CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Sponsor / Study Title:	**Nature Cell / A Phase 1/2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of AstroStem Autologous Adipose Tissue Derived Mesenchymal Stem Cells, in Patients with Alzheimer's Disease**
Protocol Number:	**AST-ADP2-US01**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Additional Contact(s): (Study Staff)	**«AdditionalStaffMemberContacts»**
Address:	**«PiLocations»**

This form is for use in a research study that may involve subjects who may or may not have the capacity to consent to take part in the study. Accordingly, when the subject cannot legally consent to take part, pronouns "you" and "your" should be read as referring to the subject rather than the person (legally authorized representative) who is signing this form for the subject. In cases where the subject's representative gives consent, the subject should be informed about the study to the extent possible given his/her understanding. During the course of the study, if the subject regains the capacity to consent, informed consent should be completed and the subject offered the ability to leave the study if desired.

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign your name at the end of this form and date it. You cannot take part in this research study until you sign and date this form.

INTRODUCTION TO THE RESEARCH STUDY

You are being asked to take part in this research study because you have Alzheimer's disease (AD). Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

AstroStem is an investigational drug developed by Nature Cell (NC), who is the sponsor of this study. An "investigational drug" is a drug that has not been approved by the U.S. Food and Drug Administration (FDA). Drugs that do not have approval by the FDA cannot be sold or prescribed by your physician.

Taking part in this study is entirely voluntary.

PURPOSE OF THE RESEARCH STUDY

The main purpose of this research study is to see if AstroStem is safe and effective for subjects with Alzheimer's disease.

INFORMATION ABOUT THE STUDY

In this study, you will either receive the active study drug, AstroStem, or a placebo-control, a saline with 30% auto serum. Auto serum is part of your blood that has been taken and will be injected back into you with the saline. Please ask the study doctor or study staff if you have any questions about this placebo control.

At your third visit, you will be randomized into one of the study groups described below. To be 'randomized' means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being in one of the two groups:

- Group A: AstroStem
- Group B: Saline with 30% auto serum

During the study, neither you nor the study doctor will know nor get to choose which study drug you are receiving ('study drug' refers to the investigation drug [AstroStem] and the placebo-control [saline with 30% auto serum]). This is done so that a fair evaluation of results can be made. This information is available to the researchers if needed in an emergency. However, one physician that will be dedicated to making the injection will know what you are receiving, and therefore will not be making any assessments.

If you decide to be in this study, you will have to take your regular AD medication (donepezil, galantamine, memantine, rivastigmine or their combinations) on a stable dose(s) until the last follow-up visit. Change of type or dose of AD medication will not be allowed.

You will be in the study for about 14 months and make a total of 14 visits to the study site.

60 people at 2 - 3 research sites will take part in this study, including up to 30 people at this study site. In order to identify 30 subjects needed, we may need to screen as many as 45 because some people will not qualify to be included in the study.

WHAT WILL HAPPEN DURING THE STUDY

You will have the following visits:
Visit 1 (Week -6) – First screening, baseline
Visit 2 (Week -4) – Liposuction
Visit 3 (Week 0) – 1st injection of AstroStem or Placebo
Visit 4 (Week 2) – 2nd injection of AstroStem or Placebo
Visit 5 (Week 4) – 3rd injection of AstroStem or Placebo
Visit 6 (Week 6) – 4th injection of AstroStem or Placebo
Visit 7 (Week 8) – 5th injection of AstroStem or Placebo
Visit 8 (Week 10) – 6th injection of AstroStem or Placebo
Visit 9 (Week 12) – 7th injection of AstroStem or Placebo
Visit 10 (Week 14) – 8th injection of AstroStem or Placebo
Visit 11 (Week 16) – 9th injection of AstroStem or Placebo
Visit 12 (Week 18) – 10th injection of AstroStem or Placebo
Visit 13 (Week 30) – 1st Follow-up

Visit 14 (Week 52)- Final follow-up

At your first study visit, the study doctor or study staff will talk to you about the study. Then, you will be asked to sign this form, which will give the study doctor and the study staff the permission to begin the screening procedure to see if you qualify to be in the study. If the study doctor says you can be in the study and you want to be in the study, you will come in after about 2 weeks for a second visit and be randomized into one of the two treatment groups.

