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# **PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT**

*The Queen Elizabeth Hospital*

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| **Title** | Steroid-Reducing Options for ReLapsING PMR (The STERLING-PMR study): a multi-centre, Phase III, parallel-group, open-label, randomised controlled trial to compare the clinical and cost-effectiveness of adding immunosuppression to steroid-tapering treatment for patients with relapsing PMR, versus steroid-tapering alone |
| **Short Title** | *STERLING PMR* |
| **Protocol Number** |  |
| **Project Sponsor** | University of Adelaide |
| **Project Funder** | NHMRC- NHIR |
| **Coordinating Principal Investigator** | *Prof Catherine Hill* |
| **Location** | *Rheumatology TQEH, 28 Woodville rd., Woodville South 5011* |
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You have been invited to take part in a research study called STERLING-PMR. Before you decide whether you want to take part, we would like to explain why we are doing the research, how we will use the information we have about you, and what the study will involve.

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 you can 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 taking part in the research project

• Consent to having 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.

**Once you have read this information, your doctor will talk to you about the study again and you can ask any questions you like.**

Take time to decide whether or not you wish to take part.

**What is the purpose of the study?**

We want to find out whether adding a disease-modifying anti-rheumatic drug (DMARD) to steroid treatment helps people with polymyalgia rheumatica.

At the moment, there isn’t enough research for us to know for sure which one of these options would be the best option for patients with PMR who have relapsed. We are doing this study to help answer this question.

DMARDS are a type of medication that can control inflammation. Research has already shown that if we start a DMARD called methotrexate as soon as PMR is diagnosed, it reduces the amount of long-term steroid a patient will need. But we do not know how much benefit DMARDs give for people with PMR who have already been taking steroids for a while and have relapsed once or more whilst they are in the process of reducing (tapering) their steroid dose.

We have designed this trial to find out whether people with PMR who have relapsed can taper and stop their steroids faster, with fewer relapses, if they start DMARDs, and what are the overall effects on their wellbeing of adding a DMARD. This will involve having two groups of people: one group that takes steroids well as DMARD, and one group that continues to take steroids without DMARDs. After 18 months we will compare the total (cumulative) amount of steroids taken by each group. The results of this research will produce information about PMR and its treatments that will help patients like you in the future.

**Why have I been chosen?**

We are inviting you to take part because you have had a relapse of your PMR and you are taking steroid treatment for it.

**What will happen to me if I take part?**

If your doctor thinks you might be suitable we will confirm this by asking some more questions, examining you, doing some blood tests and a chest x-ray. We need your consent to do these things as this is the start of the research process, which we call "screening".

If the screening tests confirm you are able to take part, you will have another visit where we will find out whether you have been chosen to have DMARD as well as steroids, or to stay on steroids without DMARD. For the results to be valid, we need to make sure it is a fair trial using *randomisation*. This means that a computer will choose randomly for you to have either DMARDs with steroids, or just steroids. Once that choice has been made, we then stick with that choice for 18 months, unless you need to stop the DMARD due to side-effects.

During the trial, we will taper your steroid treatment. There is no fixed taper rate: this will be individualised to you by the study doctor. If you are chosen to have DMARDs, you would begin on the DMARD **methotrexate**. Methotrexate is given once a week in tablet form. You would also be prescribed a vitamin called folic acid to reduce any side-effects. If methotrexate treatment doesn’t work for you, for example if it causes troublesome side-effects, we can instead give you a different DMARD treatment, **leflunomide** tablets. If leflunomide also has troublesome side-effects, then it would also be stopped. During the 18 months of the trial you would continue tapering your steroids in the normal way with the aim of reaching the lowest steroid dose that still keeps you well, or stopping steroids entirely if that turns out to be possible.

**Who is organising and funding the research?**

The study was funded by the NHMRC-NIHR Collaborative Research Grant Scheme.

This study is being run in conjunction with the University of Leeds in the United Kingdom and they have their own funding through a National Institute for Health and Care Research (NIHR) research programme. Data will be analysed in conjunction with data from the UK however the Australian arm of the project is funded by the NHMRC. The NHMRC-NIHR collaborative Research Grant Scheme is a government initiative to support international health research

**Study Visits**

**Screening phase** in which the study doctor will examine you and perform tests, some of which include knee X-rays, physical and vital examinations, blood and urine tests and questionnaires to make sure that this research project is suitable for you.

