CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE OF STUDY: A Phase 2, Multicenter, Double-Masked, Randomized, Vehicle-Controlled, Parallel-Group Study of SDP-4 Ophthalmic Solution in Subjects with Dry Eye Disease (DED)

PROTOCOL NUMBER: SDP-4-CS202

SPONSOR COMPANY: SilkTech Biopharmaceuticals (SilkTech)

STUDY DOCTOR: <<Enter Name of Investigator>>

NAME/ADDRESS of STUDY SITE: <<Enter name/address>>

TELEPHONE NUMBERS: <<Enter phone numbers below>>

Office: <<>>

After Hours: <<>>

Introduction

You are being asked to take part in a research study. The following information describes the study and your role as a participant. Before you agree to take part in this study, it is important for you to read all information in this form. This consent form explains the purpose, procedures, risks, benefits, discomforts and precautions of this study. It also explains what other treatments are available for your condition if you choose not to be in this study. It is your right to choose not to be in this study and to leave this study at any time. The results of this study are not yet known, and you may not receive any medical benefits from participating in the study.

Take your time and read this consent form carefully. Please ask the Study Doctor or the Study Staff to explain any words or procedures that you do not clearly understand or to answer any other questions you may have about this study. You may discuss your decision with your friends and family.

What is the Background and Purpose of This Research Study?

You are being asked to take part in this research study because you suffer from what is called dry eye disease. This is a common disorder of the tears that you produce in order to keep your eyes moist which can affect the surface of the eyes. Dry eye can cause inflammation and/or irritation of the surface of the eye resulting in some or all of the following symptoms: burning, stinging, itching, grittiness, scratchiness, foreign body sensation, dryness, stickiness and tired eye sensation. The symptoms are usually gradual and affect both eyes. The symptoms also tend to become more bothersome later in the day and can be worsened by environmental factors such as wind or air-conditioning.

The current study is evaluating an investigational study drug called SDP-4 that may help the symptoms of your dry eye. Investigational means it has not been approved by the Food and Drug Administration

(FDA) to be prescribed to the public. The study drug is an eye drop that is used in both eyes twice a day, once in the morning and once at bedtime.

The purpose of this research study is to determine how the study drug, SDP-4, affects how well your eyes make tears and relieves your symptoms along with testing the safety of the drops. You will be provided either the study drug, or the "vehicle". The study "vehicle" drops are the same formulation as the study "drug" drops, but do not contain the active drug (medicine).

If you participate in the study, you will receive one of the following:

- SDP-4 1.0% - one drop in both eyes twice a day
- Vehicle 0.0% - one drop in both eyes twice a day

It will be decided randomly (by chance, like flipping a coin) which drop you will receive. This will be either the study eye drop or the study vehicle, to be used for the duration of the study. This is called being "randomized" or assigned to a study eye drop. You will not know which of the eye drops you are using, and neither will your Study Doctor or the Study Staff. However, the Study Doctor can find out which group you are in if, for medical reasons, it becomes necessary to know. You will have a 1 out of 2 chance of receiving the SDP-4 eye drop or receiving the vehicle.

About 140 people, aged 18 years and older, are expected to take part in this study at about 5 clinical sites within the United States.

How Long Will I Be In The Study and What Will I Have To Do?

If you decide to take part in this study, you will visit the Study Doctor about 5 times over 10 weeks (2 ½ months). Each visit will last 1-2 hours. The first visit is to make sure you can be in the study. If you can be in the study at the end of this first visit (Visit 1), you will be given the vehicle eye drops to use for the next 2 weeks (14-16 days). During this period, you must stop using your previous eye drops and get used to using the study eye drops. This is called a "run-in" period. If you are still able to stay in the study after Visit 2, you will use the study eye drops twice a day (once in the morning and once at night) in both eyes for the next 8 weeks of the study. Once the final visit (Visit 5) has been completed, you will no longer use the study eye drops or be required to return for follow-up. If your Study Doctor feels it is necessary, you may be asked to come in for an unscheduled visit(s) during the study.

