Participant information and consent form – Study details

PLEXOVAL II - The Safety of Non-Autologous PLEXARIS OS in Wound Healing

Professor Stephen Hall, Principal Investigator

Title	A Prospective, Randomised, Double Blind, Placebo Controlled, single dose, single site phase 1 study to assess the safety and biological activity of a Human non-autologous platelet derived Extracellular Vesicle therapy vs placebo on wound healing rate following skin punch biopsy in healthy volunteer adults.	
Short title	PLEXOVAL II	
Protocol number	PXR002	
Project sponsor	Exopharm Ltd, Level 17, 31 Queen Street, Melbourne Vic 3000	
Study doctor	Prof. Stephen Hall	
Clinical contact person	Prof. Stephen Hall	03 9509 6166
24-hour medical contact	03 9387 1000	stephenhall@emeritusresearch.com

1 Would you like to take part in this clinical study?

We would like to invite you to take part in our clinical study because you are a healthy adult volunteer.

This document tells you about the study and describes what will happen if you take part. If there is anything you don't understand or want to know more about, please ask us.

If you don't know what to ask, there are some questions to consider in the *Clinical study participant information and consent form: Part A – General information*.

You might also want to talk to a relative, a friend or your GP before you make up your mind. You may also take this form away with you. If you decide to go ahead, we will ask you to sign the consent form (*the last page of this document*).

By signing it you are telling us that you:

- understand what you have read
- consent to take part in the clinical research study
- 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 signed and dated copy of this participant information sheet and consent form to keep.

2 Why are we doing this research?

In this study, we are looking at the time that a wound takes to heal using a new Investigational Product, PLEXARIS OS and how safe it is to use. It will be compared against a non-active solution (placebo).

This study is being done to test if applying the investigational product, PLEXARIS OS to wounds is safe and if it helps improve wound healing by speeding up the tissue repair process. PLEXARIS OS has not been tested in humans before and this is the first study to test it.

The main ingredient of PLEXARIS OS are tiny particles called Extracellular Vesicles (EVs). These tiny particles are released by many types of cells, but specifically in this case by a type of blood cell in your body called platelets, cells that help blood to clot for wound healing. The EV's are used by the body to transport other materials, such as proteins, lipids (oil-like material) and other cellular parts, throughout the body. It has been shown in literature from earlier studies that EV's are capable of improving wound healing. PLEXARIS OS is an experimental treatment and is not an approved treatment and therefore is not available for use outside of a clinical trial setting in Australia or anywhere else in the world.

This study may help improve our understanding of the role of EVs in wound healing and in potentially developing new treatments.

The manufacture of PLEXARIS OS involves collection of platelets from donors in the United States of America or Australia. These platelets are then either shipped to Australia from the US or collected locally in Australia, where they are processed to collect the specific EVs required for the product. The product is called "human non-autologous" as the initial blood product the EVs come from are a healthy volunteer donor person. If the blood used was drawn from yourself this would be known as "autologous". All platelet donors will be pre-screened using a questionnaire in accordance with legal requirements in order to donate blood intended for transfusion such as at the Australian Red Cross Lifeblood centres. Each donor is also screened for blood transmissible diseases (such as HIV, Hepatitis etc.) according to the legal requirements. Only blood that is negative to all screening will be used. To date there is no evidence that COVID-19 or similar sudden acute respiratory syndrome viruses as being blood borne and affecting recipients of blood donations. In Australia and the USA individuals who have lived in the UK from 1980 to 1996 cannot donate blood due to the risk of Creutzfeldt-Jakob Disease, also known as CJD and 'mad cow disease' which is a rare degenerative disease of the brain that is fatal. All blood donors are required to answer the question on having lived in the UK from 1980 to 1996 on the pre-screening questionnaire prior to being able to donate blood. Although there has been no recorded case of CJD transmission in Australia or the USA from a blood donation since measures were implemented to exclude donors who lived in the UK from 1980 to 1996, there is the rare risk of the donor person and their platelets having variant CJD / CJD that could potentially be transmitted to you.

