INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**NFlection Therapeutics, Inc. / "A Randomized, Double-Blind, Vehicle-Controlled, Parallel Group Phase 2a Study to Determine Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Activity of NFX-179 Gel in Subjects with Cutaneous Neurofibromas "**
Protocol Number:	**NFX-179-NF1-201**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

INTRODUCTION

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed research study. This consent document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to your results in this study.

If you are not completely truthful with your study doctor regarding your health history, you may harm yourself by participating in this study.

The study is being conducted for NFlection Therapeutics. Your study doctor is being paid by NFlection Therapeutics (the Sponsor) to conduct this study.

Advarra IRB Institutional Review Board (IRB) has approved the information in this consent document and has given approval for the study doctor to do the study. An IRB is an independent committee established to help protect the rights of research subjects. Although Advarra IRB has approved the information provided in this informed consent form and has granted approval for the study doctor to conduct the study, this does not mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself and then decide if you want to be in the study.

Please read this form carefully. Take your 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.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you are clinically diagnosed neurofibromatosis type 1 (NF1) with cutaneous neurofibromas (cNF) present on your skin.

NF1 is caused by mutations in the NF1 gene, which can result in cNF anywhere on the body. A new topical (applied to the skin) investigational formulation, NFX-179 Gel, is being developed to treat cNF. An investigational formulation is a study drug that is not approved by the US Food and Drug Administration (FDA). This investigational formulation of NFX-179 may or may not reduce the size of cNF.

The purpose of this study is to assess the safety, tolerability, pharmacokinetics (how much study drug is in your blood) and pharmacodynamic (what the study drug does to your body) properties of three strengths of NFX-179 Gel when applied to cNF compared to a matching Vehicle Gel. The Vehicle Gel is the same formulation as the NFX-179 Gel but does not contain any active drug. The skin's response to the gels will be evaluated and information on any side effects that may occur will be collected and evaluated. In addition the amount of active ingredient that enters your blood stream (pharmacokinetics) will be determined. The gels will be referred to as the 'study drugs' in this document.

This is the first time NFX-179 Gel will be applied on humans.

The study doctor will identify five cNF, called the Target cNF, that you will treat and the study doctor will evaluate during this study. One of the five Target cNF must be located on your face.

Photographs of the Target cNF are required for you to participate in this research study. Your identity will not be revealed in these photographs or in any information included with them. The Sponsor is taking actions to ensure you will remain unidentifiable in the study photographs (for example, using a code and not your name to identify you) however there is still a possibility you could be identified.

If you do not want photographs of your cNF taken you will not be allowed to participate in this study.

The photographs taken during the study may be used for research purposes related to the study and for presentation at regulatory agencies, at scientific meetings and, for scientific publications. In addition the photographs may be used for general corporate purposes or for marketing purposes.

During Visit 3 you will be randomly assigned by chance (like the flip of a coin) to receive either NFX-179 Gel 0.05%, NFX-179 Gel 0.15%, NFX-179 Gel 0.50% or Vehicle Gel. You have an equal chance of being in any of the four groups. You will treat the Target cNF with the same study drug once-daily throughout the 4-week study treatment period.

This is a double-blind study, which means neither you nor the study doctor will know which of the study drugs you are assigned to receive. In case of an emergency, however, the study doctor can get this information.

NUMBER OF SUBJECTS / LENGTH OF PARTICIPATION

About 48 subjects will participate in this study at approximately 6 study centers in the United States (US). Your participation in this study will last approximately 88 days and includes 7 study visits to the study center.

You are being invited to participate in this research study because you are 18 years of age or older and have been diagnosed with cNF. Research subjects must meet certain criteria to participate in this study.

Female subjects must not be pregnant or nursing and must either be of non-childbearing potential. Women of non-childbearing potential must have undergone successful surgical sterilization (hysterectomy (removal of uterus), bilateral tubal ligation (having your tubes tied) or bilateral oophorectomy (removal of ovaries) or be postmenopausal (defined as having no menses for 12 consecutive months). If a woman is of childbearing potential, she must agree to use an effective active form of birth control for the duration of the study. Effective methods of birth control are listed in the Pregnancy/Birth Control section of this document.