During the study, you will be asked to:

- Visit the Study Doctor about 5 times over 10 weeks (2 ½ months), not including unscheduled visits.
- Not enroll in any other investigational drug or device study while taking part in this study.
- Use the study eye drop as directed by your Study Doctor. This study eye drop is intended only for you and no one else can use it.
- Tell the Study Staff at each visit about any other medications you are taking, prescription or over the counter.
- Tell the Study Staff at each visit about any changes in your health since your last visit or the way that you feel.

- You will be asked to carry a study ID card with you at all times during your participation in this study. This card will be given to you by the Study Staff and will contain information about the study.

- Use medically acceptable birth control to prevent pregnancy as described in the **Pregnancy Risks** section of this consent form.

During the study, you will not be able to take certain medications by mouth or use any other eye drops except for the study eye drops. Your Study Doctor will go over your current medications and discuss these with you.

Contact lenses are not allowed to be worn during the study. If you wear contact lenses, you must agree not to wear them while you are taking part in the study.

Study Procedures

Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. You must read and sign this informed consent form. You will be given a copy of this signed and dated consent form to take home with you.

Each visit will take 1-2 hours to complete. All study assessments will be performed on both eyes. If you agree to take part in this study, you will complete the following study procedures:

Visit 1 - Screening Visit (to see if you are able to be in the study):
The following will occur during this visit:

- You will be asked to provide information about yourself including date of birth, gender, race, ethnicity, iris (colored part of your eye) color and personal data (information).

- Medical and eye histories will be recorded. You will be asked about your current health status and any important medical history and past and current eye conditions.

- A thorough list of all medications, both prescription and over-the-counter, you are taking now and have taken in the past will be recorded.

- If you are a woman who is able to become pregnant, a urine pregnancy test will be performed.

- You will be asked a couple of questions about how often your eyes are dry and how you would rate your symptoms.

- Your vision will be tested by reading letters on an eye chart. If you wear glasses, your vision will be tested using those. The Study Staff may try to improve your vision using trial lenses, if needed.

- The Study Doctor will look at the front part of your eyes and eyelids using a special microscope called a slit lamp. A slit lamp is used to help the Study Doctor determine the overall health of your eyes.

- Tear break-up time will be recorded. This is a painless exam where a small amount of orange dye called fluorescein will be placed into each eye. You will place your chin in the chin rest and forehead against the forehead strap of the slit lamp and the Study Doctor will shine a blue light in

your eyes. You will be asked not to blink for ten (10) seconds and the Study Doctor will record the time it takes for the tears on the surface of your eye to break-up and create dry spots.

- The Study Doctor will then look at the surface of your cornea (clear part of the eye), which is what covers the colored part of the eye, using the slit lamp with a blue light. If needed, more orange fluorescein dye may be placed in the eye.

- You will have a Schirmer's test to measure the amount of tears your eyes produce. Tiny paper strips are placed just inside the corner of your lower eyelids to measure the amount of tears produced in 5 minutes. Before the paper strips are placed inside your lower eyelids, an anesthetic eye drop will be put into both of your eyes. This drop will numb the surface of your eyes, so you won't feel the paper strips.

Based on your eye exam results and answers to the questions, there is a chance that you may not be able to take part in this study. If you are able to continue in the study, you will begin a "run-in" period (so that you get used to using the eye drops). The Study Doctor will give you the vehicle (no active drug) eye drops. You will use one drop two times a day in both eyes for at least two weeks (12-16 days). The Study Staff will show you or your caregiver how to put the drops in your eyes. You or your caregiver will put in the first drop while you are at the Study Doctor's office.

You will return 2 weeks later for the Baseline Visit (Visit 2). You will need to return all used and unused run-in medication at that visit.

Visit 2:
The following will occur during this visit:

- You will be asked how you are feeling and if you have had any changes to your health since your last visit.

- Current medications will be reviewed.

- You will be asked a couple of questions about how often your eyes are dry and how you would rate your symptoms on a scale of 1-100.

- You will be asked to report what type of dry eye symptoms you have been having and how you would rate them on a scale of 1-100.

- Study drop comfort assessment: You will be asked to evaluate the comfort of the eye drops using the following scale:

0 = No discomfort
1 = Mild discomfort
2 = Moderate discomfort
3 = Severe discomfort

- Your vision will be tested by reading letters on a chart. If you wear glasses, your vision will be tested while wearing your glasses.

