CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Sponsor / Study Title:	**Hamilton Health Sciences Corporation through its Population Health Research Institute / "EdoxabaN foR IntraCranial Hemorrhage survivors with Atrial Fibrillation (ENRICH-AF)"**
Protocol Number:	**ENRICH-AF**
Principal Investigator: (Study Doctor)	Qingyang Yuan, MD
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This form is for use in a research study that may involve participants who may or may not have the capacity to consent to take part in the study. When the participant cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the participant rather than the person (legally authorized representative) who is signing this form for the participant. In cases where the participant's representative gives consent, the participant should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the participant regains the capacity to consent, informed consent will be obtained from the participant and the participant offered the ability to leave the study if desired.

INTRODUCTION

You are being invited to participate in a clinical trial (a type of study that involves research). You are invited to participate in this trial because:

i) You have an abnormal heart rhythm, called atrial fibrillation, that puts you at high risk for blood clot formation and stroke, and

ii) You have suffered a previous bleeding in the head (within or around the brain), called an intracranial hemorrhage.

This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study. Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

To ensure your safety during a pandemic, you may be provided with the option of remote consent and/or study visits. Research personnel will contact you using BlueJeans, a videoconferencing system, for health care professionals to review the consent form in detail, to address your questions, and to collect necessary data for this research.

The following sections will discuss the requirements of this study and the details of your role as a participant. The study doctor or study staff will answer any questions that you may have about this form and about the study.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive outside the study.

WHY IS THIS STUDY BEING DONE?

The standard or usual treatment for patients who have had an intracranial hemorrhage and who have atrial fibrillation is uncertain. It can include either no medical treatment, use of a single agent antiplatelet (such as aspirin or Clopidogrel), or anticoagulation (drug that slows blood clotting), depending on your individual medical history.

The main purpose of this study is to find out if the use of edoxaban, a drug that slows blood clotting, in people like you reduces the risk of a stroke compared to other treatments that avoid using drugs that slow blood clotting like edoxaban.

Persons with atrial fibrillation have a high risk (about 1 chance in 15 each year) of stroke because of blood clots forming in the heart that are pumped to the brain where they block blood flow, resulting in brain cells dying. Drugs that slow blood clotting (which are called anticoagulant drugs) are widely used to prevent clots from forming and to reduce the chance of having a stroke in persons with atrial fibrillation. They carry a small (about 1 chance in 400 to 1000 each year) risk for causing bleeding in the head. For most people with atrial fibrillation, the large benefit of preventing stroke by decreasing the chance of blood clot formation is much more than the harm caused by bleeding into the head.

However, using anticoagulant drugs in persons who have had prior bleeding in the head (as you have had) has not been researched enough to know if it is beneficial overall or not.

In patients with atrial fibrillation and previous bleeding into the head, some physicians currently recommend aspirin or similar drugs that belong to a group called antiplatelet drugs due to their low risk of bleeding, despite that they are much less effective for preventing clots as compared to anticoagulants. Other physicians may recommend no drugs to slow blood clotting at all (meaning neither anticoagulation nor aspirin or similar drugs).

Edoxaban, a new generation direct oral anticoagulant, is a possible treatment option in such cases, as it has been shown to be highly effective for blood clot prevention and is associated with low rates for bleeding in the head (occurring in 4 out of 1,000 patients per year). Edoxaban is approved for use in the USA and recommended for the prevention of stroke in patients with atrial fibrillation. However, edoxaban has never been previously tested in individuals who have suffered bleeding in the head. This study will help us to discover if edoxaban is beneficial overall in people like you.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to receive treatment or care. You can receive any of the treatments being used in this study without taking part in the study, if you meet the

requirements for the treatment. Other options (in addition to the standard or usual treatment described above) may include, but are not limited to:

- no therapy at this time
- other research studies may be available if you do not take part in this study
- surgical procedures (left atrial appendage closure)

Please talk to your usual doctor or the study doctor about the known benefits and risks of these other options before you decide to take part in this study. Your usual doctor or the study doctor can also discuss with you what will happen if you decide not to undertake any treatment at this time.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

The study will enroll 1200 participants like you from approximately 20 countries across North and South America, Europe and Asia.