At your second visit, you will be randomized into either AstroStem or placebo-control group. Then regardless of your assigned group you will undergo a liposuction procedure to harvest cells that will be used to manufacture the study drug, AstroStem.

Then you will return to the clinic in about 4 weeks for the 1st injection of the final study drug product. This will either be the AstroStem injection or saline with 30% auto serum injection, depending on your assignment.

This procedure will be repeated 9 times at Visits 4-12 with 2 week interval.

If a subject has experienced infusion reaction, allergic reaction or anaphylaxis in associated with the study drug administration, the subject will be terminated early.

Following the 10th injection, you will visit the site for 1st follow-up at Week 30, then you will be asked to come in at Week 52 for the final follow-up.

If you take part in this study, you will have the following tests and procedures:

- Medical and Medication History: Ask you to answer questions about your health, your medical history, and the medications you take. This will be performed at Visit 1. This is a part of the standard of care.
- Demographic Questions: Ask you to give personal information, such as your date of birth, race, heights, and weight. This will be performed at Visit 1. This is a part of the standard of care.
- Physical Examination: You should ask the study doctor about what will happen during this exam. This will be performed at Visits 1, 3, 6, 9, 12, 13, and 14 or early termination visit. This is a part of the standard of care.
- Vital Signs and Weight: Check your blood pressure by putting a band around your arm (this will squeeze your arm for about a minute), check your pulse, listen to you breathe in and out, and take your temperature. Get your weight measured. This will be performed at every visit. This is a part of the standard of care.
- Hematology and Serum Chemistry: Take blood samples for laboratory tests. This will be performed at Visits 1, 3, 6, 9, 12, 13 and 14 or early termination visit. This is for investigational purpose. These tests will include HIV test for Screening. Positive results will be reported to the appropriate regulatory agency.
- Urinalysis: Take a urine sample to do laboratory tests. This will be performed at Visits 1, 3, 6, 9, 12, 13 and 14 or early termination visit. This is for investigational purpose.
- Pregnancy Testing (females only): Test your blood to see if you are pregnant. The study doctor or study staff will tell you if the pregnancy test results are positive. The results of the pregnancy test must be negative in order for you to be in the study. This will be performed at Visits 1, 3, 12, 13 and 14 or early termination visit. This is a part of the standard of care.
- Electrocardiogram: An electrocardiogram (ECG) measures the electrical activity of your heart. This will be performed during at Visits 1, 3, 6, 9, 12, 13 and 14 or early termination visit. This is for investigational purpose.

- Chest X-ray: Take a chest x-ray image to verify if you have a suspected active lung disease. This will be performed at Visit 1. This is part of the standard of care.
- Liposuction: Harvest adipose tissue (fat cells) from your abdomen from which to isolate the stem cells for the study treatment. This will be performed at Visit 2. This is for investigational purpose.
- Injection of Study Drug Product: Receive intravenous administration of either the study drug or the placebo-control. This will be performed at Visit 3 to 12. This is for investigational purpose.
- MRI Scans: Take a MRI scan of your brain to detect microhemorrhages (small brain bleeds), a single area of superficial siderosis (deposits of iron), or evidence of a prior microhemorrhage from the study at Visit 1. Take serial brain MRI scans to evaluate potential occurrence of cerebral vasogenic edema (excess fluid in the brain) at Visits 9, 13 and 14 or early termination visit. This is part of the standard of care.
- Questionnaires: Ask you to fill out questionnaires about your health, quality of life and the study drug. This will be performed at Visits 1, 3, 6, 9, 12, 13 and 14 or early termination visit. This is for investigational purpose.
- Blood biomarkers: Take blood samples to measure biomarkers at Visits 3, 13 and 14 or early termination visit. This is for investigational purpose. A biomarker is something found in the blood, other body fluids, or tissues that can be used to measure the progress of disease or the effects of treatment.
- Collect blood for auto-serum: Take blood samples to collect serum at Visits 2, 3, 5, 7, and 9.