- The Study Doctor will look at the front part of your eyes and eyelids using the slit lamp.

- A small amount of orange dye called fluorescein will be placed into each eye. Tear break-up time will be recorded.

- The Study Doctor will look at the surface of your cornea.

- All used and unused run-in eye drops and packaging will be collected at this visit.

At this point in the visit, if you are still able to continue in the study based on the results of the exam, you will be randomized (like pulling numbers from a hat) to one of 2 groups:

- SDP-4 1.0% - one drop in both eyes twice a day
- Vehicle – 0.0% - one drop in both eyes twice a day

You will be given your study drops to use in both eyes, twice a day for the remainder of the study. The Study Staff will again show you or your caregiver how to put in the drops, and you will start using the study drops at home the same day as your study visit.

You will return in 2 weeks for your next study visit (Visit 3).

Visit 3:
The following will occur during these visits:

- You will be asked how you are feeling and if you have had any changes to your health since your last visit.

- Current medications will be reviewed.

- You will be asked a couple of questions about how often your eyes are dry and how you would rate your symptoms on a scale of 1-100.

- You will be asked to report what type of dry eye symptoms you have been having and how you would rate them on a scale of 1-100.

- You will be asked to evaluate the comfort of the eye drops using the same scale as previous visits.

- Your vision will be tested by reading letters on a chart. If you wear glasses, your vision will be tested while wearing your glasses.

- The Study Doctor will look at the front part of your eyes and eyelids using the slit lamp.

- A small amount of orange dye called fluorescein will be placed into each eye. Tear break-up time will be recorded.

- The Study Doctor will look at the surface of your cornea.

You will return in 2 weeks for your next study visit (Visit 4). You will need to return all used and unused study drops and packaging at this visit.

Visit 4:
The following will occur during this visit:

- You will be asked how you are feeling and if you have had any changes to your health since your last visit.
- Current medications will be reviewed.
- You will be asked a couple of questions about how often your eyes are dry and how you would rate your symptoms on a scale of 1-100.
- You will be asked to report what type of dry eye symptoms you have been having and how you would rate them on a scale of 1-100.
- You will be asked to evaluate the comfort of the eye drops using the same scale as previous visits.
- Your vision will be tested by reading letters on a chart. If you wear glasses, your vision will be tested while wearing your glasses.
- The Study Doctor will look at the front part of your eyes and eyelids using the slit lamp.
- A small amount of orange dye called fluorescein will be placed into each eye. Tear break-up time will be recorded.
- The Study Doctor will look at the surface of your cornea.
- All used and unused study drops and packaging will be collected at this visit.
- You will receive another box of study eye drops to last until your next visit.

You will return in about 4 weeks for the next visit (Visit 5). Visit 5 is the last scheduled visit in this study. You will need to return all used and unused study drops and packaging at these visits.

Visits 5:
The following will occur during this visit:

- You will be asked how you are feeling and if you have had any changes to your health since your last visit.
- Current medications will be reviewed.
- If you are a woman who is able to become pregnant, a urine pregnancy test will be performed.
- You will be asked a couple of questions about how often your eyes are dry and how you would rate your symptoms on a scale of 1-100.
- You will be asked to report what type of dry eye symptoms you have been having and how you would rate them on a scale of 1-100.
- You will be asked to evaluate the comfort of the eye drops using the same scale as previous visits.

- Your vision will be tested by reading letters on a chart. If you wear glasses, your vision will be tested while wearing your glasses.
- The Study Doctor will look at the front part of your eyes and eyelids using the slit lamp.
- A small amount of orange dye called fluorescein will be placed into each eye. Tear break-up time will be recorded.
- The Study Doctor will look at the surface of your cornea.
- All used and unused study drops and packaging will be collected at this visit.

You will not receive any more eye drops after Visit 5.

You may be asked to return for an unscheduled visit if you leave the study or if you are taken out of the study for any reason. This is to ensure there have been no changes to your health during the study. You must return all used and unused eye drops in the box, pouches and vials at this visit. If you are asked to return for an unscheduled visit, you will complete all of the procedures listed in Visit 5.

What Are the Possible Risks or Side Effects of the Study Drug?