**Screening Assessments:**

* Physical examination – a musculoskeletal system exam, cardiorespiratory, abdominal, skin, head/eyes, ear/nose/throat.
* Chest X-Ray: a report from a chest x-ray performed within last 6 months prior to the screening visit is acceptable.
* Pregnancy test for women of childbearing potential
* Blood test
* Vital Signs –Blood pressure, heart rate, temperature

**Core Period (Week 0 – Week 80)**

Taking part in the study involves four visits to see the study team at the hospital. The first visit may take about 2-3 hours to complete all the tests and checks; the other visits are usually quicker. The study doctor will regularly check how you are progressing though the trial. The trial team will phone you after 4, 8 and 12 weeks to see how you are doing. At 6 months and 18 months, you will visit the hospital again for another assessment and more blood tests to assess your condition. In between the 6 and 18 month visits, you will have a phone call from the trial team every 3 months to check everything is ok. (Details below)

**BASELINE ASSESSMENTS (Week 0)**

During an appointment with the study research team the following data will be collected:

* Current steroid use
* Relevant medical history
* Blood test
* Physical examination of the musculoskeletal system including elevation of upper limbs, joint swelling/tenderness/limitation of movement, and vascular including temporal arteries
* Vital Signs – including blood pressure, heart rate, temperature
* Weight, hip and waist circumference

Questionnaires to determine your PMR disease activity

**TELEPHONE ASSESSMENTS WEEK 4, 8, 60 and 72**

During the telephone appointment we will ask some questions regarding your current medication use (Steroid and DMARD) and any side-effects or adverse events that have occurred. You will also be notified of results of DMARD monitoring tests and be told if it is ok for you to continue with your current prescriptions and if you need to have any further testing conducted.

**WEEK 12, 24, 36, 48, WEEK 80 FOLLOW-UP STUDY VISITS**

These visits will be conducted in clinic, face to face at 24 and 80 weeks after you begin the trial. All the same data will be collected as during the Baseline visit as well as reporting of any side-effects or adverse events.

**What else will I be asked to do? (Apart from the appointments listed above):**

**Complete Questionnaires**

So that we can analyse the main results of the trial, we need you to fill out a questionnaire **every 4 weeks** to tell us how much steroid you have taken over the previous 4 weeks. These can either be done online or using pen and paper and posted back to us (we will provide pre-paid addressed envelopes). The steroid questionnaire takes about 2 minutes to fill out. Every 3 months, there will be additional questionnaires that might take 20-30 minutes in total.

**Safety health testing**

At the start of the study you will have a comprehensive assessment of your health at the hospital, including some blood tests. If you’re chosen to have a DMARD then you will need some extra blood tests (every 2 weeks at first, later spacing out to monthly and finally four times per year). These “DMARD blood tests” can be done at you’re your clinical visits, your GP’s or local pathology site. The study team will be responsible for checking the blood results, letting you know if there is any problem and adjusting your DMARD dose if necessary.

You will have an additional blood test when your steroid dose reaches 4mg to monitor for side-effects.

**Keep track of my medication and blood pressure during the trial**

We will give you your own “diary card”, designed for people taking part in this study. It has space to write down each week what steroid dose you took. For people chosen to have DMARD therapy there is also space to make a record of when you take this.

The diary card also has space where you can write down your blood pressure readings, if this is checked at home or at your doctor’s. Some people who take steroids develop high blood pressure.

Methotrexate tablets are 2.5mg each in strength. Your doctor will tell you how many methotrexate tablets to take to make up your weekly dose: for example your starting dose might be 15mg (six tablets) weekly, but some people may need to start on less. You should choose one day of the week to take your methotrexate and stick to that day.

You will be given instructions about what to do during the study if you miss a dose of your medication.

**What are the alternatives for treatment?**

At the moment, the only licensed or Therapeutic goods administration (TGA) approved treatment for PMR is steroids (Prednisone/ Prednisolone).

**What is being tested in the trial?**

In this study we are not testing one particular drug but a category of drugs, called DMARDs. We want to find out whether taking a DMARD alongside standard steroid treatment is better overall than not taking a DMARD. The main DMARD being tested is *methotrexate* as this is recommended in international clinical guidelines for patients like you. But this is a “conditional” recommendation meaning there is still some uncertainty about who will benefit most. After methotrexate, *leflunomide* is most often used for PMR by UK rheumatologists. In this trial, patients chosen to take a DMARD would start on *methotrexate* but could change to *leflunomide* if necessary. So these are the two DMARDs we are testing in this study.