PROCEDURES

Before any study-related tests or procedures are performed, you will be asked to read, sign and date this consent document. The following tests and procedures will be performed to determine if you qualify to take part in this study:

- <u>Visit 1 (Week -4 to 0); Screening:</u>
    - The nature of the study will be reviewed with you
    - It will be determined if you meet all the inclusion and none of the exclusion criteria
    - Information about your age, race/ethnicity and medical history including any medicines you are using will be collected
    - The study doctor will perform a physical examination
    - An electrocardiogram (ECG, a tracing of your heart rhythm), to evaluate your heart's electrical rhythm will be conducted
    - Blood samples will be collected for routine laboratory evaluation
    - A urine pregnancy test will be performed if you are a woman who can have a baby
    - The study doctor will identify and evaluate five cNF (Target cNF) that will be treated and evaluated during the study
    - The study doctor will evaluate and measure the Target cNF

- Photographs of the Target cNF will be taken
- A member of the study staff will review the study instructions with you
- You will be given a subject instruction sheet

- Visit 2 (Week 0); randomization:
  - You will be asked about any changes in your health and the medications you are taking since the previous study visit
  - You will be asked if you followed the study instructions since the previous study visit
  - You will be asked to complete a Patient Reported Outcome Questionnaire (PRO)
  - It will be confirmed that you meet all the inclusion and none of the exclusion criteria
  - A urine pregnancy test will be performed if you are a woman who can have a baby
  - The study doctor will evaluate and measure the Target cNF
  - If you qualify you will be randomized to a study drug; if you do not qualify you will be discharged from the study
  - Photographs will be taken of the Target cNF
  - An electrocardiogram (ECG), to evaluate your heart's electrical rhythm will be conducted
  - A high-frequency ultrasound (a painless test where sound waves are delivered through the skin) to evaluate cNF size will be conducted
  - Your vital signs will be measured
  - Blood samples will be collected for routine laboratory evaluation
  - Before the first study drug application a blood sample will be collected for evaluation of the study drug's active ingredient in your blood
  - You will evaluate symptoms of irritation on the Target cNF before the first study drug application
  - You will be instructed on the proper technique for applying the study drug, then you will be supplied with study drug and make your first application while a study staff member watches
  - A study staff member will monitor you for at least 20 minutes to determine if you have any adverse events (side effects) to the first study drug application
  - After the study drug application, you will evaluate the target cNF for symptoms of irritation (such as redness, swelling, pain or itching)
  - Starting the day after this visit you will continue to apply the study drug once-daily to the Target cNF for 4 weeks
  - You must apply the study drug to the Target cNF 18-30 hours prior to your next study visit
  - A member of the study staff will review the study instructions with you and provide you with study drug

- Visits 3-4 (Weeks 2 and 3); study treatment period:
  - During this period you will apply the study drug once-daily to the Target cNF
  - You must apply the study drug to the Target cNF 18-30 hours prior to each study visit
  - You will be asked about any changes in your health and the medications you are taking since the previous study visit
  - You will be asked if you followed the study instructions since the previous study visit
  - The study doctor will evaluate and measure the Target cNF
  - You will evaluate symptoms of irritation on the Target cNF
  - Photographs will be taken of the Target cNF
  - A blood sample will be collected for evaluation of study drug in your blood
  - A member of the study staff will examine your study drug containers and collect and dispense study drug as needed
  - A member of the study staff will review the study instructions with you

- Visit 5 (Week 4); end of the study treatment period:
  - You will be asked about any changes in your health and the medications you are taking since the previous study visit
  - You will be asked if you followed the study instructions since the previous study visit
  - You will be asked to complete a Patient Reported Outcome Questionnaire (PRO)
  - Your vital signs will be measured
  - A urine pregnancy test will be performed if you are a woman who can have a baby
  - An ECG, to evaluate your heart's electrical rhythm will be conducted
  - A high-frequency ultrasound to evaluate cNF size will be conducted
  - Blood samples will be collected for routine laboratory evaluation
  - Before the study drug application at this visit a blood sample will be collected for evaluation of study drug in your blood
  - Photographs will be taken of the Target cNF
  - The study doctor will evaluate and measure the Target cNF
  - You will evaluate symptoms of irritation on the Target cNF before the study drug application
  - You will make your final study drug application
  - After the study drug application, you will evaluate symptoms of irritation the Target cNF
  - After the study drug application, the study doctor will evaluate signs of irritation on the Target cNF
  - 30 minutes, and 1, 2, and 4 hours after the study drug application blood samples will be collected for evaluation of study drug in your blood
  - The study doctor will remove each (5) Target cNF and one Non-Target cNF (not on the face) by excision (using a scalpel) 3-5 hours after the study drug application. Excision means that the doctor will cut out the

