Participant Information Sheet/Consent Form

Fiona Stanley Hospital

Title	Phase 1c Study Investigating the **SA**fety and **T**ol**E**rability of a **L**ysy**L** Oxidase **I**nhibi**T**or (PXS-6302) in the am**E**lioration of Keloids (The SATELLITE study)
Short Title	The SATELLITE study
Version Number	Version 1.4 31st October 2025
Project Sponsor	University of Western Australia
Coordinating Principal Investigator	Dr Natalie Morellini
Principal Investigator	Professor Fiona Wood
Associate Investigator(s)	Dr Suzanne Rea, Dr Helen Douglas, Dr Helen DeJong, Dr Peijun Gong
Location	Fiona Stanley Hospital

Part 1 What does my participation involve?

1 Introduction

You are being invited to take part in this research project because you have a Keloid(s). The research project is testing a new treatment for reducing Keloids. The new treatment is a Lysyl oxidase inhibitor called PXS-6302 and is a cream preparation that you apply to the Keloid. This study is testing the safety and effects of PXS-6302 on Keloids.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.
You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

This study is investigating whether a new drug, PXS-6302, can improve Keloids. The University of Western Australia (called the "Sponsor"), is developing PXS-6302 (the study drug) as a potential new treatment to reduce the volume of Keloid scars.

We are unsure why Keloids form after tissue injury. However, compared to normal skin, Keloids have more collagen (the main protein that makes up the body's connective tissues), which leads to continued growth of fibrotic scar tissue beyond the margins of the original

wound. The collagen is stable and packed because it is linked together through a process called cross-linking. Lysyl Oxidase enzymes promote crosslinking of collagen. The drug, PXS-6302, acts by preventing Lysyl oxidase enzymes from working. This makes the collagen less stable and will hopefully lead to changes in the Keloid volume over time.

This will be the third time PXS-6302 has been tested in humans and the first time it has been applied to Keloids in humans. It has not been approved in Australia by the Therapeutic Goods Administration (TGA), or in any other country, for doctors to prescribe for patients. Since this is the first time the study drug is being given to people with Keloids, its use in this study is experimental.

The purpose of this study is to test the safety and tolerability of PXS-6302 as well as if it changes the Keloid. We want to find out what effects it has on you and your health. We are doing this study in female and male volunteers to find out;

1. Does the study drug have any side effects and is it well tolerated when given over a long period of time (up to 3 months in this study)?

2. Does the study drug change Keloid volume?

3. Does the study drug stop Keloid symptoms of pain and itch?

This research has been initiated by the study doctor, Professor Fiona Wood, and is funded by Syntara Ltd. This research is being conducted by the Burn Injury Research Unit at the University of Western Australia. The research is sponsored in Australia by the University of Western Australia

3 What does participation in this research involve?

This study will use a treatment or a placebo cream. A placebo is a medication with no active ingredients or a procedure without any medical benefit. It looks like the real thing but is not.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

