INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE HEALTH INFORMATION (Part 1)

Sponsor / Study Title:	**Amytrx Therapeutics, Inc./ "A Two part, Phase I/II, Multi-center, Double-Blind, Randomized, Vehicle-controlled Study of the Safety and Efficacy of topically applied AMTX-100 CF in adult patients with Mild to Moderate Atopic Dermatitis"**
Protocol Number:	**AMTX100-AD-01 (NCT04313400)**
Principal Investigator: (Study Doctor)	**«PiFullName»**
Telephone:	**«IcfPhoneNumber»**
Address:	**«PiLocations»**

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- ➢ **This consent is for Part 1 (Phase 1) of clinical research study, AMTX100-AD-01.**
- ➢ **The Part 1 (Phase 1) of the study AMTX100-AD-01, is the first study in which the study drug, AMTX-100 *CF* topical cream, is given to humans.**
- ➢ **Being in this study is voluntary – your choice.**
- ➢ **If you join this study, you can still stop at any time.**
- ➢ **No one can promise that a study will help you.**
- ➢ **Do not join this study unless all of your questions are answered.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;

- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

Please read this consent form carefully.
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. (21CFR 50.25(c)).

Introduction

You are being invited to take part in Part 1 (Phase 1) of this clinical research study because you have been diagnosed with atopic dermatitis (also known as eczema), a skin condition that makes your skin red, dry and itchy.

The name of the study drug involved in this Part 1 (Phase 1) of the study is:

- AMTX-100 *CF*, topical cream, 1.1%

For purposes of this research, you will be referred to as a "participant".

Amytrx Therapeutics, Inc. (Amytrx), a pharmaceutical company based in US, is supporting this research study by providing study drug and funding for this research study.

Before you decide to take part in this study, it is important for you to understand why the research is being done and what it will involve. This consent form may contain words that you do not understand. Please take the time to read the following information carefully and feel free to take home an unsigned copy of this consent form to discuss this information with your family, friends, relatives and/or your study doctor or other primary care physicians (PCP). Please ask the study doctor or one of the study staff to explain any words or information that you do not clearly understand. Feel free to request more information about the study.

Once you have this information, understand the study procedures, and have had all your questions answered, you will need to decide if you will participate in this study. If you decide to participate, you will be asked to sign and date this consent form. Signed and dated copies of the consent form will be provided to you. You cannot take part in this research study until you sign and date this consent form.

Advarra IRB has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. 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. You must then decide if you want to be in the study.

What is the purpose of the study?

Your study doctor and his/her colleagues are conducting a research study with Amytrx Therapeutics, Inc. (Amytrx) to evaluate whether the study drug (AMTX-100 *CF*, topical cream, 1.1%) is safe and efficacious when used to treat Atopic Dermatitis (eczema). Atopic dermatitis (eczema) is a condition that makes your skin red, dry and itchy. This study drug is investigational because it has not been approved by the U.S. Food and Drug Administration (FDA). The results of these studies will be used to design future studies to improve treatment of atopic dermatitis.

The Part 1 (Phase 1) of the study will look at how safe different doses of the investigational drug AMTX-100 *CF*, topical cream, 1.1%, work in improving symptoms of atopic dermatitis. This Part 1 (Phase 1) of the study, AMTX100-AD-01, is the first study in which the study drug, AMTX-100 *CF* topical cream, is given to humans. Previous animal studies and pre-clinical work have shown that the study drug is both effective in treating eczema like lesions on animals, and safe at the dose which you will receive which is much lower than the doses the animals have received, however, it is unknown how safe and how well different doses of the investigational drug AMTX-100 *CF* topical cream, 1.1%, will work in human participants with atopic dermatitis at this time.

How does AMTX-100 CF work?

Atopic Dermatitis (AD) is a common, chronic, non-infectious skin condition. The main symptom of this inflammatory disease is a very itchy rash. The itch leads to scratching, and more redness, swelling, cracking, leaking clear fluid, crusting, and scaling.