You will have approximately 10 - 16 teaspoons (50 - 80 ml) or 3 – 5 teaspoons (15 - 25 ml) of blood withdrawn from a vein seven times throughout the study. The total amount of blood withdrawn during the study will be approximately 85 teaspoons (about 1.7 cups).

You may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the study doctor or study staff first to learn about any potential health or safety consequences. To help you leave the study safely, the study doctor may ask you to participate in more tests. The study doctor also has the right to stop your participation in the study at any time. This could be because it is in your best medical interest, your condition worsens, new information becomes available, you have an unexpected reaction, you fail to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

YOUR ROLE IN THE STUDY

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research subject when you are deciding to take part. Your responsibilities as a study subject include the following:

- Tell the truth about your medical history and current conditions.
- Tell the study doctor if you have been in a research study in the last 3 months or are in another research study now.
- Tell the study doctor about any problems you have during the study.
- Allow the study doctor to give you intravenous administrations of the study drug 10 times.
- The study doctor or study staff will talk to you about any food or medicines that you should not take while in this study.

RISKS OF THE STUDY

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff.

Risks of Study Drug Administration (Investigational Drug, AstroStem iv administration)

In previous clinical trials, the risks and side effects possibly related to the study drug we are studying included:

- Inflammation,
- Pain,
- Infection and/or allergic reaction at the site of injection,
- Hematoma (bruise),
- Cellulitis (skin infection),
- Pulmonary embolism (arteries in the lungs become blocked by a blood clot),
- Deep vein thrombosis (blood clot),
- Rash,
- Fever,
- Edema (swelling),
- High blood pressure,
- Joint pain,
- Non-functioning tumor promotion (tumors that do not secrete hormones),
- Diabetic retinopathy growth (diabetes complication that affects eyes),
- Worsening of atherosclerosis (hardening of the arteries),
- Cold,
- Urinary stone,
- Chest discomfort,
- Toothache,
- Dry cough,
- Backache,
- Migraine,
- Rhinopharyngitis (common cold),
- Gastrointestinal disease,
- Metabolic or nutritional disease,
- Hypertriglyceridemia (high levels of triglycerides (fats) in the blood),
- Nervous disease,
- Headache,
- Urinary system disease,
- Breathing issues,
- Chest and mediastinal (a part of the chest) disease,
- Potential occurrence of cerebral vasogenic edema,
- Suicidal ideation (thoughts) and behavior.

Risks of Placebo-Control Administration (Saline with 30% auto serum iv administration)

In previous clinical trials, the risks and side effects possibly related to saline iv administration we are conducting included:

- Pain, infection and/or allergic reaction at the site of injection,
- Rash,
- Fever,
- Fluid retention (too much fluid in your body),
- High blood pressure,
- Fast heartbeat,
- Joint pain,
- Shortness of breath.

Risks Associated with Procedures

Risks of Breach of Confidentiality: Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information.

Risks of Blood Draw: During blood drawing, you may experience discomfort, pain, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

Risks of Liposuction: For the liposuction procedure, you may experience discomfort, pain, bruising and/or bleeding for the local anesthesia and the fat harvesting process. We will do our best to ensure that the surgical conditions are sterile and safe and that the physician performing the liposuction is qualified. For more information, please consult the study doctor or study staff.

Risks of Questionnaires: During tasks that involve memory, you may become bored, fatigued, or frustrated by their difficulty. There are no physical risks to these tests. Some of the questions you will be asked on the questionnaire are personal and may make you feel embarrassed. You may skip any questions you do not feel comfortable answering, but it is important for you to give your best effort.

Risks of MRI scan: Some people should not participate in MRI studies. These include persons with shrapnel or certain metallic implants, such as prostheses (artificial body part), or aneurysm clips, or persons with electronic implants, such as cardiac pacemakers or implanted hearing devices. The magnetic field generated by the MRI machine can cause a displacement or malfunctioning of these devices. There are no other known risks to body tissues associated with the magnetic field strength used in this study. Some participants report some anxiety or claustrophobia in the MRI scanner since the head must be placed fully inside the scanner tube. If anxiety or claustrophobia occurs, please let us know and we will stop the scan and bring you out of the scanner. In addition, fatigue and physical discomfort are possible. The MRI scanner makes a great deal of noise when taking images. To minimize the level of noise, you will be fitted with disposable earplugs or headphones to wear during the procedure. These may be a bit uncomfortable to wear, and will not eliminate all sound, so that communication with you is still possible.