As with any drug, there is a risk that side effects may occur while using SDP-4.

There may be risks or side effects of SDP-4 that are currently unknown. Allergic reactions can occur with any drug. It is important to tell your Study Doctor if you start to experience any new symptoms while using the eye drops. Your Study Doctor will monitor you for side effects throughout this study.

What are the Possible Risks or Side Effects of the Study Procedures?

Possible Risks of Fluorescein Dye

The orange (fluorescein) dye used to evaluate the front surface of your eyes may cause mild, temporary discomfort to your eyes. It may also change the color of your tears or mucous when you blow your nose, turning it a yellow color. This effect is common and will usually go away within a few hours.

Possible Risks of Schirmer's Test

After the Schirmer's test, you may have a little discomfort and redness in area the strips were placed. This could last for a few hours.

Possible Risks of Anesthetic Eye Drops

The numbing drops used for the Schirmer's Test may sting for a few seconds when they are first placed in your eyes. This is common. If your eyes are sensitive, they may also appear a little red after receiving the numbing drops. It is important not to rub your eyes while they are numb to avoid scratching the surface of your eyes.

Pregnancy Risks

The effects of the study eye drops, SDP-4, on an unborn baby or nursing infant are not known. Women who are pregnant, planning to become pregnant or nursing a child may not take part in this study.

If you are a woman of child bearing potential (able to become pregnant), you must use an acceptable method of contraception (birth control) to prevent you from getting pregnant throughout your participation in the study. Acceptable methods include use of at least one of the following: intrauterine device (IUD), hormonal (pill by mouth, injection, patch, implant, ring), barrier with spermicide (condom, diaphragm), or abstinence. Your Study Doctor or Study Staff will further discuss this with you to make sure an adequate form of birth control is being used.

You will be asked to take a urine pregnancy test at the first visit and at the end of the study if you are not surgically sterile or post-menopausal (at least 1 year with no menstrual period). You must have a negative pregnancy test prior to starting to use the eye drops and must not become pregnant while in this study. If you become pregnant during this study, you must tell the Study Doctor or Study Staff right away and stop using the eye drops immediately. The Study Doctor will ask for information about your pregnancy and follow-up with you until the end of the pregnancy to record the outcome. You will no longer be able to receive the eye drops, but you will be asked to complete remaining study visits.

New Information

There may be risks of participation in the study that are unknown. There may be new information that becomes available during this study regarding risks or benefits, or any other changes to the study that may affect your decision to continue participating. You will be informed of any new information learned about this study or the study eye drops, and you may be asked to sign an updated version of this consent form, which will describe the new findings.

What Are the Possible Benefits of Taking Part?

Your dry eye may improve while you are taking part in this study; however, this cannot be guaranteed. Your eye condition may not get better or may get worse during this study. The results of this study may help people with dry eye in the future. There is a 1 in 2 chance that you will receive the vehicle (no active medicine) in this study. If SDP-4 is effective in treating dry eye, subjects receiving vehicle may not receive the same benefit as those who receive the active medicine SDP-4.

What Other Treatments Are Available?

You do not have to be in this study to receive treatment for dry eye. Other treatment options include, but are not limited to, artificial tears, punctal (tear drainage duct) plugs or prescription eye drops. The Study Doctor will discuss these other treatment options with you, including their important potential risks and benefits.

What are the Costs of Taking Part?

There will be no cost to you for your participation in this study. The assigned eye drops, study-related procedures, and study visits will be provided at no cost to you or your insurance company.

You or your insurance will be billed for any standard care, such as eye exams not related to the study, that you receive during your participation in the study.

Information from this study may lead to discoveries and inventions or development of a commercial product. If commercial products or other valuable discoveries result from the research using your data, you and your family will not receive any financial benefits or compensation from or have rights in any developments, inventions, or other discoveries that might come from this information.

Is There Payment for Taking Part in this Study?

For your time and inconvenience related to your participation in this study, you will be paid for each visit you *complete* as follows:

Visit	Payment
Visit 1	$100
Visit 2	$100
Visit 3	$100
Visit 4	$100
Visit 5	$100

If the Study Doctor asks you to return for an unscheduled visit, you will be paid $25 for each unscheduled visit you complete.