In many cases AD gets better as the years go by, and it may go away for a while or disappear altogether. AD flare-ups (getting worse at times) however can really affect quality of life. People with AD tend to have an over-reactive immune system that when triggered by a substance outside or inside the body, responds by producing inflammation. It is this inflammation that causes the red, itchy and painful skin symptoms.

AMTX-100 *CF* study drug product is a white cream with AMTX-100, a new class of medicines which target body's inflammatory responses. AMTX-100, the active ingredient, is a peptide (a type of protein), which reduces the inflammatory responses within your skin cells, thus reducing eczema symptoms. In Part 1 of the study, AMTX-100 *CF* topical cream will be applied to the eczema affected areas of your skin twice daily for seven (7) consecutive days.

This document uses words such as study treatment, study drug, medication, and participant. Please remember this is a research study and the use of these terms does not mean the use of AMTX-100 *CF* has been found to be safe or effective for your condition.

Why have I been chosen?

You have been chosen for consideration for this study because you are diagnosed with atopic dermatitis (AD), also known as eczema, and your study doctor thinks that you might be a good candidate for Part 1 of this study, based on how severe and how large your skin areas are

affected by AD. In Part 1 (Phase 1) of the study, about 25 participants with atopic dermatitis will enroll at about 5 sites within the United States.

Do I have to take part?

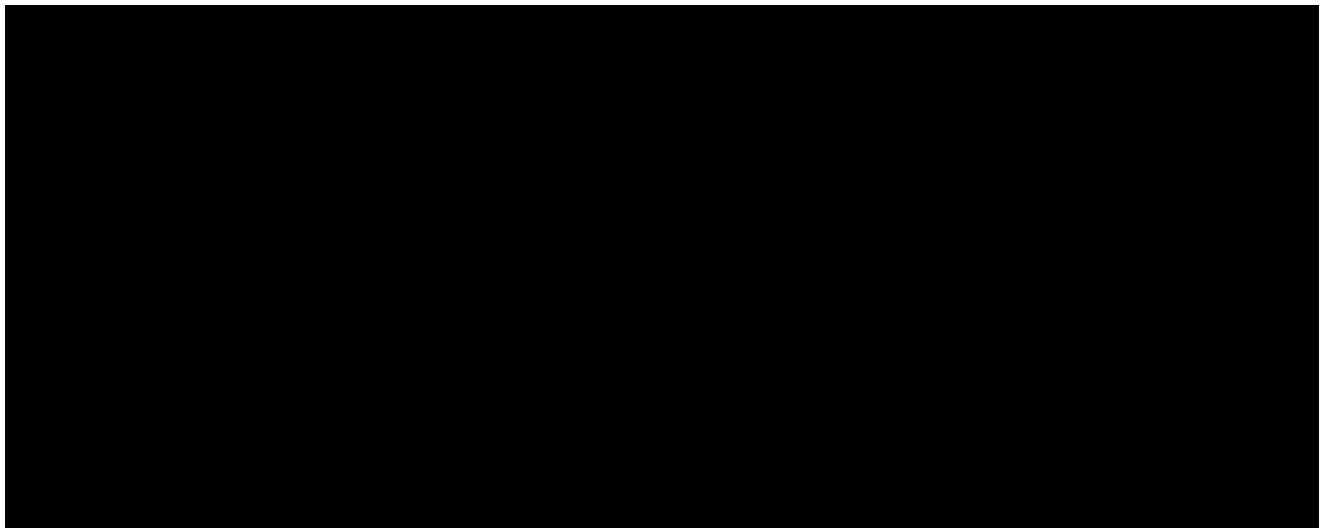
You do not have to take part in this study; it is completely voluntary. You will always be free to withdraw from the study at any time. If you withdraw during the study, you will be asked to come in for a final visit for study evaluations. You do not have to give a reason for your withdrawal from the study. This will not affect the standard of care that you will receive, and it will not result in any penalty or loss of benefits to which you are entitled. The data collected up to that point will be kept with your medical records and will be kept confidential. Your identity will not be disclosed.

General Study Design and Duration of Study Involvement

Part 1 of the study is designed to determine how much of the study drug, AMTX-100 *CF* topical cream, 1.1%, is safe to be used on body surface areas affected with AD.