Risks of X-ray: You may have a fill-in type x-ray. The risk of radiation exposure from the x-ray is too small to be measured directly and is therefore difficult to compare to everyday risks.

Risks of ECG: ECG risks include mild irritation, slight redness, or itching at the sites on your skin where the recording patches are placed.

Risks of Blood Pressure Cuff: The blood pressure monitoring device is non-invasive and the most common complaint is potential discomfort due to the blood pressure cuff inflating. If this occurs, you simply can take off the cuff.

Allergic Reaction Risks

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, or any other side effects, during the study.

Reproductive Risks

Women Who Can Get Pregnant or Are Breastfeeding

You may not take part in this study if you are breastfeeding, are pregnant, think that you may be pregnant, or are trying to get pregnant. If you are pregnant or breastfeeding, there may be risks to you and the baby that are not known at this time. Women who can get pregnant will be tested for pregnancy during the study.

You must avoid getting pregnant in order to take part in this research study. You should not have sexual intercourse or you should use 2 forms of birth control that is acceptable to you, the study doctor, and the sponsor.

It is important for you to tell the study doctor at once if you get pregnant or think that you might be pregnant while you are in the research study. If this happens, the study doctor will discuss with you what you should do. If you get pregnant, you will be asked to stop taking part in the study. You may also be asked questions about your pregnancy and the baby.

Men

The effect of the study drug on male sperm is unknown. In rare cases, drugs may damage sperm in ways that affect a child that is fathered. Affected sperm may be present in the semen for about 3 months. Therefore, it is recommended to avoid fathering a child for 3 months after the last dose of the study drug. You should not have sexual intercourse or you should use a method of birth control that is acceptable to you, the study doctor, and the sponsor. If you think that you have gotten a woman pregnant, you must tell the study doctor at once. If your partner gets pregnant during the study, you may be asked questions about the pregnancy and the baby.

Unknown Risks

You might have side effects or discomforts that are not listed in this form. Some side effects may not be known yet. New ones could happen to you. Tell the study doctor or study staff right away if you have any problems.

Prohibited Concomitant Medications

The following medications are not to be taken by subjects enrolled in this study during the trial (up to Week 52, a final follow-up visit):

- Any other investigational drug
- Any therapy that may affect Alzheimer's disease, in the judgment of the study doctor
- Immunosuppressant
- Cytotoxic drug (drug that damages cells, for example, a chemotherapy drug for cancer)
- Corticosteroids or similar steroidal anti-inflammatory medication (for example, Prednisone) on a regular basis (exceptions allowed include: regular use of steroidal nasal sprays, topical steroids, and estrogen-replacement therapy)

ALTERNATIVES TO BEING IN THE STUDY

You do not need to take part in this research study. Treatments for the symptoms of Alzheimer's disease include medications like donepezil, galantamine, memantine, rivastigmine, donepezil with memantine. Your study doctor can discuss the alternatives and the risks and benefits of these alternatives with you.

POTENTIAL BENEFITS OF BEING IN THE STUDY

You may or may not receive any direct benefit from being in the study. It is possible that you may get better, stay the same, or get worse. The benefits of participating in this study may be improvement in your symptoms of Alzheimer's disease. If you take part in this study, other people with Alzheimer's disease may be helped.

COSTS OF BEING IN THE STUDY

The study drug and all tests, procedures and visits required by the study are provided at no cost to you. The sponsor, Nature Cell Co., Ltd., pays for them. However, costs for your regular medical care, which are not related to this study, will be your own responsibility.

YOUR PAYMENT FOR BEING IN THE STUDY

You may receive up to $1050 for being in this study. You will get $75 for each study visit you complete. You will be paid at the end of each study visit. If you do not finish the study, you will only be paid for the visits you completed.