entire skin lesion using a scalpel (sharp surgical knife). You will be given numbing medication either applied to the skin or injected under the skin before the procedure. You may need to have stitches put in following the excision. You should ask the doctor to explain this procedure further if you have questions.
    - A member of the study staff will collect all of your study drug containers
    - A member of the study staff will review the study instructions with you

- Visit 6 (1-3 weeks after Visit 5) ; excision site care:
    - You will be asked about any changes in your health and the medications you are taking since the previous study visit
    - You will be asked if you followed the study instructions since the previous study visit
    - Your excision wounds will be managed following the study doctor's routine standard of care
    - A member of the study staff will review the study instructions with you

- Visit 7 (Week 8); end of the study:
    - You will be asked about any changes in your health and the medications you are taking since the previous study visit
    - You will be asked if you followed the study instructions since the previous study visit
    - You will be discharged from the study

USE OF PHOTOGRAPHS

Color photographs of your face will be taken throughout the study to document the status of the Target cNF. Your identity will not be revealed in these photographs or in any information included with them.

If you do not permit the study staff to take photographs of you as described above, then you will not be able to participate in this study. If you withdraw from the study or withdraw your permission for the study staff to take photographs of your face, you may no longer participate in the study and your photographs will no longer be used, except to the extent that the photographs have already been published and appear in print, broadcast media, internet publications, presentations or journals.

The study photographs may be used for research purposes related to the study and for presentation at the FDA, at scientific meetings and, for scientific publications.

In addition, the photographs may be used for general corporate purposes or for marketing purposes.

There will be no additional compensation for any photographs of your face.

EXPECTATIONS

While you are in this study, you must:

- Attend every study visit
- Follow all the instructions you are given
- Tell the study doctor about any changes in your health or the way you feel
- Tell the study doctor if you want to stop being in the study at any time

During the entire duration of the study you must:

- Continue to use your routine cleansers and cosmetics, but do not start using any new ones during the study
- Do not apply any non-study topical products to the Target cNF within 18 hours prior to a study visit
- Avoid exposing the Target cNF to excessive natural (for example, sunlight) or artificial (for example. tanning beds) ultraviolet radiation and use your routine sunscreen if excessive exposure cannot be avoided. This is because the study drug may make your skin more sensitive to sunlight
- Bring this instruction sheet to every visit

During the 4-week study treatment period, you must also:

- Apply the study drug to your Target cNF as directed, once daily, with at least 20 hours between applications
- Do not apply the study drug to any open wounds or obviously infected skin
- On days prior to every study treatment period visit perform your study drug application 18 - 30 hours prior to the visit
- Do not wash or submerge your Target cNF for at least 6 hours after a study drug application
- Do not apply any topical products to your Target cNF for at least 6 hours after a study drug application
- Do not allow anyone else to use your study drug
- Keep the study drug away from children
- Store the study drug at room temperature
- Bring all study drug tubes to every visit
- Bring this instruction sheet to every visit

RISKS, SIDE EFFECTS AND/OR DISCOMFORTS

Risks of NF-179 Gel:

This is the first human study of the topical formulation of NFX-179 Gel.

The active ingredient in NFX-179 Gel is a new compound that never been approved for marketing or tested in humans. Based on animal studies, where the drug was applied to the skin, side effects that might be seen include:

- Crusting of the skin
- Swelling
- Redness

- Itching
- Scaling
- Scabbing

There are similar drugs, like MEK inhibitors, that are approved as oral (taken by mouth) treatment of patients with certain types of metastatic melanoma, a serious type of skin cancer.