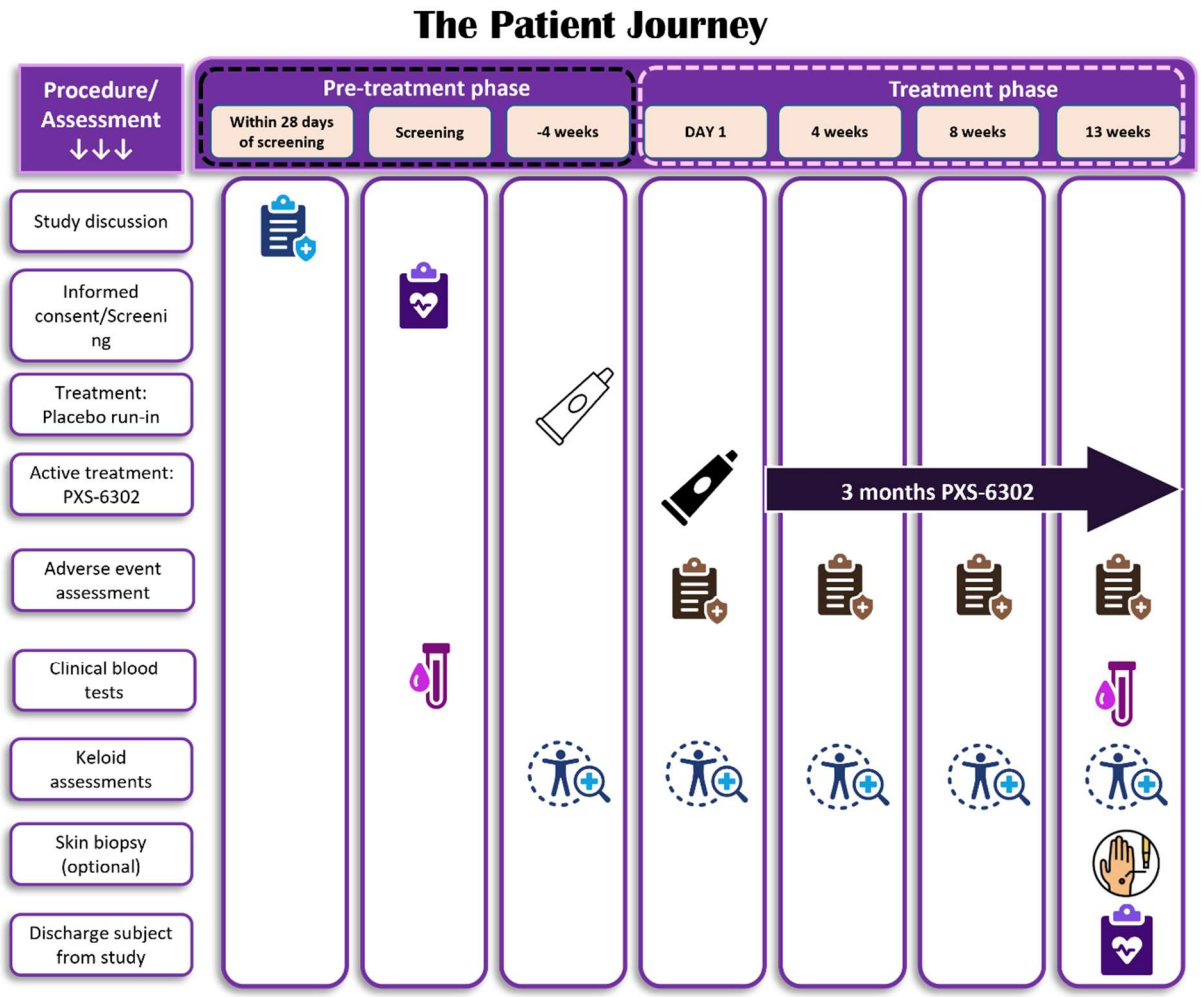
You may be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

This study will consist of three parts. The first part is a screening visit, the second part is the placebo pre-treatment phase and the third part is the study drug treatment phase. During the study we will assess your scar and collect blood to understand the effects of PXS-6302.

An overview of what being in the study will involve is shown below;



Part 1. Screening Visit – (Between 28 to 2 days before you start the study; this visit should be about 1 hour).

- A discussion with the study doctor to make certain you fully understand the study, its procedures and requirements. Please make sure you ask any questions you may have about the study before or during this visit. You will need to sign the attached Informed Consent Form to confirm you are willing to participate in this study and follow all instructions provided by the study staff, as well as abide by any study restrictions (these are detailed in the 'What are my responsibilities in this study' section).

  Please note that you will have the opportunity to receive this participant information sheet and consent form prior to coming into the clinic for the screening visit. This will allow you to review the information and discuss your potential involvement in this study with family, friends and/or a medical professional of your choosing (such as your GP). After signing the consent form in the presence of the study doctor you will have the opportunity to leave the clinic and come back at a later time, to complete the screening visit assessments outlined below, should you wish to discuss your involvement further with friends, family or a medical professional of your choosing.