The tiny EV particles that are the main ingredient of PLEXARIS OS contain DNA, small RNAs, proteins and lipids which come from the donors platelets. This would be the same as if you receive a blood transfusion.

3 Do I have to take part?

If you don't wish to take part in the clinical study, you don't have to. If you decide to take part and later change your mind, you are free to withdraw at any stage. If you choose not to take part, or if you choose to take part and then later withdraw, this will not affect your relationship with this institution.

If you choose not to join the study, the study doctor will discuss other options with you.

We must keep any information we collect about you, up until you withdraw. The company conducting the study (Exopharm Ltd), has access to this information so they can check it is correct. If you do not agree with this then we cannot allow you to join the clinical study.

4 What is involved in the study?

We first need to confirm that the study is suitable for you. For this study we will need male and female participants aged between 18 and 64 years of age who are in good health, have no skin conditions such as eczema or psoriasis, no history of heart disease, bleeding disorder, cancer or diabetes, agree to take medically acceptable contraception treatment whilst on the treatment and for 30 days following treatment (appropriate methods of birth control will be discussed with study doctor), and agree to making sure they follow all instructions in relation to the wound dressings.

You cannot take part in this study if you are pregnant or breast-feeding or intend to have a baby within 30 days following the study, have any scars or infection in an area that would be used for the study, have a history of severe allergic reactions, are taking any anti-inflammatory, immunosuppression, blood thinning or cortisone treatments. The doctor will review your medications with you, so it is important that you bring a list of what you are taking to the visit.

The study will enrol up to 15 participants. It is only being undertaken at this clinic. You will be required to take part in the study for up to 44 days. The first participant who joins the study and is treated with PLEXARIS OS will be known as the sentinel participant. They will be treated at least one week before other participants in order to evaluate any potential effects of Investigational Product. Your study doctor will tell you if you are the sentinel participant. To ensure that there is no bias in the results from this study, you will not be told which wound received Product or which received placebo. Only the study investigator will know.

Table 1 details the schedule of the visits and what will be done at each visit. There will be a total of six visits to attend and you should be prepared to be at the clinic for approximately 2 – 3 hours at the screening and Visit 1 and then approximately 1 hour for visits 2 – 5. The Day 21 visit is optional and maybe requested by the doctor in the unlikely event that scar formation or progression of wound healing is not observed at Day 14, this visit would take approximately 1 hour.

Table 1. Scheduled visit details

Study Procedure	Pre-Study Activity	Treatment Period					End of Study/ Early withdrawal
Visit No.	**Screening**	**1**	**2**	**3**	**4**	**4b**	**5**
Study Days	-1 to -14	**0**	**3 (±1)**	**7 (±1)**	**14 (±2)**	**21(±2)**	**30 (±2)**
Informed consent	X						
Eligibility Check	X	X					
Medical history	X						
Demographics	X						
Physical examination	X	X	X	X	X	X	X
Vital signs (blood pressure, pulse rate, respiration rate and temporal temperature)	X	X	X	X	X	X	X
Pregnancy test	X	X					
Laboratory test	X			X	X		X
Product administration		X					
Adverse Event record		X	X	X	X	X	X
Prior & Concomitant Medications	X	X	X	X	X	X	X
Punch biopsy to bilateral upper inner arms		X					
Wound assessment			X	X	X	X	X
Determination of treatment and control wound diameter including measurement gauge			X	X	X	X	X
Physician assessment of wound using Modified Hollander Wound Evaluation Score (MHWES)			X	X	X	X	X

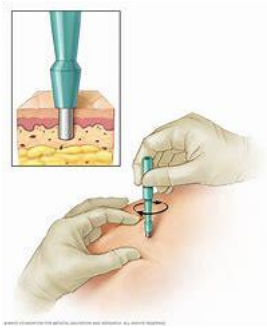
Screening Visit

If you are eligible to take part in the study and after you have signed the consent form, you will be asked to have a general blood test to look at your liver function, kidney function, blood sugar levels, cholesterol, Thyroid function, how your blood clots and your red and white blood cell counts, to make sure that your blood levels are all normal. If you are female and getting pregnant is a possibility, you will have a serum (blood) pregnancy test at the screening visit. The total amount of blood taken will be about a teaspoon-full of blood from your arm. You will also have a general physical examination including your temperature and your blood pressure and you will be asked about your medical history and any medications that you are taking.

