
Group 3: TS23 - 5 mg/kg
Group 4: TS23 - 7 mg/kg
Group 5: TS23 - 10 mg/kg

Neither you, the treatment team or the researchers conducting this study will know or choose what group you will be in. However, in the event of an emergency, the research doctor and your other physicians will be able to find out which group you were in.

The following are research specific visits for this study:

First Visit, Baseline (screening) visit, which will take about 60-90 minutes. This visit will occur when you are at the hospital.

- Completion of imaging scans
- Collection of lab specimens; about 2 teaspoons of blood

Second Visit, Randomization & Study medication administration, this visit will take about 90 minutes

- Study medication administration
- Observing and documenting any unexpected effects of the study medication

Third Visit, about 3 hours after study medication administration, which will take about 30 minutes.

- Collection of lab specimens; about 2 teaspoons of blood
- Documenting any unexpected effects of the study medication

Fourth Visit, about 30 hours, after study medication administration, which will take about 60 minutes.

- Measuring how well you are functioning after your stroke
- Completion of imaging scan
- Documenting any unexpected effects of the study medication
- Collection of lab specimens; about 2 teaspoons of blood

Fifth Visit, 72 hours or at discharge that occurs before 72 hours
Measuring how well you are functioning after your stroke

Sixth Visit, Hospital Discharge, which will take about 30 minutes.

- Measuring how well you are functioning after your stroke
- Documenting any unexpected effects of the study medication

Seventh Visit, around 30 days after study medication administration which will take about 60 minutes.

- Measuring how well you are functioning after your stroke
- Documenting any unexpected effects from the study medication

Eight Visit (final visit), around 90 days after study medication treatment, which will take about 60 minutes.

- Collection of lab specimens; about 2 teaspoons of blood

- Measuring how well you are functioning after your stroke
- Documenting any unexpected effects of the study medication

The seventh and eighth visits may be in-person or over the phone and may involve physical exams, blood draws, and asking questions.

Below are the items that are for the research purposes only:

- Baseline Visit – blood specimen and imaging scan that shows the blood flow in the brain, if not ordered as part of your standard care by your treating doctor
- Randomization & Treatment Visit – blood specimen
- Third Visit – blood specimen
- Fourth Visit – imaging scan if not ordered as part of your standard care by your treating doctor; collection of blood specimens
- Eight Visit – blood specimen

When scheduling follow-up visits, multiple attempts will be made in order to reach you. If you cannot be reached, multiple attempts will be made to reach the person(s) listed as the secondary contact. If no contact is made after multiple attempts, alternative methods will be considered in order to obtain contact with you and/or verify your health information. Examples of alternative methods of contact are reaching out to you at other scheduled medical appointments, and certified letter.

OTHER INFORMATION ABOUT STUDY PROCEDURES

The results of your research imaging scans will not be shared with you and will not be part of your medical record. The images will be sent to the study imaging core lab and will be reviewed for research purposes.

You may have to sign a separate medical procedure consent document before you have some of the procedures listed above, like the imaging scans.

This study does not involve physical risk and you are not expected to need any time to recover from participating in this study.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Principal Investigator and study staff
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Principal Investigator or research study staff to reschedule as soon as you know you will miss the appointment
- Tell the Principal Investigator or research study staff about any side effects, doctor visits, or hospitalizations that you may have

- Ask questions as you think of them
- Tell the Principal Investigator or research staff if you change your mind about staying in the study

While participating in this research study, you should not take part in any other research project without approval from the Principal Investigator of each study.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

Participation in this research involves the following risks:

Bleeding
Bleeding is a potential risk due to the mechanism of action of the study medication. This may include serious bleeding in your brain. There may also be a risk of serious bleeding in other parts of your body. Serious bleeding may be fatal. In the event of serious bleeding your doctors may give you medications to try to stop the bleeding.

To reduce the risk of bleeding, your doctors will not give you “blood thinners” (antithrombotic medications) for the first 24 hours after study drug is given.

There is limited clinical data available at this time for the study medication. You will be carefully monitored for bleeding during and after the study medication is given.

Allergic Reactions
There have been no allergic reactions to the study medication to date. You will be monitored during and after the study medication administration for signs and symptoms of an allergic reaction.

