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CONSENT FOR RESEARCH
Penn State College of Medicine
Penn State Health

Title of Project:	Pioglitazone Treatment for Hyperglycemic Acute Ischemic Stroke: Effects on the Stress-Immune Response
Principal Investigator:	Kerstin Bettermann, MD
Address:	30 Hope Drive, Suite 1300, Building B, Hershey, PA 17033
Telephone Numbers:	Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-1803. After hours call (717) 531-8521. Ask for the Neurology doctor on 24-hour call.

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

Some of the people who are eligible to take part in this research study may not be able to give consent to take part because of their medical condition. Instead we will ask the person's legally authorized representative to give consent. Throughout the consent form, "you" always refers to the person who takes part in the research study.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?

We are asking you to take part in this voluntary research study because you have had an acute ischemic stroke (AIS) in the past 18 hours and also your blood glucose (sugar) was greater than 150 at the time of hospitalization. AIS is the sudden loss of blood circulation to an area of the brain, which leads to the loss of neurologic functions (such as loss of movement, speech, vision, comprehension, etc.).

What is the purpose of this research study?

This research is being done to find out whether the study drug, Pioglitazone (commonly known as Actos), can improve recovery in acute ischemic stroke (AIS) patients with diabetes or high blood sugar.

How long will the research study last?

The study will last about 3 months and will require 1 follow-up visit to the clinic or over the telephone.

What will I need to do?
You will need to take a capsule by mouth (oral) once a day for 3 days. This capsule will either contain the study drug or a placebo, depending on which you are randomized to. You will perform some research-only neurological assessments and have blood drawn just for the study.

What are the main risks of taking part in the study?
For this study, the main risks to know about are the possible side effects of the study drug, including:

- hypoglycemia (low blood sugar)
- cold-like symptoms
- swelling (edema)
- liver dysfunction (with long-term use)
- congestive heart failure (unlikely due to the short study timeframe)
- bladder cancer (with long-term use)

What are the possible benefits to me that may reasonably be expected from being in the research?
There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include an infection reduction, which could reduce brain injury following you stroke. You may also feel an improvement in your short- and long- term symptoms and day-to-day function. Results of the study may benefit other people in the future by guiding the future treatment of stroke in patients with diabetes and/or high blood glucose levels after stroke.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You can decide to participate or not to participate.

Instead of being in this research study, your choices may include:

- Receive commercially available treatments, including standard of care treatment.
- Be part of a different research study, if one is available.
- Choose not to be treated for your medical condition.

DETAILED INFORMATION
The following is more detailed information about this study in addition to the information listed above.

1. Why is this research study being done?
This research is being done to find out whether the study drug, Pioglitazone (ACTOS), can improve recovery in acute ischemic stroke (AIS) patients with diabetes or high blood sugar.

Patients with high blood sugar levels are at a higher risk for poor outcome after a stroke, compared to patients who are not diabetic or not have high blood sugar levels. The reason for this is unclear. It may be that after a stroke, the body's defenses mechanisms in patients with high blood sugar are suppressed, resulting in more brain swelling, infections, and brain damage. In this study, we will be giving a medication that lowers blood sugar (Pioglitazone) to try and improve the body's defense mechanisms. We hope that the study drug might reduce the brain damage following a stroke by protecting the brain from stress and inflammation.

The study drug, Pioglitazone (ACTOS), is approved by the Food and Drug Administration (FDA for the treatment of type 2 diabetes. Pioglitazone is an oral tablet that has been used with diet and exercise to improve blood sugar control in adults with type 2 diabetes. The study drug is currently not

approved in the United States to specifically treat stroke, and therefore treatment with Pioglitazone in AIS is therefore considered "experimental."

Approximately 50 people will take part in this research study at Hershey Medical Center.

2. What will happen in this research study?

Prior to performing any study-related activities, we will obtain written informed consent from you. After obtaining written consent, data will be collected from your medical record for research purposes.

Once you have signed the consent form, we will randomize you to receive either the study medication (Pioglitazone) or placebo (looks like the drug, but no active medicine). You will be assigned by chance (like tossing a coin). You will have an equal chance of receiving placebo or study drug. Neither you nor the research team will know which study treatment you are receiving, but the research team will be able to get this information quickly if it is needed to ensure your safety.

Baseline

As part of routine, standard of care, a physical and neurological examination will be performed and your medical history will be taken.

Before starting your drug treatment, the following **research only** activities will be performed**.**

- Neurological assessments (a combination of observations and questionnaires), will be performed, by the research team. These may take 15 minutes to perform:
  - **Barthel index (BI).** This measures your performance in activities of daily living.
  - **Glasgow Outcome Scale (GOS).** This rates a patient's status after stroke on a scale of 1-5.
  - **Montreal Cognitive Assessment (MOCA).** This measures different parts of your thinking skills, such as attention and concentration, memory, language, etc.
- We will draw about 3 teaspoons of blood for laboratory testing, including tests of your liver function.