Visit 1 – Day 0

On this day, the Investigational Product PLEXARIS OS will be given to you. If you are female and getting pregnant is a possibility, this visit will include a urine pregnancy test prior to dosing. A physical examination will be conducted as well as checking your vital signs (temperature, pulse rate, blood pressure, respiration rate) and you will be asked about any medications you have taken and if you have felt unwell at any time since your previous visit.

Two 4mm punch biopsies will be performed on your skin in two areas on your upper inner arms that are suitable in order to form a 'wound'. The biopsy removes a skin sample from your upper inner arm. The diagram below shows what a punch biopsy looks like –a small piece of skin is removed using a circular blade that is called a punch. Typically, they are taken if you have a lesion on your skin like a sun spot. The skin where the biopsy will be taken will be cleaned with an alcohol swab first. A local anaesthetic will then be injected into the area before the biopsy to numb the area. The doctor will then perform the biopsy once confirming with you the area feels numb. Once the small pieces of skin have been removed, they will be disposed of in accordance with clinic procedures.



One punch biopsy wound will be treated with the Investigational Product – one injection will be given subcutaneously under the skin just next to the wound margin.

The second punch biopsy wound will be given a sterile placebo solution (this will be sterile salt water) again, given subcutaneously just under the skin next to the wound margin. As part of the blinding of the study you will not know which wound has received which solution. Only the study Investigator will know which wound received the Product and which wound received the placebo. A dressing will be placed over the wounds. We will ask you to remain in the clinic for approximately 1 hour after the Investigational Product is administered to ensure that you do not get a reaction from the injections. You will be asked to keep the dressings on until the next visit and to let us know if you are concerned when you go home. You can expect to be in the clinic for approximately 2 - 3 hours. You will be instructed on how to take care of the wound dressings, which should stay in place until your next visit. The dressings are waterproof, so you are able to take a shower. It is not recommended to swim until the dressings have been removed at the Day 3 visit.

In the rare event that there is persistent bleeding after receiving the punch biopsy, the study doctor may need to put in a single stitch prior to dressing the wound.

<u>Visit 2 – Day 3 follow up</u>

At this visit, the dressings will be removed and the wounds will be washed with some sterile saline (salt water solution) prior to examination. A physical examination and an assessment of the wounds including measurements will be taken and recorded. Your vital signs will also be checked (temperature, pulse rate, blood pressure, respiration rate), and you will be asked about any medications you have taken and if you experienced any negative effects from the injections or have felt unwell at any time. You will go home without a dressing after this visit. You can expect to be in the clinic for about 1 - 2 hours at this visit.

<u>Visit 3 and Visit 4 – Days 7 and 14 follow up</u>

At both of these visits, a blood sample will be taken to look at your liver function, kidney function, blood sugar levels, cholesterol, Thyroid function, how your blood clots and your red and white blood cell counts and the results reviewed. The wounds will be reviewed and measurements will be taken and recorded. You will also have a physical examination including checking your vital signs and be asked about any

medications you have taken and if any negative effects have occurred since your last visit. You will be sent home again without a dressing. You can expect to be in the clinic for about 1 - 2 hours at this visit.

Visit 4 b – Optional Day 21 follow up

If the study doctor observed that either of the wounds have not properly healed at your Day 14 visit, they will ask you to return at Day 21 to further check the wound. The wounds will be reviewed, and measurements recorded. Generally a scab is formed over the punch biopsy within a few days showing that the wound healing process has begun and it is likely that the 4mm punch biopsy will have healed within 2 to 4 weeks. A physical examination will be performed and your vital signs will also be checked (temperature, pulse rate, blood pressure, respiration rate).

Visit 5 – Final Visit – Day 30 follow up

This is the end of treatment and your final visit. At this visit a blood sample will be taken to look at your liver function, kidney function, blood sugar levels, cholesterol, Thyroid function, how your blood clots and your red and white blood cell counts. The wounds will be reviewed, and measurements recorded. A final physical examination including checking your vital signs will be performed and a final review of your medications and any negative effects since your last visit will be conducted. You can expect to be in the clinic for about 1 - 2 hours at this visit. If there are any ongoing negative effects at this visit, the study staff may contact you after this visit to follow-up on these and continue to assess your health.