WHAT WILL HAPPEN DURING THIS STUDY?

This type of study is called a "randomized clinical trial." If you decide to participate in this study, you will be assigned to one of two groups randomly (like flipping a coin). There will be a 50% chance of being assigned to receive edoxaban and a 50% chance of being assigned to non-anticoagulant medical therapy (no specific therapy for the prevention of blood clots, or therapy with aspirin or another antiplatelet drug). Both you and your study doctor will know which group you are assigned to.

For those participants who are assigned to receive edoxaban, within 19 days of their stroke, they will have 50% chance of being assigned to early study treatment (14-19 days) or 50% chance of being assigned to delayed study treatment (28-33 days) initiation. This time will be calculated from the date of the previous bleeding in your head. The study doctor will explain to you when you should start taking your first dose of study drug.

Should you be assigned to the edoxaban group, the study doctor will determine the dose of edoxaban to be used in your case (60 mg or 30 mg once daily, determined by your kidney function, body weight and use of certain medications). They will also determine when you should start taking edoxaban.

Non-anticoagulant medical therapy may include either no study treatment or use of a single agent antiplatelet. There are a number of possible drugs you could receive depending on your medical condition. These might include aspirin or drugs like Clopidogrel. Your study doctor will discuss the best choice for you. If you have side effects while you are in this study, the study doctor may make changes to the study treatment.

WHAT ARE THE STUDY PROCEDURES?

Clinical Laboratory Assessments:

Local laboratory results performed for eligibility and relevant standard of care results will be collected on case report forms. During follow-up, your kidney function will be monitored at least once every 12 months, or more frequently if needed based on your particular kidney function. Your study doctor can use their judgement to determine if any additional follow up laboratory testing is required.

Questionnaires:

You will be given the Montreal Cognitive Assessment (MoCA) to assess your cognitive ability with respect to attention, concentration, memory, language and many other areas. The test will be administered at randomization, the 12-month visit and at the end of the study. Each questionnaire will take about 15-20 minutes to complete. The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

Brain Magnetic Resonance Imaging (MRI) Sub-Study:

If your study site is participating in the MRI substudy you may have an MRI, which is a test that uses a magnetic field and pulses of radiowave energy to make pictures or organs and structures inside the body. The substudy will use MRI scans to look for evidence of recent or old bleeding from the very small blood vessels in the brain (cerebral microbleeds) and see if this is associated with any change in the effects of treatment with edoxaban or non-anticoagulant medical therapy.

<u>WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?</u>

You will be asked to complete the following procedures while in the study. Some of these tests/procedures may be done as part of your standard care, in which case the results may be used. Some of these tests may be done more frequently than if you were not taking part in this study and some may be done only for the purpose of the study. If the results show that you are not able to continue participating, the study doctor(s) will let you know.

1. Screening/baseline visit
    - ✓ Sign and date the informed consent form
    - ✓ Provide your medical history along with demographics (such as age, gender) and physical (such as weight, height) information
    - ✓ Review of your clinical bloodwork and request for new blood collection if needed
    - ✓ Have your blood pressure and heart rate measured

2. Randomization visit (may be the same day or different day as screening/baseline visit)
    - ✓ You will be randomly assigned to either edoxaban or non-anticoagulant medical therapy. If you are randomly assigned to take edoxaban, and the visit is completed by BlueJeans , the study medication will be sent to you by bonded courier (e.g. UPS, FedEx, etc.).
    - ✓ Complete questionnaires that assess different brain functions

3. Follow up visits (you will visit your study doctor every 6 months)
    - ✓ Inform your study doctor or study nurse of any hospitalizations and/or other significant illnesses
    - ✓ Collect vital signs (such as blood pressure, heart rate)
    - ✓ Changes in your medications
    - ✓ If you were given edoxaban, return packaging
    - ✓ Complete questionnaires (12-month visit only)
    - ✓ Blood collection for kidney function at least every 12 months