The duration of your participation in Part 1 (Phase 1) of this study will be approximately up to six (6) weeks and include four (4) in-clinic study visits to the study center and one (1) participation confirmation call by telephone . The study will be conducted in 3 Parts. After the initial screening period of the Part 1 study (up to 3 weeks), you will enter study treatment period of the Part 1 study (7 days), followed by follow-up period of the study (around 2 weeks). During the study treatment period, fourteen (14) doses of AMTX-100 *CF* topical cream, 1.1%, will be applied to all the AD-affected areas as instructed by the study doctor, twice daily for 7 consecutive days, regardless of whether your AD affected skin areas become better or clear.

There are five (5) different dose levels of AMTX-100 *CF* topical cream, 1.1%, that will be administered in this study. The dose level (group) that you will be assigned to will depend on timing, how large your AD affected areas are, and per the study doctor determination:



*Participant will be eligible to unique dose level, depending on how large the skin areas involved with atopic dermatitis is.

**Amount of AMTX-100 *CF* topical cream, 1.1%, will be applied to all treatable AD affected areas on your skin, depending on how large your skin areas involved with atopic dermatitis is.

[redacted]

NOTE:
The study doctor will conduct dermatologic evaluations on you to evaluate your symptoms of atopic dermatitis on each clinical visit. These evaluations will include questionnaires, assessment scales and pictures of AD affected skin areas to confirm the atopic dermatitis diagnosis and, determine how severe symptoms of atopic dermatitis are.

The questionnaires, assessment scales and pictures will not include any identifying information about you (name, address, phone number, physical appearance, etc.), but will be labeled with a unique subject ID number assigned to you to protect confidentiality and some of them may be uploaded to a secure internet portal. The applicable study team members will need specific login credentials to be able to access the questionnaires, assessment scales and pictures on this secure internet portal. No one other than the study team will have access to this portal. The questionnaires, assessment scales and pictures may be used by the study Sponsor (Amytrx Therapeutics, Inc) or people or companies working with the Sponsor for research purposes only as described above and will not be sold to other people or companies for commercial purposes. De-identified pictures may or may not be used in future publication. The questionnaires, assessment scales and pictures uploaded to the secure internet portal will be destroyed immediately after study analyses completion.

Your Responsibilities
As a participant, your responsibilities include:

- Follow your study doctor's or study staff's instructions
- Ensure that you keep your appointments for all visits;

- Ensure that you apply a thin layer of **assigned amount** of study drug, AMTX-100 *CF* topical cream, to **all assigned AD-affected areas, twice daily for 7 consecutive days (thirteen (13) doses in total at home)** throughout the study, as instructed by the study staff;
- While you apply study drug,
    - Avoid removing or occluding the study treatment by wearing loose-fitting clothing;
    - Avoid wiping your skin;
    - Avoid swimming after application;
    - Bathing the treated areas will be allowed once daily and should be done at least every 3 days;
    - Bathing/washing the treated areas in between morning and evening dose should be avoided within 8 hours after application;
- You may have some help from others when you apply AMTX-100 *CF* topical cream for skin areas which are hard to reach.
- Record study treatment administration information in patient diary, as instructed by the study staff, and return patient diary and used study drug tubes to site;
- You may use basic moisturizers/emollients to non-study drug treated skin areas (skin areas where study drug cream is not applied);
- Report any changes in your health or medications to the study doctor. You should not make any changes in your medications for atopic dermatitis unless instructed by the study doctor. In case your study doctor initiates any treatment for worsening symptoms of atopic dermatitis, ensure that you follow the treatment, instructed by the study doctor;
- There will be no restriction of what you can eat during the study, unless food items known to yourself or study doctor to trigger AD symptoms;
- If you are a woman of child bearing potential, you must use an acceptable method of birth control (for example, diaphragm, intrauterine device (IUD), condom, hormonal contraceptives, or abstinence) during your participation in the study or be surgically sterile (for example, hysterectomy, bilateral tubal ligation, or bilateral oophorectomy), so that you do not become pregnant. If you are found to be pregnant after you receive first dose of study drug, your participation in the study will be terminated, but your pregnancy will be followed up to term to evaluate if there are any safety concerns with you or your child.
- If for any reasons you are withdrawn from the study, withdrawal visit and follow up visit assessments will be performed.