If you do not complete this study, for any reason, you will receive payment for the study visits you do complete. If you do not complete an entire study visit, you will not receive payment for that visit.

Payment will be made in the form of <<XXXX>> and will be provided to you << insert site specific payment schedule>>.

Do I have To Take Part?

Your participation in this study is voluntary. You may decide to not participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. Your decision to participate in this study will not interfere with your future care at this facility.

Your Study Doctor, and/or the Sponsor may stop your participation in the study without your permission at any time for the following reasons:

- You withdraw (take back) your consent
- The Sponsor stops the study
- It is in your best interest to stop taking part

Your Study Doctor, the Investigator and/or the Sponsor may stop you from using the eye drops but ask that you still complete the study visits for the following reasons:

- You experience an injury related to the study
- You are a female who becomes pregnant
- You request to stop taking the eye drops
- You do not take the study eye drops as instructed

The Sponsor may stop the study at any time without giving a reason. If you wish to leave this study before completing all the visits, please inform the Study Doctor or Study Staff by telephone using the number listed on the first page of this consent document. The Study Doctor or Study Staff will ask you to return for one more visit to complete the procedures listed above in Visit 5 if possible, and at a minimum, collect all used and unused study drops.

Any information collected from you up to the point you exit the study remains part of the study database and may not be removed.

Your Primary Care Physician (PCP) should know that you are taking part in this study. You should take steps to inform your Primary Care Physician of your participation in this study.

What Happens if I have an Injury from Taking Part in the Study?

If you have any side effects after taking the study eye drops or are injured during the study, you must tell your Study Doctor as soon as possible. Your Study Doctor will make sure you receive medical treatment.

If side effects or other physical injuries are a direct result of receiving the study eye drops or study procedures, immediate medical care will be provided to you. The study Sponsor, Silk Technologies, Ltd., will cover any reasonable costs to treat such an injury. If an injury results for any of the following reasons, the Sponsor may not cover the costs of treatment:

- You did not follow the instructions given to you by your Study Doctor or Study Staff.
- You caused your own injury.
- The Study Doctor or Study Staff did not follow the study plan
- The injury is a normal progression of an underlying, pre-existing medical condition.

If your injury or illness is not a direct result of being in this study, you or your medical insurance will be billed for the cost of treatment.

The Sponsor has no plans to provide compensation for any types of expenses other than the cost of immediate medical treatment of an illness or injury that is a direct result of receiving the study eye drops or the study procedures. This does not prevent you from pursuing other legal options. You do not give up any legal rights by signing this form.

To help avoid injury, it is very important to follow all study directions given to you by your Study Doctor or Study Staff.

How is My Health Information Used and Disclosed (shared)?

Your study-related medical records and this consent form may be reviewed and/or copied by the Sponsor and its representatives, Alpha Independent Review Board (Alpha IRB), and regulatory authorities, such as the U.S. Food and Drug Administration (FDA), and the Department of Health and Human Services (DHHS).

Your identity will remain confidential to the extent required by applicable law. If your protected health information is shared with the parties listed above and/or others who are not required to comply with the laws that protect the privacy of your protected health information, it will no longer be protected by such law and could be used or disclosed in ways other than those listed above.

If the results of this study are published, you will not be identifiable in the published study results.

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

Who Can I Contact with Questions or Concerns?

You have the right to ask questions about this study at any time and are encouraged to do so. If you have questions, concerns, or complaints about this study or need to report a study related injury, contact the Study Doctor or Study Staff at the telephone number(s) listed on page 1 of this consent form.

If you are unable to reach anyone at the numbers listed above, and you need medical attention, please go to the nearest emergency room. Please remember to bring your Study ID card with you.

If you have questions, concerns or complaints about your rights as a research volunteer or about taking part in this study, or to obtain information or offer input, you may contact Alpha Independent Review Board (IRB), Attn: Marianne Thornton, toll free at (888) 265-5766 between the hours of 8:00am-5:00pm Pacific Time.

Alpha Independent Review Board
1001 Avenida Pico, Suite C #497
San Clemente, CA 92673
(888) 265-5766 (toll free)

Alpha IRB is a group of people who perform an independent review of research studies to protect the rights and welfare of study participants. Although Alpha IRB has approved the information provided in this informed consent form and has approved the Study Doctor to conduct the study, this does not mean Alpha IRB has approved you being in the study, or that the study is without risks. You must consider the information in this consent form for yourself and decide if you want to be in this study.