4. End of study visit (you will be asked to come in for a final visit at the end of the study)
    - ✓ Inform your study doctor or study nurse of any hospitalizations and/or other significant illnesses
    - ✓ Collect vital signs (such as blood pressure, heart rate)

- ✓ Changes in your medications
- ✓ Complete questionnaires that assess different brain functions
- ✓ If you were given edoxaban, return packaging (edoxaban will not be provided to you after your participation in the study ends)
- ✓ Determine the treatment plan appropriate for your medical condition
- ✓ Follow-up visits (you will visit your study doctor every 6 months)

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

After randomization, you will be asked to come back to the study doctor's office every 6 months for resupply of the study treatment. We expect you to be in the study for approximately 3 years.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

Your participation in this study is voluntary. Your decision not to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

You may choose to be withdrawn from the study after providing consent **for any reason**.

However, even if you decide not to participate in the study anymore, the information about you that was collected as part of the research project between the date you signed and dated this form and the date you withdraw your consent may still be used, to protect the quality of the research results. No new information about you will be collected and used. If you withdraw, we may ask your permission to contact you or additional contact to find out about your health at the end of the study even if you have decided not to continue participation.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study doctor may stop your participation in the study early without your consent for reasons such as:

- The study intervention does not work for you
- You are unable to tolerate the study intervention
- You are unable to complete all required study procedures
- New information shows that the study intervention is no longer in your best interest
- The study doctor no longer feels this is the best option for you
- The Sponsor decides to stop the study
- The Regulatory Authority/ies (for example, the United States Food and Drug Administration [FDA]) or research ethics board withdraw permission for this study to continue
- If you plan to or become pregnant

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form.

If you are removed from this study, the study doctor will discuss the reasons with you and plans will be made for your continued care outside of the study.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not expected. All precautions will be taken to avoid this. Both edoxaban and aspirin (or another antiplatelet drug) can cause bleeding, while the risk for bleeding in the head appears to be similar.

Risk associated with Edoxaban:

Edoxaban is an anticoagulant, which is the medical term for a blood-thinning agent. Anticoagulants slow down clotting and prevent clots from forming and growing, meaning you may bleed more. Bleeding can occur at any site and may be severe, life-threatening, and even fatal. Minor bleeds (for example, nosebleeds, bleeding gums, bleeding from the digestive tract, genitourinary tract, or bruising) while on edoxaban are common, affecting approximately 10-13% of people per year. Edoxaban has not been previously tested in a trial in participants with prior bleeding in the head. In those with atrial fibrillation but without prior bleed in the head, edoxaban was shown to be associated with a bleed in the head in 3-4 in 1,000 participants per year. It is not known if this risk of bleed in the head is higher in participants with atrial fibrillation with prior bleed in the head.

Direct-acting Oral Anticoagulants (DOACs), including edoxaban, are not recommended for people with a history of thrombosis who are diagnosed with **antiphospholipid syndrome**. In particular, for participants that are triple positive (for lupus anticoagulant, anticardiolipin antibodies, and anti-beta 2-glycoprotein I antibodies), study treatment with DOACs could be associated with increased rates of recurrent thrombotic events compared with vitamin K antagonist therapy. You would not be eligible for this study if your study doctor determines that you have antiphospholipid antibody syndrome.

Risks associated with Aspirin (and other antiplatelet agents):

Aspirin belongs to a group of drugs called antiplatelets. These slow down clotting and prevent clots from forming and growing in a way that is different from edoxaban's mechanism of action. As a result, you may bleed more, from any site. This could result in minor bleeds (nosebleeds, bleeding gums, small amount of blood in the urine or stool, or bruising) or major bleeds (including bleeding in the head). Bleeding can occur at any site and may be severe, life-threatening, and even fatal.

Bleeding while on aspirin is common. In a study in high-risk participants with atrial fibrillation, aspirin (at common dosages) was shown to be associated with non-major bleeding in 7-8% of participants per year. In this study, bleeding in the head while on aspirin occurred in 4 out of 1,000 participants per year. In participants with prior bleeding in the head, aspirin (and other antiplatelet agents) did not increase the risk of another bleed in the head compared to participants not taking any drugs that slow blood clotting. The risk of another bleed in the head was 2 out of 100 participants per year.