Common adverse effects associated with the use of these oral study drugs in clinical trials include:

- Skin rash
- Acne like eruptions
- Dry skin
- Itching (pruritus)
- Inflammation around the fingernails and toenails
- Diarrhea
- Tenderness and swelling in the mouth
- Abdominal pain
- Swelling of the lymph glands
- High blood pressure (hypertension)
- Bleeding of mucous membranes (such as the linings of the nose and mouth)
- Blood chemistry abnormalities including increased liver enzyme levels (possible liver injury), anemia (low red blood cell count which may cause fatigue or shortness of breath) and reduce blood albumin levels (may cause swelling)

Due to the anticipated minimal blood levels of NFX-179 associated with the topical formulation of NFX-179 it is anticipated that there will be a low frequency of these side effects and that if they occur, they will be mild.

Risks of the Vehicle (inactive part of the gel)

- **Vehicle Gel:** The Vehicle Gel does not have any active ingredient. It looks like the NFX-179 Gel but is not designed to treat any disease or illness. It is designed to be compared with the NFX-179 Gel to learn if the NFX-179 Gel has any real effect. If you receive the Vehicle Gel your condition will not be treated with study drug and may become worse, stay the same or improve.

Procedure Risks:

You may feel discomfort during some of the protocol required tests and these tests may also have risks, such as:

- **Blood samples:** Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.
- **ECG:** You may have mild irritation, slight redness, or itching at the sites on your skin where the recording patches are placed.

- **Skin excisions (removal of cNF with a scalpel):** Possible side effects from skin biopsies include pain, soreness, and/or tenderness at the excision site, bleeding, infection, skin discoloration, and permanent scarring. Removed lesions may grow back. Most side effects are temporary.

UNFORESEEN RISKS
Since NFX-179 Gel is an investigational product, there may be other risks that are unknown. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening.

RISKS TO THE UNBORN
Pregnancy/Fetal Risks: The effects of NFX-179 Gel on a pregnancy, embryo or an unborn child are unknown and **may be hazardous**.

PREGNANCY / BIRTH CONTROL
If you are pregnant, planning to become pregnant or are breastfeeding a child, you cannot participate in this study.

If you are a woman who can have a baby, in order to reduce the risk of pregnancy, you must use an effective active method of birth control while you are participating in this study, and up to 30 days after the last application of study drug. If you are already using a method of birth control, the study doctor or study staff will discuss with you whether your current method of birth control is acceptable for use during this study.

For the purposes of this study, the following methods of birth control are considered effective and acceptable to use during this study:

- Combined (estrogen and progestogen containing) oral, transdermal or intravaginal hormonal contraception associated with inhibition of ovulation
- Progestogen-only oral, implantable, injectable, intrauterine device (IUD) or hormonal contraception or intrauterine hormone-releasing system associated with inhibition of ovulation.
- Intrauterine device (IUD)
- Intrauterine hormone-releasing system (IUS)

If you think that you have become pregnant during the study or within 30 days of stopping the study drug, it is important that you inform the study doctor immediately. If you become pregnant or think that you may be pregnant, you will be removed from the study and the study doctor will refer you to seek obstetric care, the cost of which will be your responsibility. The study doctor will request to track your pregnancy and will report the pregnancy to the Sponsor.

ALTERNATIVE TREATMENT
There is no approved drug therapy for the treatment of cNF. There are surgical treatments available to treat the signs and symptoms of cNF. You should feel free to discuss these alternative treatments and the associated risks and the potential benefits

for your cNF with the study doctor. You do not have to be in this study to receive these treatments for the signs and symptoms of your cNF.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

BENEFITS
You may benefit because of your participation in this study. There is, however, no guarantee that you will benefit from your participation. Results from this study may benefit others in the future.

COMPENSATION FOR PARTICIPATION
«Compensation»

You will be paid up to a total of $xx.xx if you complete this study. You will be paid for the visits you complete according to the following schedule:

- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.
- $xx.xx for Visits xxx.

If you do not complete the study, for any reason, you will be paid for each study visit you do complete.

You will be paid _____ ***[“after each visit,” “annually,” “bi-weekly,” etc.]***

If you have any questions regarding your compensation for participation, please contact the study staff.

[OR]

You will not receive any monetary compensation for your participation in this study.

If you have any questions regarding your compensation for participation, please contact the study doctor at the telephone number listed on page one of this consent document.

CONFIDENTIALITY
Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this informed consent document (under "Confidentiality" or "Authorization to Use and Disclose Protected Health Information").