It’s important that you should only agree to take part in the study if you would be prepared to take methotrexate if this is what is chosen for you. You might have heard of methotrexate as a medication used to treat cancer. In cancer methotrexate is given at high doses. At these high doses it can cause a lot of side-effects. **We do not use these high doses of methotrexate in rheumatology. Methotrexate prescribed in rheumatology is taken just once per week.** The low-dose, weekly methotrexate used in rheumatology works in a different way to high-dose methotrexate: it tells the immune system to causeless inflammation by boosting natural anti-inflammatory signals. The side-effects of low-dose methotrexate, if they occur, are usually mild, manageable and improve with time.

Methotrexate treatment is part of everyday practice in rheumatology, so your study doctor has a high level of expertise in this and can answer any questions or concerns you may have about whether this would be right for you. You will be provided with the consumer medicine information sheet to keep, which will give you more information in Methotrexate.

**How long does treatment go on for?**

The treatment in the trial is for 18 months.

**The most important information needed from you during this trial?**

In this trial, we will be looking at results from the group of patients taking DMARD compared to the group not taking DMARD.

The main way we will know which group does better is by comparing how much steroid each group needs during the whole 18-month period (which we call “cumulative steroid dose”).

Every 4 weeks, on a Monday, we will ask you to fill out a brief questionnaire to tell us how much steroid you have taken over each of the previous 4 weeks, and whether you’ve had a PMR relapse/flare that has needed an increase in steroid dose. **It is really important you send us this questionnaire** so that, at the end, we can add up all the steroid you have needed over the 18 months. You can choose to do this questionnaire online, or on paper (we will pay for the postage).

**What if the treatment doesn’t help?**

## If your PMR relapses again during the study, you would increase your steroid dose just as you would if you weren’t in the study. DMARDs can take some months to have their full effect. If you think your DMARD is not helping, please talk to your study doctor who can advise on whether you need to switch from methotrexate to leflunomide, or stop DMARD altogether.

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

To keep you safe, if you get a new health problem during the trial you should always tell a member of the study team and/or your GP so they can advise you on whether it might be due to the DMARD, steroids, the PMR itself, or from another health problem. In particular, if you are admitted to hospital for any reason it is important that you tell a member of the study team.

**Side** **effects of Steroids**

You might already have already noticed some side-effects from your steroid treatment. Some steroid side-effects tend to be related to cumulative steroid dose and that’s why we are measuring that over the trial. It’s important to balance the risks against the benefits, though: if steroids help the pain and stiffness of PMR, that’s important too. Long-term steroids should never be stopped abruptly as this is not safe. Please talk to your doctor if you’re worried about steroid side-effects.

Side effects associated with the use of corticosteroids such as prednisolone include, but are not limited to:

* + - Insomnia (trouble sleeping)
    - Nervousness
    - Increased appetite
    - Indigestion
    - Dizziness or light-headedness
    - Joint aches or pain
    - Glaucoma (increased pressure in the eye)
    - Cataract formation
    - Headache
    - High blood pressure
    - Retention of fluid resulting in swelling
    - Weight gain
    - Decreased bone density

**Side effects of DMARDS**

Use of methotrexate is an established safe and well-tolerated treatment for rheumatoid arthritis. Not everyone has side-effects from DMARD therapy. If side-effects do happen, they tend to be mild. For example, some patients notice a change in their sense of taste, feeling sick or off their food, loose stool or stomach-aches. For methotrexate, which is taken once per week, any side-effects tend to be most noticeable the day after taking it. Taking a vitamin called folic acid can help a lot with this. Leflunomide is usually taken every day. Side-effects of DMARD quite often get better with time as your body gets used to the new treatment. That is why we often start DMARD at a small dose and then increase it after 2-4 weeks. In the early days, you will need blood tests every 2 weeks

The most common side effects of methotrexate are nausea, vomiting and diarrhoea. These can be reduced if methotrexate is taken with food or in the evening. Mouth ulcers can occur, but the use of folic acid or folic acid supplements makes this less likely. Skin dryness, a variety of skin rashes and increased sensitivity to the sun may also occur. You should wear sunscreen and a hat when out in the sun. Some people report mild tiredness, headache and mental clouding. Some also experience a temporary increase in muscle and joint pain after taking the weekly dose. There are some rare but potentially serious side effects with methotrexate, including a drop in the number of white blood cells and platelets, inflammation of the liver (hepatitis) or the lungs, hair thinning, and nodule formations. The development of some of these side effects (e.g. blood abnormalities) will be monitored closely and you will be required to have serial blood test monitoring (every 3 months after more regular monitoring when initiating therapy).