This study is sponsored by Silk Technologies, Ltd. referred to as "the Sponsor". The Study Doctor is being paid by the Sponsor to carry out this study.

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.

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

Acknowledgment of Consent and Provision of Authorization:

I have read this consent document which is in a language that I can read and understand. The study has been discussed with me and my questions about the study and possible risks and side effects have been answered. I am aware that by signing this consent form I am authorizing (giving permission for) the use and possible disclosure (sharing) of my protected health information. I am also aware that by signing this form I will not be giving up any of my legal rights. I am aware that I may withdraw my consent and authorization at any time by contacting the Study Doctor listed on page 1 of this form, in writing, and telling the Study Doctor that I withdraw my consent and authorization.

Based on this information, I volunteer to take part in this study.

_____	_____	_____
Printed Name of Adult Participant	Signature of Adult Participant	Date
_____	_____	_____
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

How is My Health Information Used and Disclosed (shared)?

During the course of the study, the Study Doctor will collect personal and health-related information about you. This information will be used to learn about how safe and effective the study eye drops will be. Your protected health information (PHI) is generally information that is, or has been, gathered or kept by the Study Doctor as a result of your healthcare. This includes data (information) gathered for this research study that can be traced back to you. Using or sharing ("disclosing") such data must follow state and federal privacy laws and rules. All efforts, within reason, will be made to keep your PHI private in accordance with the applicable privacy laws and rules. By signing the consent form for this study, you are agreeing to ("authorizing") the use and likely sharing of your PHI. All such use and likely sharing must comply with applicable state and federal privacy laws. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

Your study-related medical records and this consent form may be reviewed and/or copied by the Sponsor, Alpha Independent Review Board (Alpha IRB), the ethics committee overseeing this study, and regulatory authorities, such as the U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) or similar regulatory authorities in other countries.

Your identity will remain confidential to the extent required by applicable law. If your protected health information is shared with the parties listed above and/or others who are not required to comply with the laws that protect the privacy of your protected health information, it will no longer be protected by such law and could be used or disclosed in ways other than those listed above.

If the results of this study are published, you will not be identifiable in the published study results.

What if I choose not to share my information?

Your consent and authorization to use or share your PHI does not expire for 50 years, unless you tell the Study Doctor otherwise. You have the right to revoke (withdraw or take back) your consent and authorization to use or share your PHI **at any time as follows**. If you want to revoke your consent, you must write to the Study Doctor at the study site address listed on page 1 of this consent form and

inform the Study Doctor that you withdraw your consent and authorization. After the Study Doctor receives your written withdrawal, the Study Doctor will then stop collecting study-related data about you. But, the study-related data already collected before receipt of the writing where you withdrew your consent may still be used for reporting and research quality. If you withdraw your consent and authorization, you will no longer be a participant in this study.

Possible Transfer of Your Health Information Out of the Country
The study Sponsor may send your study data (with a code number, but not your name) outside of the United States for the reasons described in this form. Please know that the laws in other countries may not provide the same level of data and privacy protection as in the United States and those laws may not stop your study data from being disclosed to others not involved in the study.

Your Right to See and/or Copy Your Study-Related Health Information
You may see and copy your study-related health information for as long as the Study Doctor is required to keep this information. You may also, under applicable privacy and data protection laws, have the right to ask that any mistakes in your study-related health information be corrected. However, you may not be able to see or copy your study-related health information until after the study has been completed. Otherwise, it could affect the study.

By signing this authorization document, you are giving your permission to use and give out your PHI. If you do not give your permission, you will not be able to be in this study.

You will be provided with a copy of this signed document.

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. Except as specifically outlined in this form, I am not giving up any legal rights by signing and dating this form.

_____
First and Last Name of Adult Participant (Print)

_____ _____
Signature of Adult Participant Date

STATEMENT OF PERSON EXPLAINING AUTHORIZATION

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

_____
First and Last Name of Person Explaining Authorization (Print)

_____ _____
Signature of Person Explaining Authorization Date