STUDY STAFF PAYMENT

Nature Cell Co., Ltd. is paying the study doctor and study staff for their work in this study.

COMPENSATION FOR INJURY

If you become ill or are hurt 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.

Nature Cell shall reimburse for reasonable and necessary medical expenses (the "Covered Expenses") incurred by study subjects for medical care, including hospitalization, in the treatment of adverse reactions arising from study drugs, devices, intervention, procedures and tests following their administration or use in accordance with the protocol, which expenses were not caused by negligence or misconduct of any person in the employment of study site or to your own failure to follow instructions.

Nature Cell is not responsible for expenses that are due to pre-existing medical conditions or underlying disease.

You still have the right to make a claim through the legal system even if you sign this form, accept medical care, or accept payment for medical expenses.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. 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.

PROTECTING THE PRIVACY OF YOUR HEALTH DATA

Certain people and organizations will need to see, copy, and use your health data so that they can do their part in the study. They are called 'authorized users.' Authorized users will be given access to and may make copies of your health data. This health data may or may not include your name. It may be traced back to you even if it does not include your name.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

Authorized users may include:

- Representatives of Nature Cell Co., Ltd.
- Representatives of KCRN Research LLC
- Representatives of Chesapeake IRB (a Research Ethics Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US governmental agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Labs working with the sponsor on this study.
- Other authorized users.

Your health data needs to be shared for the research and other reasons. Therefore, complete privacy of your health data cannot be promised. However, sharing your health data will be guided by professional standards and the law.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

Information from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you.

For your safety, the study doctor should tell your regular health care provider that you are in this study.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff <u>listed on the first page of this form</u> with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

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

Please reference the following number when contacting the Study Subject Adviser: Pro00019946.

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.

BEING A STUDY VOLUNTEER

Entering a research study is voluntary.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.
- You need additional medicine.
- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

NEW INFORMATION ABOUT THE STUDY

You will be told about any new information found during the study that may affect whether you want to continue to take part.

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ _/____/____
Signature of Legally Authorized Representative (if applicable) Date

_____
Printed Name of Legally Authorized Representative (if applicable)

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject or the subject's legally authorized representative the nature and purpose of the above study. There has been an opportunity for the subject or the subject's legally authorized representative to ask questions about this research study. I have been available to answer any questions that the subject or the subject's legally authorized representative has about this study.

_____ ____/____/____
Signature of Person Explaining Consent Date

_____
Printed Name of Person Explaining Consent

HIPAA Authorization Agreement
Permission to Review, Use and Release Information about You

If you decide to be in this study, the study doctor and research team will use and share health data about you to conduct the study. Health data may include:

- Your name.
- Address.
- Phone number.
- Date of birth.
- Medical history.
- Information from your study visits, including all test results.

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the research team may share health data about you with authorized users. Authorized users may include

- Representatives of Nature Cell Co., Ltd.
- Representatives of KCRN Research, LLC.
- Representatives of Chesapeake IRB (a Research Ethics Review Board that reviews this study).
- The Food and Drug Administration (FDA) and other US governmental agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Labs working with the sponsor on this study.
- Other authorized users.

The sponsor and those working for the sponsor may use the health data sent to them:

- To see if the study drug works and is safe.
- To compare the study drug to other drugs.
- For other research activities related to the study drug.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law.

Your permission to use and share health data about you will not end unless required by state law. If state law applies, your permission to use and share health data about you will end on December 31, 2067.

You may take back your permission to use and share health data about you at any time by writing to the study doctor. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that has already been gathered may still be used and given to others as described in this form.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

If you decide not to sign this form, you will not be able to take part in the study.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____
Signature of Research Subject Date

_____
Printed Name of Research Subject

_____ ____/____/____
Signature of Legally Authorized Representative Date

_____
Printed Name of Legally Authorized Representative

STATEMENT OF PERSON EXPLAINING AUTHORIZATION

I have carefully explained to the subject and legally authorized representative the nature and purpose of this form. I have been available to answer any questions that the subject and legally authorized representative has about this form.

_____ ____/____/____
Signature of Person Explaining Authorization Date

_____
Printed Name of Person Explaining Authorization