5 Who is conducting and paying for this research?

The study sponsor is Exopharm Ltd. Exopharm Ltd are conducting the research and have engaged the services of a Contract Research Organisation, Avania Pty Ltd, to perform the study monitoring at the research site. Your study doctor is being remunerated to conduct the study by the Sponsor, Exopharm Ltd. The study doctor and research site will not allow a conflict of interest to compromise their position or this research study.

6 What if something new comes up during the study?

If we find anything new about the investigational product or the study itself while the study is under way, the study doctor will discuss with you what it means and whether you want to continue in the study. If you decide to continue in the clinical study, we will ask you to sign an updated consent form.

7 What will happen to the confidential information about me?

We will keep all personal information confidential and securely stored.

All of the collected data will be coded. No personal information about you, such as your name and address will leave the clinic, and in all study information sent out from the clinic you will be identified with a code number only.

8 What information will be collected, and how will it be stored?

Australian and Victorian privacy law gives you the right to request access to your information that the researchers have collected and stored. The law also gives you the right to request corrections to any information about you that you disagree with. Please contact the study team listed in section 19 of this document if you would like to access your information.

We will not disclose your information without your permission, except in compliance with the law. Information about you may be obtained from your health records held at this institution and may be obtained from other health services for the purposes of research. Should you wish to cease treatment we would like the option to maintain follow up. If you sign the consent form, you agree to the study team accessing health records if they are relevant to your participation in this study.

During the study, information will be stored securely in a locked research office. At completion of the study, the data will be stored for a minimum of 15 years in line with good clinical practice guidelines. After this time, the study staff may confidentially dispose of this information by shredding. The re-identifiable/coded (it is possible to use the code to re-identify you) information held by the Sponsor, however, will not be destroyed.

Your health records and any information obtained during the research project may be subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities, authorised representatives of the Sponsor and Bellberry Human Research Ethics Committee. By signing the consent, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above. Information about your participation in this research project may also be recorded in your health records.

Your name will not be disclosed outside of this research institution. All information collected for the study will be labelled with a unique code assigned to you, not your name or medical record number. This code number will be linked to your identity by a key to the code. The study doctor will keep the key to the code. This key will be viewed by appropriate Sponsor personnel and regulatory authorities for the purpose of verifying study procedures and the data.

All blood and tissue samples that are collected as part of this study will be handled, assessed, and destroyed by the laboratories affiliated with the study centre as per standard of care. No samples will be stored for further research.

A publicly-accessible description of this clinical study will be available on the Australian & New Zealand Clinical Trials register, www.anzctr.org.au, as required by the National Statement on Ethical Conduct in Human Research (2007), section 3.3.12. This website will not include information that can identify you. At most, the websites will include a summary of the results. You can search this website at any time

9 What are my responsibilities during the study?

If you agree to participate in this study, you agree to be responsible for ensuring that all instructions you are given are followed. You also agree to comply with the other conditions in this document. If you cannot, or do not wish to accept this responsibility, then we cannot accept you as a participant in the study.

10 Can I have other medicines or procedures during this clinical study?

During this clinical study you can keep taking your regular medications.

It is important that you tell us about any procedures or medications you may be using. This is in your interest as well as being important for the study, because they may interact or interfere with the procedure. You must tell us about any prescription or over the counter medications, vitamins or herbal remedies you are taking. You must tell us if you are having any alternative procedures for example, acupuncture etc. It is important you let us know about any changes to these whilst you are taking part in the study.

11 What possible benefits might I get by taking part?

This research will not provide you with any personal benefit. By taking part you may be helping other people in the future and further the understanding of the wound healing process.

12 What risks do I run by taking part?

Medical procedures, medicine and tests often have side effects. You may have no side effects, some or all of the side effects listed below. These side effects 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 also 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 the intervention 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 procedure. Your study doctor will discuss the best way of managing any side effects with you. Some unwanted effects may actually not be related to the study, nevertheless it is important to document these.