  Following your consent, you will undergo a complete medical examination which will include:

- Documentation of demography (race, gender, ethnicity);
- Medical/surgical history;
- A full physical examination. Your overall health will be assessed which may include assessment of your general appearance, head, neck, ears, eyes, nose, throat, skin, cardiovascular system, respiratory system, gastrointestinal system, and neurological system; height and weight will also be measured. You will not be required to undress for this examination but may be required to move or lift parts of your clothing out of the way to allow examination of the chest, back and abdomen. For your privacy, this will be done behind a closed curtain;
- Vital sign measurements (blood pressure, pulse rate, breathing rate and temperature).

- You will be asked about any medications that you are taking, or any other products that you are currently using, as some medications must not be taken before or during the study.

- You will be asked how you are feeling. Please make sure you tell study staff as much information as possible.

- A sample of blood (approximately 17 mL, or slightly more than 3 teaspoons) will be taken from a vein in your arm with a needle and syringe – this will be used to perform tests to assess your general health. If you are of childbearing potential, the blood collected will also be used to conduct a pregnancy test.

- At the conclusion of screening, provided you are eligible and willing to participate in the study, a study staff member will contact you and explain the details of the study to you, including re-confirming the study dates and restrictions.

- There may be reasons why you are not allowed to take part in this study. The study doctor or staff will discuss these with you.

Part 2. Placebo treatment

If you are eligible and you choose to take part in the study, you will be given a tube of placebo cream. You will be shown how to apply this cream to the Keloid and given the cream to take home. The cream comes in a special device to make it easy to apply. You will be required to apply this to your Keloid(s) 3 times per week for 4 weeks, every Monday, Wednesday and Friday.

On the day that you are given the Placebo, you will also undergo some baseline scar assessments, which are listed below.

Part 3. Treatment period

You will be given a tube of cream containing the study drug on day 1 when you commence in the study. If you have multiple Keloids, you will also be given another tube of cream containing placebo. You will be shown how to apply this cream(s) to the Keloid(s) and given the cream to take home. The cream comes in a special device to make it easy to apply. We will also give you a sheet of instructions to take home to remind you what to do.

On Day 1 the study drug will be applied with you in the clinic. Each day after you leave you will need to apply this drug to the scar area three times per week, every Monday, Wednesday and Friday. This may change depending on how you tolerate the cream. You will be provided with product to take home with you. The study nurse will instruct you on how to apply and store the product at home. It is important that you keep to the instructions on where and how to apply the cream during the study period. Please avoid showering, using body lotions, perfumes and sprays and sun exposure within 2 hours prior to application of the

cream. The first dose will be administered as cream which will be applied by a study nurse to your Keloid. You will be asked to allow the study drug to absorb into the skin for at least 1 hour, then no restrictions on touching or covering the area will apply. On each day you have a clinic appointment (4 weeks and 8 weeks) DO NOT apply the cream. We will do this at your appointment or you will be asked to do so later in the day.

You will need to come back after 4 weeks, 8 weeks and 13 weeks after starting the treatment phase of the study. At each visit we will conduct;

- Physical examination.
- Measurement of your vital signs.
- Questionnaires based on how your scar looks and feels and how it impacts your life.
- You will be asked how you are feeling and if you had any changes in your health or taken any new medications. It is very important to tell the study staff about anything that has changed so that it can be properly recorded before you have any study medication. These changes won't necessarily keep you from continuing in the study, so please make sure you tell study staff as much information as possible.
- Photographs will be taken of the application site
- We will also take a 3D photograph of the site using a handheld visible light scanner. This will take the same time as a standard photograph (a few seconds).
- You will also be taken to the Medical Imaging Department to have non-invasive sonography (ultrasound) to measure how thick the scar is, the density of collagen, scar elasticity (elastography) and blood flow to the scar (colour Doppler imaging). This will take about 30-45 minutes.
- At the Day 1 and 13 weeks, we will use a new type of scanning device that uses Optical coherence tomography (OCT) to measure the Keloid. This will involve a small piece of silicone being placed on the site and a scan of 10mmx10mm area will take up to 3 minutes to complete. We will also scan the same area of normal skin. OCT uses visible light and there is no risk to taking part in this additional scan. The OCT scan will take approximately 10 minutes.
- At 13 weeks we will also take blood samples (up to approximately 15 mL or slightly more than 3 teaspoons).