The study doctor, the Sponsor or persons working on behalf of the Sponsor, and under certain circumstances, the FDA and the IRB will be able to inspect and copy confidential study-related records which identify you by name. Therefore, absolute confidentiality

cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

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.

COMPENSATION FOR INJURY

If, during the course of this study, any injury occurs to you as a direct result of the administration of the study drug or properly performed study procedures, the Sponsor agrees to pay all medical expenses necessary to treat such injury: 1) to the extent you are not otherwise reimbursed by medical, third party or government insurance; 2) provided you have followed the directions of the study doctor; 3) the study doctor and the study staff followed the protocol directions.

You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for negligence or intentional misconduct by signing and dating this consent document.

There are no plans to provide financial compensation for such things as lost wages, disability or discomfort due to injury. To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

COSTS

There will be no charge to you for your participation in this study. The study medication, study-related procedures, and study visits will be provided at no charge to you or your medical insurance company.

WHOM TO CONTACT ABOUT THIS STUDY

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

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

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

Please reference the following number when contacting the Study Subject Adviser: Pro00043941.

VOLUNTARY PARTICIPATION / WITHDRAWAL
Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

If you decide to withdraw from this study, please contact the study doctor to discuss any follow-up care that may be necessary. There is no increased risk of side effects due to your withdrawal from the study.

The study doctor or the Sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons, including competitive enrollment (subject enrollment will be terminated when the target number of subjects has entered the study treatment phase).

If you leave the study for any reason, the study doctor may ask you to have some end-of-study tests for your safety.

PRIMARY CARE PHYSICIAN / SPECIALIST NOTIFICATION OPTION
Please check one line below to indicate whether you want us to notify your primary care physician or your specialist of your participation in this study.

_____ Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ I do not have a primary care physician/specialist.

_____ The study doctor is my primary care physician/specialist.

Name and address of family doctor or primary health care provider:	Name: Address:
Telephone and Fax Number:	Tel: Fax:

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____
Subject's Printed Name

_____ _____
Subject's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

During your participation in this research study, the study doctor and study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the study) and record it on study documents. The study doctor will keep this personal health information in your study-related records (that we will refer to as "your study records").

If you have consented for the study staff to take and use your non-identifiable photographs, the photographs will become part of your study records. In addition, the study doctor may obtain, and include in your study records, information regarding your past, present and/or future physical or mental health and/or condition. Your study doctor may ask you to sign a separate authorization to obtain some or all of your medical records from your regular doctor. Your study records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (or "PHI").

PHI that will be collected during this study include:

- Your name
- Address
- Your birth date, sex, race and ethnicity
- A history of your medical conditions
- Study photographs; these photographs, and any information included with them, will not identify you and they may be used for scientific presentations, for general corporate purposes or for marketing purposes
- A personal identification number such as your driver’s license number or your social security number
- Results of medical test results such as laboratory tests of your blood, and other information from your study visits
- If you are a woman who can have a baby, pregnancy tests results

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization." Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing and dating, you are agreeing to allow the study doctor and study staff to use your PHI to conduct this study. The study doctor will not use your PHI for any other purposes.

By signing and dating this Authorization, you also are agreeing to allow the study doctor to disclose PHI as described below:

- Representatives of the Sponsor (NFlection Therapeutics, Inc.), and anyone working on behalf of the Sponsor to conduct this study. The Sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures and commercial products. The study staff will assign a code number and/or letters to your records, which means that you will not ordinarily be identified in the records sent to the Sponsor. The Sponsor may, however, look at your complete study records that identify you. In addition, the Sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to make sure the information is correct.
- Representatives of Advarra IRB, (an Institutional Review Board that reviews this study)
- The Food and Drug Administration (FDA) and other US federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the researchers and sponsor and need to access your information to conduct this study.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study

Your health data will be used to conduct and oversee the research, including for instance:

- 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.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this document, not to see or copy some or all your PHI until the Sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization will expire 50 years from the date you sign and date it unless you revoke (cancel or withdraw) it sooner.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study doctor, at the address listed on the first page of this consent form, stating that you are revoking your Authorization to Use and Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue to participate in this study.

You will receive a copy of this Authorization after you have signed and dated it.

_____ _____

Signature of Subject Date

_____

Printed Name of Subject

_____ _____

Signature of the Person Obtaining the Authorization Date

_____

Printed Name of the Person Obtaining the Authorization