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. Tell the study doctor if you have any problems. Your study doctor will monitor for and discuss the best way of managing any side effects with you, should they occur.

Very rarely DMARDs can cause a sort of flu-like illness (pneumonitis), in which case we would stop the DMARD. Some leflunomide can stay in the body for up to 2 years after you stop taking it, but if necessary the leflunomide can be eliminated from the body by taking a short course of a medication called cholestyramine. Your study team can prescribe this if need be.

Unlike steroids, it is safe to stop a DMARD without needing to taper the dose. For example, if you need to take a course of antibiotics we’d normally advise stopping the DMARD for that period. Or, if you do need to stop the DMARD due to side-effects, it can be stopped straight away. Please keep your doctor informed if you do need to stop your DMARD for any reason.

Folic acid belongs to the vitamin B group. Rare side effects (affecting more than 1 in 10,000 but less than 1 in 1,000 patients) include allergic reaction, e.g. itchy/red skin, rash, swelling of the face, lips, tongue or throat or difficulty breathing or swallowing, shock (cold sweaty skin, weak pulse, dry mouth, dilated pupils), and stomach and intestines reactions, e.g. loss of appetite, feeling sick, a bloated feeling, wind.

**Medications and alcohol**

When you start a new medication there is always the risk you may have a side-effect. However, if you get troublesome side-effects from the DMARD, the DMARD can be stopped at once, or the dose can be reduced. We will also advise you on how you can mitigate the side-effects, for example by following a healthy diet. In particular, **people who take DMARDs are advised not to drink alcohol to excess**, as excess alcohol can cause liver damage and DMARDs could cause problems for someone who has liver damage. Your study doctor will advise you on what would be your personal recommended maximum alcohol intake, depending on your other medications and health conditions; some people may be advised to avoid alcohol altogether.

**Emotional distress**

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

**Infections**

infections whilst on steroid and/or DMARDS possess unique risks and that the treatment will need to be monitored and adjusted by the study doctor if you get an infection during the trial. If you develop an infection, you should seek medical advice and contact your study team.

**Vaccines**

If you need to have a **live** vaccine please talk to your doctor. It is safe for you to receive any **non-live** vaccine while taking steroid or DMARD treatment. This includes vaccines that protect against flu, pneumonia, shingles and COVID-19 including booster vaccinations. If you are taking methotrexate, you may consider stopping the methotrexate for 2 weeks after the COVID-19 booster vaccine as this will slightly improve the body’s ability to respond to the booster vaccine.

**Pregnancy and contraception during treatment**

Methotrexate and leflunomide should **not** be taken by pregnant people, as these DMARDs can cause miscarriage or harm the foetus in the womb. If you are pregnant, breast-feeding or are planning to become pregnant in the next 2 years, then unfortunately you cannot take part in this study. We will do a pregnancy test at your first visit if applicable.

Also, if you take part in the study and if there is any possibility of you or your partner becoming pregnant during the study, you as a couple must use a reliable form of contraception.

If you change your mind while you're taking part in this study and decide you do want to try for a baby, please discuss with your doctor as soon as possible. After stopping methotrexate, the European Medicines Agency organisation has recommended waiting 6 months before trying to conceive. The best time for a male partner to stop taking methotrexate before trying to conceive is not known. For leflunomide, it would be 2 years unless you take a course of cholestyramine to clear the leflunomide from your body.

Methotrexate does not affect a person’s ability to have children in the long term. For female participants, 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. For male participants, 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 or your partner do become pregnant while you are taking part in the study, we will be obliged by law to collect some information about the mother and child and their health. The information we collect will not identify the mother (if it isn’t you) or child. We need to do this so that medicine regulatory bodies can collect information about medicine safety during pregnancy.

Please talk to your doctor if you have any questions or concerns about pregnancy.

**Exposure to Ionising Radiation**

If you decide to take part in this study and are randomised to the DMARD arm of the study, you will have a chest X-ray (unless you’ve had one recently for other reasons) that you would not have had if you did not take part. The reason is that if you happen to develop any new chest symptoms while you’re in the study, and your doctor wants you to have a chest X-ray, it’s useful for them to have a previous chest X-ray to compare it with. We would usually do a chest X-ray in any patient who is about to start a DMARD.

## This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.02 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal and theoretically is approximately equivalent to the risk of travelling 600,000 km in a passenger vehicle in Australia.