Study drug/placebo administration

You will be given the study drug or placebo within 18 hours of the start of your stroke or last known well time. Both groups (study drug and placebo) will receive an oral (by mouth) capsule every 24 hours for 3 days for a total of 3 doses. If you are unable to swallow the capsule, it will be given to you via your feeding tube.

Your blood glucose (sugar) level will be measured by a finger stick 2 hours after your first capsule and then at regular points as determined by the standard of care protocol for stroke patients.

Day 1 (24 +/- 2 hours from taking your 1st oral capsule)

Before receiving your drug treatment, the following **research only** activities will be performed**.**

- Any adverse events will be documented
- Any other medications that you are taking will be documented
- About 2 teaspoons of blood will be taken for laboratory tests and biomarkers.

You will then be given your second oral capsule.

Day 2 (24 +/- 2 hours from taking your 2nd oral capsule)

Before receiving your drug treatment, the following **research only** activities will be performed**.**

- Any adverse events will be documented

- Any other medications that you are taking will be documented
- About 3 teaspoons of blood will be taken for laboratory testing tests and biomarkers.
    - We will check your liver function blood results prior to capsule administration

You will then be given your third (and final) oral capsule.

Day 3 (24 +/- 2 hours from taking your 3rd oral capsule)
At this visit the following **research only** activities will be performed**.**

- Any adverse events will be documented
- Any other medications that you are taking will be documented
- About 2 teaspoons of blood will be taken for laboratory tests and biomarkers.

Discharge Day (this will occur when you are discharged from the hospital)
A routine, standard of care physical and neurological examination will be performed and the following neurological tests will be conducted:

- National Institutes of Health Stroke Scale (NIHSS): a tool used to quantify the impairment caused by a stroke
- Modified Rankin Scale (mRS): measures the degree of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability

The following **research only** activities will be performed**.**

- Neurological assessments will be performed:
    - Barthel index (BI)
    - Glasgow Outcome Scale (GOS)
    - Montreal Cognitive Assessment (MOCA)
- Any adverse events will be documented
- Any other medications that you are taking will be documented

Day 90 (+/- 30 days) post-discharge visit
(will be done at your routine clinic visit or by phone if you cannot travel to the clinic))
A routine, standard of care physical and neurological examination will be performed and the following neurological tests will be conducted:

- National Institutes of Health Stroke Scale (NIHSS): a tool used to quantify the impairment caused by a stroke
- Modified Rankin Scale (mRS): measures the degree of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability

The following **research only** activities will be performed**.**

- Neurological assessments will be performed:
    - Barthel index (BI)
    - Glasgow Outcome Scale (GOS)
    - Montreal Cognitive Assessment (MOCA)
- Any adverse events will be documented
- Any other medications that you are taking will be documented

Schedule of Study Activities

	Baseline (0-18h from symptom onset)	**Day 1:** 24+/-2h after first dose of study drug/ placebo	**Day 2:** 24+/-2h after second dose of study drug/ placebo	**Day 3:** 24+/-2h after third dose of study drug/ placebo	**Discharge**	**Day 90:** ± 30 days follow-up visit
Screening/Enrollment	X					
Informed consent	X					
Administration of study drug or placebo	X	X	X			
Clinical scales: NIHSS, mRS, BI, GOS, MOCA	X				X	X
Blood for laboratory tests and biomarkers	X (pre-treatment)	X (pre-treatment)	X (pre-treatment)	X		
Liver function test	X (pre-treatment)		X (pre-treatment)			
Medical history	X (pre-treatment)					
Physical and neurological examination	X (pre-treatment)				X	X
AEs and concomitant Medications		X	X	X	X	X
Blood glucose assessment via finger stick	X*					

BI = Barthel Index; GOS = Glasgow Outcome Scale; MOCA = Montreal Cognitive Assessment: mRS = modified Rankin Scale; NIHSS = NIH Stroke Scale

*finger stick glucose measurements will be performed 2h after initial study drug administration (time of peak of pioglitazone concentration) and subsequently at regular time points as determined by the standard of care protocol for stroke patients.

What are my responsibilities if I take part in this research?
If you take part in this research, your major responsibilities will include:

- Participating in the above outlined study visits.
- For your safety, you must tell the study doctor or nurse about all the prescription drugs, herbal products, over-the-counter drugs (OTC), vitamins and other supplements you are taking. Check with the study doctor before starting any new medicines (including prescription, OTC drugs, vitamins and herbal supplements) or changing doses of medications that you are already taking.