PLEXARIS OS is an experimental drug, therefore the risks to human participants have not been fully evaluated. You will be informed as soon as possible of any new information about PLEXARIS OS that could influence your willingness to continue to take part in this study.

There have not been any previous human studies performed on PLEXARIS OS however, several clinical studies have been done on similar active ingredients (Extracellular Vesicles). These studies were "autologous" as the participants donated their own blood (platelets) in order for the EVs to be sourced and used as the treatment they were given compared to PLEXARIS OS which is not from your own blood (platelets). The clinical studies in humans demonstrate EVs are generally well tolerated and have a good safety profile.

The blood product to make the PLEXARIS OS comes from a healthy volunteer donor person. Any risk of catching a disease from this blood product is controlled for by screening the donor and the blood as would be done for a normal blood transfusion. Infectious blood borne diseases such as HIV and Hepatitis are all tested for to ensure only blood that is safe for transfusion is used in the making of the product. Note, there is the possibility that the blood used for this product could contain an unknown virus although this risk is remote.

Potential side effects (adverse events) include but are not limited to:

- Stinging upon application of the local anaesthetic which is used to reduce the pain induced by the punch biopsy - mild
- Pain or tenderness or swelling at the site of the punch biopsy – mild to moderate
- Short term bruising or bleeding at the site of the punch biopsy – mild to moderate
- Nausea (feeling sick) or Fatigue (feeling tired) – mild to moderate
- Skin feeling itchy or looking red – mild to moderate
- Fever and/or infection – mild to severe
- Allergic reaction to the investigational product – mild to severe
    - Signs of an allergic reaction can be itching, flushed or pale skin, low blood pressure, difficulty breathing, feeling faint or dizzy, feeling sick or vomiting. If you suffer a severe allergic reaction you may need to call triple zero for help.
    - You will be kept at the site for at least one hour after you have been given the treatment to monitor for any reaction
- Scarring at the site of the punch biopsy – mild to moderate
- Pain or bruising where blood is drawn for lab tests – mild to moderate

You will be allowed to take pain relief for any pain associated with the punch biopsy or any adverse event – contact your study doctor to discuss the appropriate pain relief to take. You must tell your study doctor what you have taken so the details can be recorded. Please call the study site if you have any concerns or questions between study visits.

13 How will you use any tissues or samples you take from me?

If you agree to participate in this study, the skin samples extracted from the punch biopsy will be disposed of according to the clinic's standard procedures and will not be stored or used for future research.

There are no genetic tests in this study.

14 What happens if I suffer severe side effects as a result of my participation in this study?

If you suffer any complications as a result of this study, please contact us as soon as possible.

In case of an emergency, contact 000.

If you are injured as a result of your participation in this clinical investigation you may be entitled to compensation. There are two avenues that may be available to you to seek compensation.

1) Sponsors of clinical trials in Australia have agreed that the guidelines developed by their industry body, Medicines Australia, will govern the way in which compensation claims from injured participants are managed by sponsors.

However, as guidelines, they do NOT in any way dictate the pathway you should follow to seek compensation. The sponsor is obliged to follow these guidelines. These guidelines are available for your inspection on the Medicines Australia website https://medicinesaustralia.com.au/code-of-conduct/lodging-responding-to-a-code-of-conduct-complaint/. Alternatively, your study doctor can provide you with a hard-copy of the guidelines.

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

It is the recommendation of the independent ethics committee responsible for the review of this trial that you seek independent legal advice before taking any steps towards compensation for injury.

The Sponsor for this study maintains insurance for the study in accordance with relevant national regulations which provides coverage for compensation for injury directly resulting from participation in the study conducted in accordance with the study protocol.

15 Will you pay me to participate in this study?

You will be paid a total of $1500 to participate in this investigational study. This amount covers both your time and inconvenience to take part in the study, as well as any travel and parking costs. You will be paid in instalments with the balance paid on completion of your last visit. There are no additional costs associated with taking part in this research project. All medication, tests and medical care required as part of the research project will be provided to you free of charge

16 What happens when the study ends?

After attendance at the Day 30 visit you will be exited from the study and any information that is applicable to your ongoing care will be provided. If in the rare instance the wound has not healed as expected, the study doctor will recommend further follow up as is deemed appropriate.