- Please make sure you let the study doctor or study staff know of any symptoms you may be feeling before leaving the clinic, so the study doctor can properly assess you before you leave.

5 If you have more than one Keloid

If you have more than one Keloid, you will have the option to apply two different creams to two different Keloids. You will receive two different tubes of cream which will be colour coded. One will be the placebo and one will be the active drug. You and the Researcher will not know which is which. You will be required to apply the same cream to each keloid throughout the study, in the same way as above. All assessments will remain the same but both keloids will be assessed separately where appropriate.

6 Other relevant information about the research project

This study is being conducted at Fiona Stanley Hospital and will involve 20 study participants. This study is following on from a human trial conducted in Western Australia during 2022-2023, which investigated whether PXS-6302 improved scars.

7 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Fiona Stanley Hospital.

8 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Your study doctor will discuss the current options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

9 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, it is possible that there may be changes to the appearance of the Keloid. The study

will help us understand how we might use this drug to determine whether using it can improve Keloids. This may benefit other patients with Keloids in the future.

10 What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Erythema (skin reddening, from cream application)	sometimes	Mild	Few days
Localised bruising and mild pain at the site of the needle (from blood collection)	Every time blood is taken	No more than minor discomfort	A day
Bleeding, pain (from skin biopsy)	rarely	Mild	1-2 days
Impaired kidney or liver function	Extremely rare	Mild	A few weeks

The effects of PXS-6302 on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm for at least 6 months after the last dose of study medication.

Both male and female participants are strongly advised to use effective contraception during the course of the research and for a period of 6 months after completion of the research project. You should discuss methods of effective contraception with your study doctor. If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant. You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

11 What will happen to my test samples?

As part of this study we are collecting blood samples, skin swabs and optional skin (keloid).
The blood samples will be used for two purposes;
1. One sample will be used for standard clinical tests to ensure the drug is not having any effects on your health. This will include normal clinical tests of liver function and blood cell counts to make sure there are no negative effects of the drug. These samples will be tested in a clinical laboratory and the results stored. Any abnormal findings will be reported to the study doctor and they will contact you.

2. The second sample will be sent to Agilex Biolabs, a company in South Australia to test the levels of the drug in your blood. We do this to make sure there is not too much drug being absorbed that may be bad for your health. The company testing the levels of drug will not have any identifying information about you and all samples are sent with a study code instead.

At 13 weeks we will collect an ethanol swab on the Keloid surface. This process is painless. We may also take a small 3mm diameter skin biopsy (optional) from your Keloid. The skin samples will be sent to Syntara Ltd in NSW. The samples will be used to test how much drug is in the Keloid, and whether it has blocked the lysyl oxidase enzyme from working. Syntara will not have any identifying information about you and all samples are sent with a study code instead.

The samples are destroyed when they are analysed. Therefore none of your samples will be used for other research studies or stored longer than is needed to do the analysis.

12 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form. Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

13 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your Keloid. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor if you are using any moisturisers, creams, oils or emollients on your Keloid. You will not be able to apply other treatments to the scar area during this study. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor will explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

14 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results.

15 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

• Unacceptable side effects

• Decisions made by local regulatory/health authorities.

16 What happens when the research project ends?

When the study ends the drug will not be available for use to treat keloids. Further studies will be required before regulatory approval could be obtained. There will be no restrictions on your use of other treatments for keloid(s).

Once the study is completed and the data is analysed we will produce a summary of the findings of the study. This summary will be made available from different sources and will also be published on the Fiona Wood Foundation website (fionawoodfoundation.com) on the research page.

Part 2 How is the research project being conducted?