Common side effects and other reactions to aspirin (occurring in up to 1 in 10 participants) include:

- Abdominal pain
- Nausea
- Upset stomach
- Heartburn

In case of a life-threatening bleeding, there is no antidote available. If bleeding occurs during study treatment with aspirin, it is necessary to wait until the blood-thinning effects of aspirin wear off (may take approximately 5 days), or blood product transfusion may be necessary.

These could include intravenous infusion of clotting-factors in the form of clot-promoting cells (platelet transfusion).

You should call the study doctor if you have signs and symptoms of clinically significant bleeding, for example:

- Bleeding (such as nose or gum bleeding) that does not stop within 10 minutes
- Coughing or throwing up blood
- Dark-colored urine or black stools
- Red or black-and-blue marks on the skin that get larger

Risks associated with blood draws:

You may have pain or bruising at the site where the blood is drawn. You may feel faint. An infection at the site of the blood draw is possible.

Risks of allergic reactions:

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms.

Risks associated with MRI Scans:

There are no known long-term effects from having MRIs. MRI machines use strong magnets to take images of your brain. If you have an implanted pacemaker or other metal device, you are not able to go in the MRI machine. There is a questionnaire that you will be asked to complete to ensure that you are safe to go into the MRI machine. A very small minority (less than 1%) of participants will experience mild tingling, muscle twitching, or claustrophobia. The MRI machine can be quite noisy as the images are acquired, but you will be given earplugs.

Reproductive Risks:

Since the effects that edoxaban may have on an unborn child are not known, you should not become pregnant or father a child while participating in this study.

Post-menopausal female participants must not have had their periods for at least 12 months prior to screening or at least 6 weeks post-surgical bilateral oophorectomy (with or without hysterectomy) prior to screening. Women of childbearing potential must have a negative serum pregnancy test within 7 days prior to randomization or urine pregnancy testing within 24 hours of randomization.

An effective method to avoid pregnancy should be used while you are receiving study treatment, such as hormonal contraceptives, intrauterine devices, spermicide and barrier, or abstinence. Ask your study doctor about counseling and more information about preventing pregnancy during your participation. Pregnant and breastfeeding women are excluded from this study.

Heterosexually active women of childbearing potential must use highly effective methods of contraception for 32 days after discontinuation (duration of study drug plus 30 days duration of one ovulatory cycle).

If you are female and become pregnant while on this study, you should notify your study doctor immediately. The study doctor will want to follow your pregnancy and record its outcome.

If you are male and your female partner becomes pregnant while you are on this study, you should notify your study doctor immediately. The study doctor may want to ask your partner for her permission to follow the pregnancy and record its outcome.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no guaranteed direct medical benefits to you from participating in this study. To date, there is no scientific evidence that edoxaban has a clear net benefit (as determined by reduction of stroke risk at the cost an increased bleeding rate) as compared to aspirin or no therapy in individuals with high-risk atrial fibrillation and prior bleeding in the head (within or around the brain). We hope that the information we get from doing this study could potentially benefit patients in the future and may improve knowledge in the treatment of this group of patients.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

All information related to this research study will remain confidential and to the extent permitted by applicable laws and/or regulations and will not be made publicly available. Data (information) derived from this study will be used for research purposes. Your personal data/special categories of personal data (such as your name, address, date of birth, age, sex, ethnic background, etc.) and data about your health (such as past medical history, hospital records, operative reports, immunization, allergy reports, clinic notes, your study treatment and your response to study treatment, etc.) will be collected, used and stored for this study.

The collection, use, and storage of your data is required to answer the questions asked in this study and to publish the results. We ask your permission for the use of your data. Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Hamilton Health Sciences through its Population Health Research Institute (PHRI), the Sponsor of this study
- Anyone who has been hired by the sponsor (for example, controller/monitor)
- Advarra Institutional Review Board (IRB), who oversees the ethical conduct of this study
- The study site and affiliated sites, to oversee the conduct of research at this location
- The United States Food and Drug Administration (FDA)

Information that is collected about you for the study (called study data) may also be sent to the organizations list above.