Development of Antibodies
An antibody is something that your body makes to help fight against bacteria and viruses. There is a small chance that you may develop antibodies to the study medication. There are no effects of these antibodies on you except there may be a chance that you will not be eligible to receive study medication, TS23, in the future. You will be monitored during the study for any signs of this.

Risk of Overdose
There is currently no information available regarding potential overdose of TS23. In case of suspected overdose, you will be closely monitored in an inpatient, supervised setting. The risk of severe bleeding may be increased. There are no known agents that are effective at reversing the effect of the study medication.

Risks associated with Imaging Scans
You will receive imaging scan(s) as part of the study.

The study will require a repeat computed tomography (CT) of the head. The study will also require a Computed Tomography Angiogram (CTA) or Magnetic Resonance Angiogram (MRA). If your first CTA or MRA showed a blockage of a blood vessel in the brain an additional perfusion scan that uses computed tomography (CTP) or magnetic resonance (MRP) will be required.

Risks of Contrast Media
These scans may use a contrast media so that we will be able to see your blood vessels more clearly. The contrast media is injected into a vein during the scans. There are some risks associated with the use of contrast media.

Risks of Gadolinium-based contrast media (GBCD) during a MRA Perfusion Scan

Headache, nausea, vomiting, dizziness, and a cold sensation may occur in 1 out of 100 people during injection of the contrast into a vein.

Mild allergic-like reactions occur in less than 1 out of 1000 people receiving GBCD. The main symptom is itchy skin. Severe and sudden life-threatening allergic reactions occur in less than 1 out of 10,000 persons receiving GBCD. You will be monitored for all possible allergic responses during the procedure.

Risks of Iodinated or Noniodinated Contrast Media during CTA or CT Perfusion scans

Mild allergic reactions may occur in less than 4 out of 100 people receiving this media. Severe and sudden life-threatening allergic reactions may occur in 1 out of 1000 persons receiving this media. You will be monitored for all possible allergic responses during the procedure.

Noniodinated Contrast Media can cause nephrogenic systemic fibrosis (NSF) in people with acute kidney injury or severe chronic kidney disease. This condition causes tightening of the skin, organs and other tissues. Iodinated contrast media can, in rare cases, also contribute to kidney damage. If you have severe chronic kidney disease, you will not be asked to participate in this study.

Contrast media may leak out of the vein into the surrounding arm tissue in 2 to 6 people out of 1000. If this happens you may experience burning or pain in the surrounding area as well as minimal swelling or redness. This can be treated with an ice pack to the area and should be gone within 15 minutes.

Radiation Risk
This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation is approximately equivalent to a uniform whole-body exposure of between 2.51 and 4.86 years of exposure to natural background radiation. This use involves minimal risk and is necessary to obtain the research information desired.

Protected Health Information Risk
The protected health information collected as part of the study will be kept to a minimum and stored in a password protected database. This information is kept confidential and only shared with those involved directly with the study.

Risks associated with blood samples
You will also have a blood sample collected though a standard blood draw . Risks of having your blood drawn include faintness, inflammation of the vein, pain, bruising, bleeding at the site of the puncture and rarely, infection.

Other reactions to the study medication
There is a potential risk of a mild infusion reaction (redness, itching, swelling, rash or pain) associated with administration of TS23. There is a low risk of a severe infusion reaction (fever, chills, dizziness, headache, muscle ache, low blood pressure, or trouble breathing). You will be monitored closely for the possibility of these reactions.

Some people in the study will get placebo instead of the study medication TS23. Receiving the placebo is the same as not receiving anything for your stroke. Please ask the study doctor or study staff if you have any questions about placebo.

There may be unknown or unforeseen risks associated with study participation.

WHAT ARE THE REPRODUCTION RISKS?

Pregnancy & Breastfeeding

The study medication has not been studied in women that are pregnant or breastfeeding so the effects on an unborn baby or infant are unknown. This study will not include pregnant women or women that are breastfeeding.

If you become pregnant while in this research study, you will need to notify your research team immediately. The research study will want to continue to follow your pregnancy through 7 days after the birth of your infant. Information on your delivery and infant will also be collected.

If you are a male and your female partner becomes pregnant during the first 7 days after receiving the study medication, then we will ask to follow the outcome of the pregnancy. In order for the investigators to collect this information, your female partner will be asked to sign an informed consent form for disclosure of this information.