Research Study Visits, Procedures and Assessments

Screening Part:

Screening Visit (Visit 1)

At the Screening Visit, the study doctor will check to see if you are eligible to participate in this study. After you sign and date this informed consent form and receive a copy, the following procedures will be done at the screening visit. If you are not eligible for the study, the study doctor will explain the reasons and arrange for the prescribed standard conventional therapy to continue.

The following procedures will be performed during the **"**Screening Visit (Visit 1)**"**:

- [redacted]

This visit will take about 2-3 hours of your time.

Visit 2

You will not be required to come to the clinic for this visit. If the results from the "Screening Visit" procedures are acceptable to the study doctor, the site study staff will call you and ask you a few questions on any changes in your medical condition or medications used and confirm your willingness to continue the participation in the study. During this call you will be scheduled for next visit and study treatment part of the study. If you are not eligible for the study, you will be explained the reasons and arranged for the prescribed standard conventional therapy to continue. This phone-call will not take more than 20 minutes of your time.

Study Treatment Part:

Baseline Visit (Visit 3: Day 0)

The Baseline visit (Visit 3) will occur within 21 days after the Screening Visit.

Below procedures will be performed at Visit 3, before you receive any study drug:

- [redacted]

[redacted]

First Study Drug Dose Application

Your first dose will be applied topically by a licensed medical professional or trained study staff. You will be trained on administration techniques, including how thick the cream layer should be on your skin, how to measure needed amount and how to record study drug application conditions in patient diary given to you. Study drug cream tubes, plastic cards and precision balance to weigh the correct amount of assigned study drug will be provided to you and you will be instructed to bring back the study drug tubes (even if they are empty) and the precision balances at next visit (Visit 4). All other 13 doses will be applied by yourself and/or by a caregiver at home. Ensure to use as instructed and to follow directions while using by the study staff.