**Blood tests**

Having blood taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated. Blood samples are collected by a qualified venipuncturist. We endeavour to make the collection process as simple and as stress free as possible.

## What are the possible benefits of taking part?

We have designed the study protocol to reflect good clinical practice and the latest guidelines on how to treat PMR. The study team at the hospital have been selected for their expertise and knowledge about PMR and its treatment. By taking part, you will also contribute to raising awareness and improving medical and scientific knowledge about PMR. This is very valuable in itself, because so few research studies have been done into PMR compared to other rheumatic conditions.

**Reimbursement**

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

**What if something goes wrong?**

In between the scheduled calls and visits, if you have a health problem, please call the trial team on *8222 7369* and we can take appropriate action. If it is an Emergency please call 000 or go to your nearest hospital.

**Clinical contact person**

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| --- | --- |
| Name | Carlee Ruediger |
| Position | Clinical Trial manager |
| Telephone | 8222 7369 |
| Email | [Carlee.ruediger@sa.go](mailto:Carlee.ruediger@sa.go)v.au |

**What happens when the research study stops?**

At the end of the study, we hope that many patients will have stopped their steroid treatment and may also decide to stop their DMARD, if they have been randomised to receive DMARD and / or you are still taking steroid tablets at the end of the trial and want to continue or start a DMARD, please speak to the study doctor; arrangements can be made for this via your ongoing care.

**Additional Optional research**

We may ask you for some extra blood samples to help future researchers discover more about PMR and its treatment. You would be given information and asked to sign a separate consent form if you were to agree to participate. We would take these samples at the time of your study visits.

**What if relevant new information becomes available?**

Sometimes during the course of a study, new information becomes available. If this happens your doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide not to continue, your GP will continue your care. If you decide to continue, you may be asked to sign an updated consent form. Occasionally on receiving new information, your doctor may consider it to be in your best interests that you stop taking any further study treatment.

**What will happen if I become incapacitated?**

During the trial, if due to other medical conditions you no longer have capacity to consent, we would keep following the treatment plan chosen for you. This might need you to have some blood tests from time to time, but you would not need to have any additional study visits or x-rays that you wouldn’t have as part of your usual care for your PMR.

**What will happen if I don’t want to carry on with the study?**

You can stop taking part in all of this study, or in any part of it, at any time, simply notify the study co-ordinator that you no longer wish to take part. You do not have to give a reason why, however, we would like to know the reason if you are willing to say, because this can be useful when we produce the results of the study.

Before deciding to stop, you should talk to your study doctor or nurse. They can advise you and may be able to deal with any concerns you may have. If you decide to stop taking part at any time, it will not affect the standard of care you receive.

If you decide to stop taking your DMARD, study visits and assessments can still go ahead, if you agree to this.

The trial is designed so that the main way of finding out whether DMARDs are useful or not is to compare the amount of steroid patients actually take month by month during the trial. Therefore, it is important you do complete these questionnaires if you can. There are also some extra questionnaires about the impact of your PMR and its treatment on you as a person, including emotional impact, because we would also like to understand whether DMARDs make any difference to these. If the extra questionnaires are too much, you don’t have to do these ones.

If you tell us that you want to stop completing any questionnaires, we will stop asking you to complete them. You can still take part in the trial if you stop these, and you can change your mind later and start completing them again, if you want.

If you decide to stop study visits or assessments, then to make sure the research is still reliable, we will need to keep the information we have already collected about you, and include it in the study analysis.

Unless you clearly tell us you don’t want us to, we will keep any blood samples you have given for future research purposes.

## Will my taking part be kept confidential?

There are a few things you should know about how your confidentiality will be affected if you agree to take part in this study.

* Your **GP, and the other doctors involved in your healthcare, will be kept informed** of your participation in this study. This is because they might need to know you took part when they treat you for anything in future.
* Your **healthcare records may be looked at by authorised individuals** from the research team , the regulatory authorities or other authorised bodies to check that the study is being carried out correctly. This will only be done in line with your hospital’s policies to ensure your records are secure.
* We would like to **collect a copy of your completed consent form**, if you agree to take part in the study. This is so that we can check you have definitely agreed to take part. This means people in the study team who are authorised to deal with consent forms will see your name, this data will be transferred and stored at the CTRU at University of Leeds. However, these people are trained to treat your information with care, and the consent form will be stored securely at all times.
* With your permission we will record your mobile phone number and/or e-mail address so we can send you text reminders and e-mails about completing your questionnaires and about the study.
* The biological samples taken from you in this study will be sent to the hospital laboratory with your name on, so that when they are analysed, the results can be sent back to your doctor who can be sure that the results are definitely yours and not someone else’s. The staff at the lab will be bound by their professional responsibilities to keep all your information private and confidential.