Any information that leaves the study site will be de-identified (identifying information will be removed from the documents). In addition, the results of the study will be reported to the sponsor, the FDA and perhaps to other regulatory agencies. In the event of any presentation or publication regarding this study, your identity will remain confidential. Your de-identified

information and results will be archived by the study doctor and sponsor as per applicable laws and/or regulations.

By signing and dating this informed consent form, you agree to such inspection and disclosure.

With your permission, the study doctor will notify your general practitioner or primary care physician about the study so that if you need to see him/her for any reason he/she is aware you are taking/using a study drug.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor/health care provider will/may be informed that you are taking part in a study so that you can be provided with appropriate medical care. If you do not want your family doctor/health care provider to be informed, please discuss this with the study team.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

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.

Information on this study will also be posted in a similar format on a European Web site at http://www.clinicaltrialsregister.eu.

WHAT IS THE COST TO PARTICIPANTS?

You are not responsible for any costs for the required study visits, examinations, procedures or the cost of edoxaban.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will receive a parking pass for your onsite study visits to cover the cost of parking.

WHAT IF I AM INJURED DURING THIS RESEARCH STUDY?

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured, then they will help you get the care you need.

If you are injured as a result of taking the study drug(s) or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third-party coverage.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

By signing and dating the consent form, you do not waive your legal rights and you do not release the study doctor, the study site, the sponsor or their representatives from legal responsibility of negligence.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information.

WHOM TO CONTACT ABOUT THIS STUDY?

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

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

- By mail:
  Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00041777.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the

information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

CONSENT

By signing and dating this form, I have agreed to be a participant in the medical research study described in this form, to be carried out under the supervision of the study doctor.

I have read the informed consent document for this study. I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the study and what I will be expected to do. I have been given enough time to ask questions about the study and to decide whether or not to participate. My questions have been answered satisfactorily.

I agree to take part in this study. I agree to cooperate fully with the study doctor and will contact him/her immediately if I suffer any unexpected or unusual symptoms during the trial.

I understand that my participation in the trial is voluntary and that I may refuse to participate or may withdraw from the trial at any time, without penalty or loss of benefits to which I am otherwise entitled.

I agree that the results of the study may be passed on to the appropriate authorities and to the sponsor. Encoded data (as detailed in this information and consent form) about me could be transferred to or handled in countries other than my own. In such cases appropriate safety measures will be taken in order to protect my data privacy rights. My name and address will be kept confidential. The study doctor and study staff, representatives of the sponsor, research ethics board, or local or foreign regulatory authorities will be granted direct access to my medical records and other records relating to this study to verify the information collected. My results will be archived by the study doctor and sponsor as per applicable laws and/or regulations. By signing and dating this document, I give permission for this review of my records, passing on of my information to the sponsor and the appropriate authorities, and storage of my information.

I understand that I will receive a signed and dated copy of this informed consent.

Participant name (printed)	Signature	Date: (DD MMM YYYY) and Time (24 hr. clock)
Legally Authorized Representative's name (printed)	Signature	Date: (DD MMM YYYY) and Time (24 hr. clock)

*If signed and dated by a legally authorized representative; state the relationship and identify below the authority to act on the individual's behalf.

***Legal Authority:**

☐ Parent

☐ Power of Attorney Healthcare

☐ Authorized Legal Representative

☐ Other:_____

I, the undersigned, acknowledge having provided all the necessary information for comprehension of this protocol to the individual mentioned above.

Name of person authorized to obtain consent (printed)	Signature	Date: (DD MMM YYYY) and Time (24 hr. clock)

I, the undersigned, acknowledge that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the participant or the participant's legally acceptable representative, and that informed consent was freely given by the participant or the participant's legally acceptable representative.

Name of witness (printed)	Signature	Date: (DD MMM YYYY) and Time (24 hr. clock)

Please note: More information regarding the assistance provided during the consent process should be noted in the medical record for the participant if applicable, as well as noting the role or relationship of the impartial witness.