After First Study Drug Application

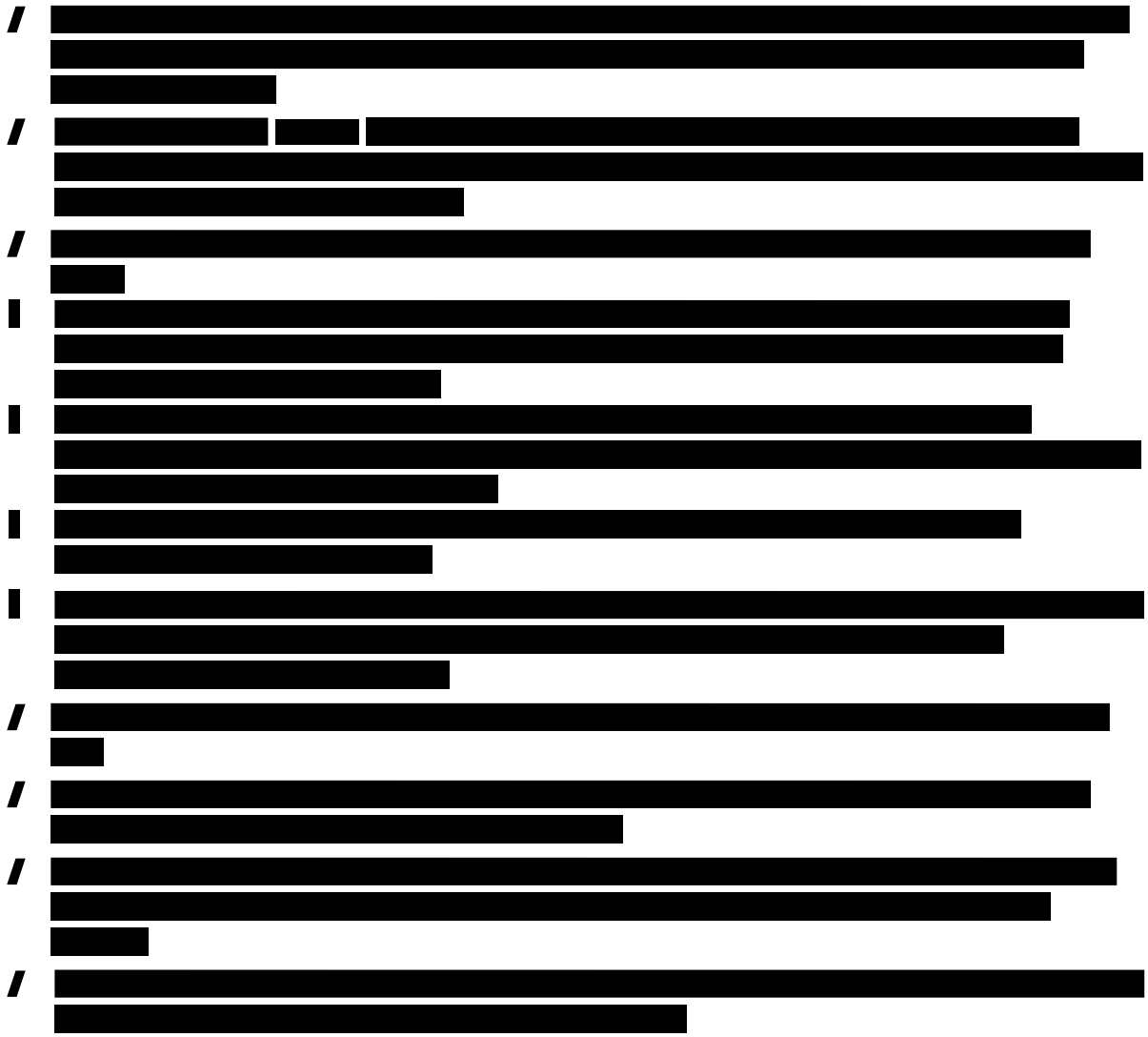
Your study doctor will monitor your condition, any possible side effects and the study treatment regimen as described below:

[redacted]

This visit will take about 2-3 hours of your time.

End of Study Treatment Visit (Visit 4: Day 7)

At visit 4 after you receive 14 doses in total (1 dose in-clinic and 13 doses at home), the study evaluations will continue and your study doctor will monitor your condition, any possible side effects and the treatment regimen as described below:



This visit will take about 2-3 hours of your time.

Follow-Up Part:

After completion of Visit 4 procedures, all participants will be followed up for 2 weeks to further assess safety and efficacy of study treatment.

Follow-Up Visit (Visit 5: Day 21±2)
During the follow-up visit, the following assessments will be performed:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

This visit will take about 1-2 hours of your time.

Withdrawal Visit:
For participants who withdraw/are discontinued prematurely during study treatment period, "Withdrawal visit" assessments will be performed. Visit 4 assessments will be performed as the withdrawal visit evaluations. For all withdrawn/discontinued subjects during study treatment period, the Follow-up visit (Visit 5) will happen 2 weeks after the withdrawal visit evaluations.

What are the risks of taking part?

This Part 1 (Phase 1) of the study, AMTX100-AD-01, is the first study in which the study drug, AMTX-100 *CF* topical cream, is given to humans.

There are risks to taking part in any research study. AMTX-100 (active ingredient) and AMTX-100 *CF* topical cream (drug product) are still undergoing testing and there may be side effects that are unknown at this time.

[redacted]

[redacted]

Animal studies have not indicated that AMTX-100 or AMTX-100 *CF* topical administration might be associated with allergic reactions.

Since AMTX-100 (active ingredient) and AMTX-100 *CF* topical cream (study drug product) have not been studied in humans and AMTX-100, active ingredient, is a new class of medicines for atopic dermatitis, side effects in humans are not known. You may or may not experience side effects of skin irritation observed in the animal study, however, this is unlikely because the skin irritation in animal studies was determined to be due to not appropriately washing off the study cream administration sites between AMTX-100 *CF* twice daily applications for 14 days. **To reduce the risk of skin irritation**, **bathing the treated areas** will be allowed once daily and **should be done at least every 3 days** keeping normal daily hygiene.