The investigation product will not be made available to you after your participation ends in the study.

17 Could the researchers stop the study early?

Yes, and if it does, the study doctor will let you know, explain the reason behind the decision and arrange for regular health care to continue if appropriate.

The study could be stopped for any of the following reasons:
- At the discretion of the Sponsor, Exopharm
- Unacceptable side effects of the investigational product
- The investigational product being shown not to be effective
- The study drug being shown to work and not need further testing
- If the ethics committee who provide approval of the study decide it is in the best interest to stop the study

18 Will the results of the study be published?

The intention of this study is to gather data, however the data will be de-identified. The deidentified results of the trial may be published in peer review journals or presented at conferences. You can ask for a copy of the study results on completion of the study. This may take some time so please discuss this with the study doctor.

To protect your privacy, no information will be published that could identify you as a participant in this study.

19 Who do I contact if I have a question or complaint?

We have included several contacts for you below. Who you contact depends on what information you need:

For all study enquiries or if you want to talk to the study team at any time:

Name	Professor Stephen Hall
Position	Principal Investigator
Telephone	(03) 9509 6166
Email	stephenhall@emeritusresearch.com

If you experience any side effects or complications as a result of this clinical study, you should contact the study team as soon as possible. They will arrange appropriate medical help.

24-hour medical emergency is available by contacting 000 or going to your nearest hospital.

If you need to talk to the institution where this research is being conducted, contact: Emeritus Research

Name	Cheryl Coleman
Position	Clinical Operation Manager
Telephone	(03) 9509 6166
Email	cherylcoleman@emeritusresearch.com

If you wish to discuss the study with someone not directly involved, particularly about policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Human Research Ethics Committee. The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Operations Manager, Bellberry Limited on 08 8361 3222.

20 What do I do if I need to seek compensation for injury?

If you are injured or experience severe side effects, you can take your complaints or requests for compensation to:

Name	Cheryl Coleman
Position	Clinical Operation Manager
Telephone	(03) 9509 6166
Email	cherylcoleman@emeritusresearch.com

21 Insurance

All study doctors are required to have insurance.

22 The consent form

Sign the consent form only after you have made up your mind to take part in this clinical study. If you wish, we will arrange for someone to read the form to you in a language you understand. You must be provided with a signed and dated copy of the participant information and consent form for your personal record.

Consent form

Title	A Prospective, Randomised, Double Blind, Placebo Controlled, single dose, single site phase 1 study to assess the safety and biological activity of a Human non-autologous platelet derived Extracellular Vesicle therapy vs placebo on wound healing rate following skin punch biopsy in healthy volunteer adults.	
Short title	PLEXOVAL II	
Protocol number	PXR002	
Project sponsor	Exopharm Ltd, Level 17, 31 Queen Street, Melbourne Vic 3000	
Study doctor	Prof. Stephen Hall	
Clinical contact person	Prof. Stephen Hall	03 9509 6166
24-hour medical contact	03 9387 1000	stephenhall@emeritusresearch.com

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

Declaration by participant

- I am 18 years of age or older
- I have read, or have had read to me, and I understand the participant information and consent form.
- I have had the opportunity to discuss this with an independent person.
- 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 clinical study as described and understand that I am free to withdraw at any time during the study without affecting my future health care.
- I understand the purposes, procedures and risks of the research described in the information sheet.
- I give permission for my doctors, other health professionals, hospitals, laboratories or ambulances outside Emeritus Research to release information to Emeritus Research concerning my medical history, disease and treatment for the purposes of this study. I understand that such information will remain confidential.
- I consent to my treating doctor/s being notified of my participation in this study and any clinically relevant information noted by the study doctor in the conduct of the study.
- I understand that I will be given a signed copy of this document to keep.

Signature _____ Date_____

Name of participant (please print) _____

Declaration by study doctor

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

Signature _____ Date_____

Name of study doctor (please print) _____