This information is important for both medication safety and public health concerns.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there may or may not be a direct benefit to you.

We hope the information learned from this research study will benefit other patients with strokes in the future.

WHAT OTHER CHOICES FOR CARE ARE THERE?

The alternative to participating in this research study would be to receive standard of care medical treatment, based on your physician's discretion.

WHAT IS THE CLINICAL TRIALS REGISTRY?

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

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.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide not to participate, you do not lose any benefits to which you would otherwise be entitled. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you.

You will be told of any important new information that is learned during the course of this research study, which might affect your health, welfare or your willingness to continue participation in this study.

Nothing in this consent document waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Study center/sponsor employees and their family members do not have to be in this study. No one should influence or pressure you to be in this study. An employee's or his/her family member's decision to be in the study, or to leave the study early, will not affect the employee's job or job benefits.

WHAT IS A CERTIFICATE OF CONFIDENTIALITY?

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed and dated consent document.

You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

Any results from research related tests or assessments will not be used in your clinical care.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

There are no extra costs for you to participate in this study.

Blood tests and imaging scans that are not standard of care will not cost you anything and are paid for by the study. You will not have to pay for any study visits.

The study will provide the study medication.

Before you agree to be in this study, you should contact your health-care payer/insurer to see if your plan will cover the costs required as part of your participation. You can ask the study doctor or study staff to find out more about costs.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

If you come into the office for your day 30 and day 90 visit, you will receive $75.00 for each visit for your travel.

Compensation will be made using a reloadable debit card. The debit card will be assigned to you at the first paid study visit and used to load payments at the end of each study visit throughout your participation in this research study. Details of the system are explained on an additional information sheet. Payment will be loaded onto your debit card within two days of your visit.

If you receive payments for being a part of this research study, you will be asked to complete an Internal Revenue Service (IRS) form. The amount you receive may count as income and may affect your income taxes. Your social security number will be required to complete the IRS form.

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator. Your hospital or physician's office will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance. If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs.

You do not waive any liability rights for personal injury by signing this form.
The University of Cincinnati has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier outside of NIH StrokeNet. Your research records may be disclosed outside of the University of Cincinnati, but in this case, you will be identified by a unique code number. This information will be kept in a secure location and access limited to research study personnel. 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**.**

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

Authorization to Use Your Health Information for Research Purposes

A federal regulation known as the Privacy Rule gives you certain rights concerning the privacy of your health information. Researchers covered by this regulation are required to get your authorization (permission) to use and disclose (share with others) any health information that could identify you. You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you.

If you sign this informed consent document, you are giving permission for the use and disclosure of your health information for purposes of this research study. You do not have to give this permission. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this document. However, if you do not sign this document, you will not be able to participate in the study.

Who Will Use and Disclose My Health Information? The study doctor and research staff (the study team) may use your health information to conduct, review, and determine the results of the study. The study team may also use your information to prepare reports or publications about the study. However, your name will not appear in any report or publication without your permission.

What Health Information will be Used and Disclosed? The study team will record your medical history, the treatment you receive, and the results of examinations and tests done during the study, on study forms. The study team will send the completed study forms to the study sponsor. Representatives from the groups identified below may need to look at your medical records to make sure that the information on the study forms is correct or that the study was

conducted properly. Your medical records may include other health information about you and may include documents that directly identify you. Reviews like that will take place at the study center or where the medical records are stored and can take place after the study is over.

Who Will Receive My Health Information? Your study information or medical records (as described above) or both may be shared with the following people or groups:

- The Office for Human Research Protections (including the FDA) in the U.S. Department of Health and Human Services.
- The funders of this research, National Institute of Health and Translational Sciences, Inc.
- The representative of companies/institutions working on the study on behalf of the Sponsor may have access to, inspect and review your information during and after the study for verification of clinical and scientific research procedures and/or data.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study.
- Other collaborating institutions.
- The results of imaging studies may be disclosed to outside institutions, not directly involved in this research study, as part of a collaborative imaging project. Your name and other identifying information will not be disclosed.
- Department of Health and Human Services (DHHS) agencies, including the FDA.
- The StrokeNet Central Institutional Review Board and any other committees responsible for overseeing the research.
- StrokeNet Central Institutional Review Board Human Research Protection Program staff.
- The StrokeNet National Data Management Center (NDMC), housed in the Data Coordination Unit (DCU) in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC).