You will be monitored carefully during the administration of study drugs and will be watched carefully for side effects or any allergic reactions. As with any study 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

You need to tell your study doctor or study staffs immediately if you experience any side effects, any unfavorable signs or symptoms. If any safety concerns arise, the study treatment may be stopped.

Some redness, faintness, pain and swelling may happen due to the blood draws. You may experience bruising or bleeding at the site where the needle was placed. There is also a slight possibility of infection.

If you do not understand what any of these side effects mean, please ask the study doctor or the study staff to explain them to you.

It is unknown whether or not AMTX-100 and AMTX-100 *CF* topical cream will have any effect on unborn children or babies. It is unknown if AMTX-100 can pass through breast milk and it is

unknown if this can cause harm to your child. This has not yet been investigated. Therefore, females who are pregnant or planning on becoming pregnant or who are breastfeeding will not be included in the study. If you are a woman of child bearing potential, you must use an acceptable method of birth control (for example, diaphragm, intrauterine device, condom, hormonal contraceptives, or abstinence) during your participation in the study or be surgically sterile (for example, hysterectomy, bilateral tubal ligation, or bilateral oophorectomy), so that you do not become pregnant. If you become pregnant during the study, please inform one of the research staff as soon as possible. Your pregnancy will be followed up to term.

Your symptoms associated with atopic dermatitis may not get better or may become worse during this study.

What are the possible benefits of taking part?

You may or may not directly benefit from taking part in this study. The study treatment you receive may help to improve your atopic dermatitis symptoms. However, this cannot be guaranteed. The information that we get from this study may help us, and your study doctor, to treat future patients with this disease in a better way.

Are there costs for participating?

All study procedures will be provided at no charge to you.

Reimbursement for study participation:
«Compensation»

[redacted]

Alternatives to participation

You do not have to participate in this study to receive treatment for your condition. You should discuss with the study doctor what other alternatives are available and which ones are best for you. Depending on your condition, the study doctor might suggest alternative approaches such as revising your current medication dosages or changing your medications. Other alternatives might involve adding non-medication treatment options including phototherapy, or other methods which can be discussed with your study doctor.

What if something goes wrong?

Compensation (payment) for any injury caused directly by taking part in this study will be covered by Amytrx Therapeutics, Inc, if the medical expenses are not covered by your medical insurance, a government program or any other third party. This applies in cases where it is likely

that such injury results from the study treatment or any other procedure carried out in accordance with the plan for the study. The sponsor has no plans to compensate you where such injury results from any procedure carried out which is not in accordance with the plan for the study. Your legal right to claim compensation for injury is not affected or waived in any way.

If you are injured as a direct result of the use of the study drug, Amytrx Therapeutics, Inc will pay for medical expenses for the treatment of the injury that are not covered by your medical insurance, a government program or any other third party. Medical care will be provided to you through the study doctor and/or institution to treat any physical injury incurred as a direct result of the use of the study drug. You must agree to cooperate in obtaining any proceeds from insurance or other third party coverage that may be available to you with respect to the costs of such medical care. No financial or other form of compensation (such as lost wages or discomfort) will routinely be available to you for such injuries; however, 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 mistakes or intentional misconduct by signing and dating this consent document.

You should talk to the study doctor if you have any questions regarding the study treatment during the study, if you feel you did not receive the study treatment you expected, or any other concerns. The name and phone number of your study doctor is printed on the first page of this consent form.

If you experience a side effect or injury that may be related to this study or if you have an unscheduled visit for medical care for any reason, please contact the study doctor listed on page one of this informed consent.

If you claim to have become sick or injured from participating in this study, Amytrx Therapeutics, Inc. may give information that identifies you to its insurance carrier. This information will be used by the insurance carrier solely for the purpose of resolving your claim. 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.

Will my taking part in this study be kept confidential?