3. What are the risks and possible discomforts from being in this research study?
There are risks to being in any research study. One risk is that you may get a study drug or dose of a study drug that does not help treat your disease or the study drug may make your disease worse.

Another risk is that there may be side effects that are currently unknown or that are unpredictable. All the side effects of Pioglitazone are not known. The effects of Pioglitazone when combined with other medicines or substances, such as alcohol, may not be fully known.

As with all medicines, Pioglitazone can cause side effects, although not everybody gets them. Not all side effects are known, so you may experience side effects that are not listed below

S**ide effects of ACTOS include**:

- Hypoglycemia (low blood sugar): symptoms of low blood sugar can vary from person to person. Possible symptoms of low blood sugar which are not specific to treatment with Pioglitazone, may include the following. Tell your study doctor immediately if you experience any of these symptoms.
    - weakness
    - trembling
    - feeling faint
    - a fast heartbeat/heart (palpitations)
    - confusion/disorientation
    - and in rare circumstances, coma
- Cold-like symptoms: such as:
    - headache
    - sinus infection
    - muscle pain
    - sore throat
- Swelling (edema): caused by excess fluid trapped in your body's tissues. Dose-related swelling may occur following long-term treatment with Pioglitazone. However, in this study only 3 doses are given therefore swelling is unlikely to occur, would be temporary, and would not cause a risk to you.
- Liver dysfunction: long-term Pioglitazone treatment may cause the following, although these are unlikely to occur during the short treatment time in this study:
    - liver dysfunction
    - nausea
    - vomiting
    - stomach pain
    - unusual or unexplained tiredness
    - loss of appetite
    - dark urine or jaundice

- Congestive heart failure: fluid retention may occur and can worsen or lead to congestive heart failure, although this is unlikely to occur during the short treatment time in this study.
- Bladder cancer: Long term use of Pioglitazone may increase the risk of bladder cancer. Patients with active bladder cancer or history of bladder cancer will therefore not be included in this study

Everyone in the study will be watched carefully for any side effects, and the study medication may be stopped if it is not tolerated or if concerning side effects develop. You should talk to your study doctor about any side effects you have while in the study. If you suffer any of these side effects (or any others not listed) or you think you are experiencing a side effect, during this study, please tell your study doctor immediately. Any side effects or other health issues occurring during the study will be followed up by the study doctor.

Risks associated with study procedures

- Risk of randomization in clinical trials: You will be assigned to a treatment program by chance. The treatment you receive may prove to be less effective or to have more side effects than the other research treatment(s) or other available treatments. If you are in the group that receives the placebo, your symptoms may get worse. Both study drug and placebo groups will receive unaltered standard of care.
- Blood samples: Taking blood may cause discomfort, bruising and, very rarely, infection where the needle goes into your skin. You may also experience dizziness, nausea, or fainting during blood taking. If you do not feel well while blood is being taken from you or after it has been taken, please tell the study doctor or a member of the study team.

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

You may or may not benefit from taking part in this study. There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include an infection reduction, which could reduce brain injury following your stroke. You may also feel an improvement in your short- and long- term symptoms and day-to-day function.

4b. What are the possible benefits to others?

The results we get from this study may guide the future treatment of stroke in patients with diabetes and/or high blood glucose levels after stroke.

5. What other options are available instead of being in this research study?

You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

- Receive commercially available treatments, including standard of care treatment.
- Be part of a different research study, if one is available.
- Choose not to be treated for your medical condition.

Before you decide if you want to be in this research, we will discuss the other choices that are available to you. We will tell you about the possible benefits and risks of these choices.

Because it is investigational, the therapy offered in this research is only available to you if you take part in the research study.

6. How long will I take part in this research study?
If you agree to take part, it will take you about 3 months to complete this research study. You will be asked to visit the research site 1 time for a follow-up visit. This will be conducted by phone if you are unable to travel to the clinic.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?
7a. What happens to the information collected for the research?
Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

In our research files at Penn State Health (PSH) and Penn State College of Medicine (PSU) we will include these identifiers: your name, address, phone number, date of birth, medical record number, and a code number.

- A list that matches your name with your code number will be kept in a locked file in Dr. Bettermann's office
- Your research records will be labeled with your code number and your initials and will be kept in a safe area in Dr Bettermann's research office.
- A copy of this signed consent form will be included in your PSH medical record. This means that other PSH healthcare providers will know you are in this study.
- Your research samples will be labeled with a code number and will be stored in the Dr. Bettermann's lab in the Department of Neural and Behavioral Sciences.
- Results of some of the research-related clinical tests (including but not limited to some laboratory blood results) will be kept in your PSH medical record.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. What will happen to my research information and/or samples after the study is completed?
We may use your research information and your biological samples in future studies or may share your information or biological samples with other investigators for future research without your additional informed consent. Before we use or share your information or samples we will remove any information that shows your identity.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will contact you to let you know what they have found.