Will My Information be Protected by the Privacy Rule After it is Disclosed to Others? The University of Cincinnati, UC Health and affiliates are required by the Privacy Rule to protect your health information. After your information is shared with others, such as the study sponsor, it may no longer be protected by the Privacy Rule. The people who receive this information could use it in ways not discussed in this form and could disclose it to others. The sponsor will use and disclose your information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, the sponsor may reanalyze the study data at a later date or combine your information with information from other studies for research purposes not directly related to this

study. The goal of any such research would be to learn more about drugs, devices or diseases or to help design better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, its business partners, or companies it hires to provide research-related services.

What Happens if I Leave the Study Early? If you stop participating in the study early for any reason, the study team will tell the sponsor why. If the study team asks you to come to any more study visits and you agree, the study team will send the sponsor information from those visits as well. All information collected about you may continue to be used and disclosed.

Will My Authorization Ever Expire? This Authorization does not have an expiration date. The study team may need to correct or provide missing information about you even after your study participation is over and a review of your medical records may also take place after the study is over.

May I Take Back My Authorization? You have the right to take back (revoke) your Authorization at any time by writing to the person in charge of this research study whose information is listed on the front of this document. If you revoke your Authorization, the study team will not collect any new health information about you. However, they can continue to use and disclose any already-collected information if that is necessary for the reliability of the study. The sponsor can also still keep and use any information that it has already received. If you revoke your Authorization, you can no longer continue to participate in the study.

May I Look At My Study Information? You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you will need to wait to see your study records until the study is completed.

Future Use

Your private information and biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make medical or billing decision about you (e.g., if included in your official medical record).

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study. Please initial your selection below.

____I **want** the researcher to inform my primary care physician/specialist of my participation in this study.
____I **do not want** the researcher to inform my primary care physician/specialist of my participation in this study.
____I do not have a primary care physician/specialist.
____The researcher is my primary care physician/specialist.

Who Can Answer Your Questions?

If you have questions, concerns, complaints and or suggestions about this research study or to report a research-related injury, please contact the Principal Investigator: Yasmin Aziz, MD at 513-558-2968.

You can also call the StrokeNet CIRB at 513-558-5259, Monday-Friday 8AM--5PM EST if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.
- Have questions, concerns, complaints and/or suggestions about the research, cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

Investigator Information:

Eva A. Mistry, MBBS, MSCI
Principal Investigator Name

University of Cincinnati
Local Site Name

Yasmin Aziz, MD 513-688-5405
Local Principal Investigator Name Telephone Number 24 hr. Emergency Contact

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. If I do not participate or if I discontinue my participation, I will not lose any benefits or any legal rights. My participation in this research is completely voluntary. I have received (or will receive) a copy of this signed and dated document for my records and future reference. I have been given the information about the use and disclosure of my health information for this research study.

I give my consent to participate.

_____ _____
Name of Participant (PRINT) Date

_____
Signature of Participant (18 or older with capacity to consent)

Or

_____ _____
Signature of Legally Authorized Representative Date

_____ _____
Print Name of Legally Authorized Representative Relationship to Participant

Person Obtaining Consent

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the participant has been provided with the Experimental Subject's Bill of Rights, if appropriate, that I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent document, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____ _____
Signature of Person Obtaining Consent Date

_____
Name of Person Obtaining Consent (PRINT)

The following witness line is to be signed only if the consent is provided as a summary document and accompanied by a short form foreign language consent.

The following witness line is to be signed only if the consent is provided as a summary document and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Name of Witness (PRINT)

WITNESS STATEMENT:

The participant or LAR is unable to read or sign this consent document because of the following reason(s). Please mark the appropriate response(s):
___The participant or LAR is non-English speaking.
___The participant or LAR is illiterate.
___The participant or LAR is visually impaired.
___The participant or LAR is physically unable to sign the consent document. Please describe: _____
___ Other (please specify): _____

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

_____ _____
Signature of Impartial Witness Date
(may be interpreter if participant/LAR is non-English speaking)

_____
Name of Impartial Witness (PRINT)