If you agree to take part in this study, your identity and medical records will be kept confidential and will not be disclosed outside of the hospital/study site/family physician's office unless required by law. Your medical records may be inspected by Amytrx Therapeutics, Inc (the company sponsoring the study). Your records may also be inspected by a company Amytrx Therapeutics, Inc has delegated some study management to, Amarex Clinical Research, LLC. (Amarex), for purposes of analyzing the study results and monitoring the study. Regulatory authorities such as the U.S. Food and Drug Administration (FDA) and Institutional Review Boards (IRB) may review study results and participants records to check that the study is being conducted correctly. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

What if new information becomes available?

During the course of a research study, new information may become available about your disease or the study treatment that is being studied that might change your decision to be in this study. If this happens, your study doctor will discuss this with you and whether you want to continue in the study. If you decide to withdraw, your study doctor will make arrangements for your prescribed standard conventional therapy to continue. If you decide to continue in the study you will be asked to sign and date an updated consent form.

Also, on receiving new information your study doctor might consider it to be in your best interest to withdraw from the study. The study doctor will explain the reasons and arrange for your prescribed standard care to continue.

What will happen to the results of the research study?

Once the study has finished, the information will be analyzed and a clinical study report will be written to record the results. This process can take about 6 months. Your study doctor will be kept informed of the results from the study, and a paper detailing these results will probably be published in an appropriate medical journal. You can also ask the study doctor for the results of the study.

Who is organizing and funding the research?

The company sponsoring and funding this research study is Amytrx Therapeutics, Inc. The study site and/or your study doctor is receiving financial support from the sponsor for undertaking this study.

Voluntary participation / Withdrawal

Your participation in this study is voluntary. You may decide not to participate or may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. Tell the study doctor if you are thinking about stopping or have decided to stop. The study doctor will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping your participation so that your doctor can evaluate any risks from the study drug and discuss what alternative follow-up care and testing could be most helpful for you. If you withdraw during the study, you will be asked to come in for withdrawal visit, followed by safety follow up visit for safety reasons. Even if you don't want to return for follow-up visits and blood tests, we would still like to collect information by phone or available medical records about your disease status.

Early Termination:

Your participation in this study may be stopped at any time by the study doctor, the sponsor (Amytrx Therapeutics, Inc.), the FDA, and/or the IRB without your consent for any of the following reasons:

- If it is in your best interest;
- If you do not consent to continue in the study after being told of changes in the research that may affect you;
- If you do not follow research directions;
- If you experience any serious side effects to the study drug;
- If lost to follow-up;
- If you are found to be pregnant;
- If the study is stopped early by the Sponsor (Amytrx), the IRB, the independent Data Safety Monitoring Committee (DSMC) or any regulatory agencies such as the U.S. Food and Drug Administration (FDA);
- Administrative reasons;
- Or any other reason as determined by the study doctor or the study sponsor.

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 Investigator 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: Pro00042081.

PRIMARY HEALTH CARE PROVIDER NOTIFICATION OPTION

I consent to having my family doctor or primary health care provider notified by the study site of my participation in this study and/or any significant findings related to my health (please check yes or no).

☐ Yes (If yes, please complete the information below)

☐ No

☐ 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	Tel:

Do not sign and date this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

[redacted]

[redacted]

[redacted]

[redacted]

PARTICIPANT STATEMENT OF CONSENT

I confirm that I have read this consent form (or it has been read to me) and the content of this form has been explained to me. I confirm that I have had the opportunity to ask questions and all of my questions were answered to my satisfaction. I agree to participate in this study and comply with the requirements to the best of my ability.

My participation in this study is voluntary and I AM free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

I agree to take part in the above study.

I consent to the use of all anonymized data that is collected from me during this study being used, either individually or pooled with other participants, in the analysis of this study, in printed publications, or for other purposes as determined by the sponsor, Amytrx Therapeutics, Inc. (The word **Anonymized** means that it will not be possible for you to be identified from the data that is collected).

By signing and dating this consent form, I have not given up any of my legal rights.

_____
Printed Name of Participant

_____	_____	_____
Participant's Signature	Date	Time

STATEMENT OF PERSON CONDUCTING INFORMED CONSENT DISCUSSION AND THE INVESTIGATOR

I, the undersigned, certify that to the best of my knowledge that participant named above had the study fully and carefully explained, including the nature, risks, and benefits of his/her participation in the research study; and all questions were answered to the study participant's satisfaction. I confirm that the study participant freely and voluntarily gave consent to participate in this research study before any study-related procedures were performed. A medical problem or language or educational barrier has not precluded this understanding.