7c. How will my identifiable health information be used?
In general, under federal law (including the Health Insurance Portability and Accountability Act – HIPAA or privacy laws) your health information is private. By signing this form, you are authorizing us to collect, use,

and disclose your identifiable health information, sometimes referred to as "Protected Health Information" or "PHI" under HIPAA, for the purposes of this research study. We will use and disclose your information only as described in this form, in the PSH Privacy Notice, and as may be required or allowed under the applicable privacy laws.

The research team may use the following health information:

- Past, present, and future medical records, including identifiable information
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- PSH/PSU research staff involved in this study
- The PSH/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The PSH/PSU Human Subjects Protection Office
- The PSH/PSU Research Quality Assurance Office
- Non-research staff within PSH/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Organizations that provide independent accreditation and oversight of hospitals and research
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- The PSH/PSU pharmacy

These groups may also review and/or copy your original PSH/PSU records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable health information and samples may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

We may remove identifying information from your protected health information. Once we do this, the remaining information will not be subject to the privacy laws. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.
Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- The study drug (Pioglitazone) or placebo will be provided by the study at no cost to you while you take part in this study.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
- The research-related tests and procedures that will be provided at no cost to you include:
    - Blood laboratory and biomarker testing done only for the research study
    - Neurological assessments performed only for the research study (BI, GOS, and MOCA)

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you

believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment. You should also let any health care provider who treats you know that you are in a research study.

PSH/PSU compensation for injury

- There are no plans for PSH/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?

You will not receive any payment or compensation for being in this research study.

It is possible that your research information and/or specimens (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

10. Who is paying for this research study?

Funds from the Penn State Clinical and Translational Science Institute will be used to support this research.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect medical information from your routine medical care.

If you agree, this data will be handled the same as research data. If you withdraw completely from the research study, no further information will be collected and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled.

Your research doctor may take you out of the research study without your permission.

- Some possible reasons for this are:
  - continuing the research would be harmful
  - your condition has become worse,
  - you did not follow the instructions of the study doctor
  - you experience serious side effects
- Also, the Principal Investigator of the research may end the research study early.

- If your participation ends early, you may be asked to visit the research doctor for a final visit.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?
Please call the head of the research study (principal investigator), Dr. Kerstin Bettermann at (717) 531-1803 or the Neurology doctor on 24-hour call at (717) 531-8521 if you:

- Have questions, complaints or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the research protection advocate in the PSH Human Subjects Protection Office (HSPO) at (717) 531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the Penn State College of Medicine's Clinical Research web site at http://med.psu.edu/clinical-research/faqs for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

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.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization
Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject
By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name

Subject's Legally Authorized Representative
By signing below, you indicate that you give permission for the subject to be in this research and authorize the subject's information to be used and shared as described above.

_____
Printed name of subject

_____	_____	_____	_____
Signature of Legally Authorized Representative	Date	Time	Printed Name

Check the applicable box below indicating authority to act for subject:
☐ Court-appointed legal guardian
☐ Health Care Power of Attorney
☐ Health Care Representative: _____
Relationship to Subject

ASSENT FOR RESEARCH

The research study has been explained to you. You have had a chance to ask questions to help you understand what will happen in this research.

You Do Not have to be in the research study. If you agree to participate and later change your mind, you can tell the researchers, and the research will be stopped.

You have decided: **(Initial one)** ___ To take part in the research.
___ NOT to take part in the research.

_____	_____	_____
Signature of subject	Date	Printed Name

OR

☐ Assent not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Witness to Consent for Limited English Speaking Subjects (Using a "Short Form" written in the subject's own language)

Witness Statement: As someone who understands both English and the language spoken by the subject or subject representative, your signature indicates that the English version of the consent form was presented orally in the language of the subject or subject representative, and that the subject or subject representative was given the opportunity to ask questions.

_____	_____	_____	_____
Witness Signature	Date	Time	Printed Name

Witness to Consent of Subjects Who Cannot Read or Write

Witness Statement: Your signature indicates that you were present during the informed consent discussion of this research for the above named subject, that the information in the consent form and any other written information was presented orally to the subject or subject representative, that the subject or subject representative was given the opportunity to ask questions, that the informed consent decision was freely made by the subject or subject representative who indicated consent and authorization for participation by (check the box as applicable):

☐ Making a mark
☐ Other means: _____
(fill in above)

_____	_____	_____	_____
Witness Signature	Date	Time	Printed Name