**What will happen to any samples I give?**

The blood tests done for this study will be processed in your local pathology laboratory.

**Will any genetic tests be done?**

No, there will be no genetic tests done as part of this research project.

**What will happen to the results of the research study?**

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. We will make sure you have a chance to find out the results of the study, if you would like them.

* We will also report back to consumer groups such as Arthritis Australia as the trial progresses and as the results emerge. Please be aware that it may take about 5 years for the primary (first) analysis to be done.
* **Who is organising and funding the research?**
* The study was funded by the NHMRC-NIHR Collaborative Research Grant Scheme.

**Complaints and Compensation**

If the participant suffers 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 for the participant. If the participant is eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

The participant for seeking compensation if the participant suffers an injury as a result of their participation in this research project may be able to seek compensation through the courts.

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

**Complaints contact person**

|  |  |
| --- | --- |
| Name | Carlee Ruediger |
| Position | Clinical Trial manager |
| Telephone | 8222 7369 |
| Email | [Carlee.ruediger@sa.go](mailto:Carlee.ruediger@sa.go)v.au |

**Who has reviewed the study?**

The Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) 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 CALHN Research Services on 08 7117 2229 or at Health.CALHNResearchEthics@sa.gov.au.

**Reviewing HREC approving this research** **and HREC Executive Officer details**

|  |  |
| --- | --- |
| HREC Name | Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) |
| Position | HREC Support officer |
| Telephone | 08 7117 2229 |
| Email | [health.CALHNresearchethics@sa.gov.au](mailto:health.CALHNresearchethics@sa.gov.au) |

**Contact Details**

If you have any further questions please contact:

**Clinical contact person**

|  |  |
| --- | --- |
| Name | Carlee Ruediger |
| Position | STERLING PMR Clinical trial manger |
| Telephone | 08 8222 7369 |
| Email | Carlee.ruediger@sa.gov.au |

**Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form. This information sheet is for you to keep**



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**PARTICIPANT CONSENT FORM**

|  |  |
| --- | --- |
| **Title** | Steroid-Reducing Options for ReLapsING PMR (The STERLING-PMR study): a multi-centre, Phase III, parallel-group, open-label, randomised controlled trial to compare the clinical and cost-effectiveness of adding immunosuppression to steroid-tapering treatment for patients with relapsing PMR, versus steroid-tapering alone |
| **Short Title** | STERLING PMR |
| **Project Sponsor** | University of Adelaide |
| **Project Funder** | NHMRC- NHIR |
| **Coordinating Principal Investigator** | Prof Catherine Hill |
| **Location** | Rheumatology TQEH, 28Woodville rd, Woodville South 5011 |
|  | ***Please initial each box*** |

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.

1. I understand the purposes, procedures and risks of the research described in the project
2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that even if I withdraw from the above study, the data and samples collected from me will be used in analysing the results of the study and in some cases further information about any unwanted effects of my treatment may need to be collected by the study team.
3. I understand that my healthcare records may be looked at by authorised individuals from the study team, regulatory bodies or Sponsor in order to check that the study is being carried out correctly.
4. I understand that my name and email address and/or phone number will be passed to the CTRU for the sole purpose of issuing the study questionnaires.
5. I agree to a copy of this Consent Form and questionnaire responses being sent to the CTRU.
6. I agree that my GP, or any other doctor treating me, will be notified of my participation in this study.
7. I agree to take part in the study.

**The following points are OPTIONAL.**

Even if you agree to take part in this study, you do not have to agree to this section.

Please tick

✓

No

Yes

I agree to my mobile telephone contact details being sent to the Leeds Trials Unit for the purposes of sending me text messages about the study.

I agree to my e-mail address details being sent to the Leeds Trials Unit for the purposes of contacting me about the study.

**Patient:**

Signature…………………………………………………………………………………

Name (block capitals)……………………………………………….……………………

Date………………………………………………….……………………………………

**Investigator:**

I have explained the study to the above named patient and they have indicated their willingness to participate.

Signature…………………………………………..……………………………………

Name (block capitals)……………………………………………….…………………

Date………………………………………………….……………………………………

(1 copy for patient; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)