17 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your data will be stored electronically using a secure REDCap database hosted by the Sponsor, the University of Western Australia. Any hard copies of documentation (for example copies of your consent) will be stored in a secure cabinet at Fiona Stanley Hospital, 4th Floor burns outpatient clinic. The REDCap database will only be accessible by the investigator team in an identifiable format. For the purposes of statistical analysis, deidentified data will be sent to Syntara Ltd via secure file transfer. No identifiable information will be provided to any person not named as an investigator on this form.

Some samples are being analysed externally – for example your blood samples and skin biopsies. These samples will be provided using only a study code. The data will be returned to the investigator team and entered into the REDCap database. At no time will information that could identify you be shared with the laboratories analysing the samples.

Data for this project will be stored for 15 years. Paper documentation will be destroyed using a shredder and electronic data will be deleted.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records, for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to participation in this research project. It is anticipated that the results of this research project will be published and/or presented at a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about participation in this research project may be recorded in your health records. In accordance with relevant Australian and/or Western Australian privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information. Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

18 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:

1. The pharmaceutical industry has set up a compensation process, with which the Sponsor of this research project, the University of Western Australia, has agreed to comply. Details of

the process and conditions are set out in the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial. In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. The research staff will give you a copy of the Guidelines together with this Participant Information and Consent Form. If you have any questions about the Guidelines, please ask to speak to Dr Natalie Morellini.

2. You may be able to seek compensation through the courts.

19 Who is organising and funding the research?

This research project is being conducted by the University of Western Australia (Skin Integrity Research Institute and Burn Injury Research Unit),and is sponsored in Australia by the University of Western Australia. The research is being funded by Syntara Ltd (formerly Pharmaxis). Please note that all of the appointments will be conducted at Fiona Stanley Hospital.

By taking part in this research project you agree that samples of your blood or tissue (or data generated from analysis of these materials) may be provided to Syntara Ltd. Syntara Ltd may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Syntara Ltd.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Syntara Ltd, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.
The University of Western Australia will receive a payment from Syntara Ltd for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

20 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research

project have been approved by the HREC of South Metropolitan Health Service, smhs.hrec@health.wa.gov.au; Reference number (PRN): RGS00000007294
This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2023). This statement has been developed to protect the interests of people who agree to participate in human research studies.

21 Further information and who to contact

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the study research team on 0411 460 506 or any of the following people:

Clinical contact person

Name	*Fiona Wood*
Position	*Director Burns Service WA*
Telephone	0480 370 824
Email	*Fiona.wood@health.wa.gov.au*

Complaints Contact person

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Position	Manager, Research Support and Development Unit (RSDU)
Telephone	(08) 6152 3214
Email	Smhs.rgo@health.wa.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research

South Metropolitan Health Service Human Research Ethics Committee
Contact person: Ethics Coordinator Phone: 08 6152 2064.
Email: smhs.hrec@health.wa.gov.au

Consent Form

Title	A Phase 1c Study Investigating the **SA**fety and **T**ol**E**rability of a **L**ysy**L** Oxidase **I**nhibi**T**or (PXS-6302) in the am**E**lioration of Keloids (The SATELLITE study)
Short Title	SATELLITE Study
Version Number	1.4 31st October 2025
Project Sponsor	University of Western Australia
Coordinating Principal Investigator	Dr Natalie Morellini
Principal Investigator	Professor Fiona Wood
Associate Investigator(s)	Dr Suzanne Rea, Dr Helen Douglas, Dr Helen DeJong, Dr Peijun Gong
Location	Fiona Stanley Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to University of Western Australia concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I consent to the storage and use of blood and tissue samples taken from me for use, a study nurse taking photos of my scar, as described in the relevant section of the Participant Information Sheet, for this specific research project

☐ I consent to having a skin biopsy on my Keloid(s) at 13 weeks

☐ I consent to being contacted for future research

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature

Form for Withdrawal of Participation

Title	A Phase 1c Study Investigating the **SA**fety and **T**ol**E**rability of a **L**ysy**L** Oxidase **I**nhibi**T**or (PXS-6302) in the am**E**lioration of Keloids (The SATELLITE study)
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Location	Fiona Stanley Hospital

Declaration by participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, relationship with those treating me or relationship with [Insert site].

Name of Participant (please _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.