I reviewed the consent form with the participant and answered the participant's questions. The participant appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the study when you want to?

_____ _____ _____

Signature of Person Conducting Informed Consent Discussion | Date | Time

_____

Name of Person Conducting Informed Consent Discussion (if different from Study Doctor)

I, the undersigned, certify that to the best of my knowledge the study participant named above had the study fully and carefully explained, including the nature, risks, and benefits of the participant's participation in the research study.

_____ _____ _____

Signature of Study Doctor (If different from above) | Date | Time

Original copy to be kept with the researcher; one copy to be given to the subject; one copy to be kept with the subject's medical records.

Authorization to Use and Disclose Protected Health Information (HIPAA Authorization)

While you are participating in this research study, the study doctor and his/her study staff will collect and create personal health information about you and record it on study forms. This information may include health histories, examinations, and results of tests. The study doctor will keep this information in study records. He/she may also gather information regarding your past, present, and/or future medical conditions from your primary medical doctor. These records may also include personal information such as your birth date, social security number, or medical record numbers which could be used to identify you. This type of information is called "Protected Health Information" (PHI).

Under a United States federal law called the "Privacy Rule" or Health Insurance Portability and Accountability Act of 1996 (HIPAA), no one's PHI that is gathered and obtained during research can be used to conduct the research or be given to anyone for research purposes without one's permission. Because of this rule, you may not participate in this study unless you give your permission to use and disclose your PHI.

By signing and dating this authorization, you are giving permission for the study doctor and his/her study staff, along with the Sponsor (Amytrx Therapeutics), Amarex Clinical Research (the Contract Research Organization) and the Regulatory authorities such as the U.S. Food and Drug Administration (FDA) and Institutional Review Boards (IRB) to use your PHI to conduct this study, to monitor your health status, and possibly to develop new tests, procedures, and commercial products.

You are also agreeing to allow your PHI to be disclosed to the study sponsor and any representatives working with them. The sponsor may also give your PHI to the FDA or other regulatory agencies. Study staff will assign a code number to you for this study. This will help to protect your identity; however, the sponsor may look at your complete study records which will identify you. The sponsor will also send representatives to your study doctor's office to oversee how the study is being conducted. These representatives will review your PHI to make sure the information is correct. The IRB may also have access to your PHI to meet its oversight responsibilities. These disclosures help to make sure that all information related to the research is available to those who need it.

Your identity will remain confidential, except for the disclosures described above and detailed specifically in the consent page, and will not be shared with others, unless it is required by law. If your PHI is given to the parties listed above or to anyone who is not required to follow federal law, your PHI will no longer be protected by the "Privacy Rule" and could possibly be used or disclosed in ways other than those listed here.

You have the right to see and make copies of your PHI. You are agreeing, however, not to see or make copies of your PHI until all of the sponsor work has been completed. At that time, you may ask to see your records.

Your HIPAA Authorization will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner. You have the right to cancel or withdraw this authorization at any time. If you cancel this authorization, your PHI will no longer be used for this study, unless it is necessary (based on your earlier authorization) to complete analysis (tests) and reports for this research.

To cancel your permission to use PHI, you must send a written notice to your study doctor's office at the address listed on page one stating that you are canceling your authorization for them to use or disclose your protected health information. If you cancel this authorization, you will not be allowed to continue in this study.

Subjects will receive a signed and date copy of this document.

AUTHORIZATION

I authorize the use and disclosure of my health information to the parties listed in the HIPAA authorization for the purposes described above.

_____
Printed Name of Participant (Study Subject)

_____ _____ _____
Participant's Signature Date Time

_____
Printed Name of the Person Obtaining the Authorization

_____ _____
Signature of the Person Obtaining the Date

Original copy to be kept with the researcher; one copy to be given to the subject; one copy to be kept with the subject's medical records.