Place Patient Label Here

Participant Information Sheet/Consent Form

Interventional Study *-Adult providing own consent*

Austin Health

Title	The effect of low-dose oral minoxidil in transgender and gender-diverse individuals assigned female at birth with androgenic alopecia while on testosterone: A double-blinded, placebo-controlled randomised trial
Short Title	The effect of minoxidil in trans people with androgenic alopecia while on testosterone
Protocol Number	1.4
Project Sponsor	University of Melbourne
Coordinating Principal Investigator/ Principal Investigator	A/Prof Ada Cheung
Associate Investigator(s)	Dr Gia Toan Tang, Professor Rodney Sinclair, Mrs Kylie King
Location	Austin Health, Sinclair Dermatology

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research trial. This is because you are using testosterone therapy for gender affirmation and are experiencing scalp hair loss (also known as male pattern balding or androgenic alopecia) as a side effect. The research trial is testing whether minoxidil tablets may prevent hair loss in trans and gender diverse people using testosterone. Minoxidil is an already established treatment for androgenic alopecia in cisgender men. We use the term transgender (or trans) in this document to include anyone with a gender that is different for that presumed for them at birth including people with binary (male and female) and non-binary identities.

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

Please read this information carefully. Please ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to take part, you may wish to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. Your standard healthcare will not be influenced whether or not you take part.

If you decide you want to take part in the research trial, we will seek your consent electronically via an email link where you can sign electronically. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research trial
• 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 able to download a PDF version of the consent form. If the email electronic consent system is not working, we will ask you to sign a hard copy and you will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Medications, drugs and devices have to be approved for use by the Australian Federal Government. Minoxidil is approved in Australia to treat hypertension, but is used off-label to treat various hair loss disorders including androgenic alopecia. Therefore, it is considered an experimental treatment for androgenic alopecia related to testosterone therapy. This means that it must be tested to see if it is an effective treatment to minimise hair loss.

The results of this research will be used by the research team member Dr Gia Toan Tang to obtain a *Doctor of Philosophy* degree.

This research has been initiated by the study team member, Associate Professor Ada Cheung.

3 What does participation in this research involve?

We require your agreement and signature on the consent form before doing any research trial assessments. All research trial assessments will be conducted predominantly at Sinclair Dermatology (2 Wellington Pde, East Melbourne) but may also occur at Heidelberg Repatriation Hospital (Austin Health).

The research trial medication we are using is minoxidil. It is given sublingually (under the tongue) twice a day, with or without meals. We recommend you to have it at 08:00AM in the morning and 8:00PM at night.

The placebo we are using will also come in tablet form and contain sweetened polyethylene glycols. It is safe and has been used in other medications to treat constipation. Polyethylene glycol allergy is very rare, despite it being widely used. However, there are some reports of immediate serious allergic reaction including anaphylaxis which can cause swelling of the face, lips and throats as well as difficulty breathing.

The research trial medication/placebo will be dispensed by an AHPRA-registered professional pharmacist who is also compounding the sublingual minoxidil/placebo. The packaging will be in a bottle with your name, your research trial number as well as the medication written as ‘Minoxidil/Placebo’ to ensure that the research staff and yourself do not know what you are receiving.

You will be required to collect the medication from Smart Pharmacy Compounding at Sinclair Dermatology in person.

There are 2 groups in this research trial: minoxidil or placebo. There will be a 50:50 chance you will be in one of these groups because you will be randomly assigned to the group. Tablets will look the same whether you receive the minoxidil or the placebo. The minoxidil group will be given 0.45mg twice daily and the dose will be increased up to a maximum dose of 1.35mg twice daily (equivalent to 2.7mg daily). The placebo group will take the equivalent number of tablets in order to maintain double-blinding. Neither the research trial staff team member nor you will know what treatment group you have been assigned to until the end of the research trial. During

the trial, you will be given the research trial medication (placebo or minoxidil) and you will need to gradually increase the number of tablets as per the following schedule:

- For the first 2 weeks, take **ONE** tablet (which will contain 0.45mg of minoxidil or matching placebo) twice a day (total 0.9mg/day of minoxidil)
- For the next 2 weeks after that, take **TWO** tablets (0.9mg of minoxidil if on minoxidil or matching placebo) twice a day (total 1.8mg/day of minoxidil)
- Then, take **THREE** tablets (1.35mg of minoxidil if on minoxidil or matching placebo) twice a day until the end of the clinical trial (total 2.7mg/day of minoxidil).

You will be following this gradually increasing tablet schedule regardless of whether you are in the placebo or minoxidil group. There is no standard adjustment schedule for sublingual minoxidil as it is a relatively safe medication. Low-dose sublingual minoxidil has been used worldwide and is often given without the need to adjust the dose. The purpose of the gradual increase in dose in this clinical trial is to minimise any potential side effects and allow participants to hopefully better tolerate sublingual minoxidil.

In this research trial, blood tests are required by your treating doctor to monitor your health and medication dose. Detailed blood tests are required at your last visit to assess the pharmacokinetics of minoxidil, which is how your body absorbs, metabolises and removes minoxidil (if you are taking any). We are also interested in the results of your regular blood tests, in particular, your testosterone levels during the research trial, to correlate it with the hair growth and distribution in your scalp at the time.

There are 6 visits for this research trial. You will be required to attend an initial baseline visit (week 0) on Monday and then Thursday (week 0+3), then at week 6, 12, and then week 24 on Monday (week 24) and Thursday (week 24+3). Though not compulsory, you may be asked to attend week 12+3 visit and week 18 depending on how you are going or if we are concerned about side effects. We may ask for bloods to be taken to monitor hormones and organ function, as well as measure pharmacokinetics of minoxidil. However, the pharmacokinetics component of minoxidil is unlikely to go ahead.

Each main visit (week 6, 12, 24) will take up to an hour.

In the rare event that we want to measure pharmacokinetics of minoxidil, we will be collecting blood samples at your week 24 visit to analyse how your body absorbs, metabolises and removes minoxidil, it is important that on your appointment that week you **DO NOT** take your dose at home.

In order to take multiple blood samples, an intravenous (IV) catheter (known as a “drip”) may be inserted. An IV catheter is a thin plastic tube that is inserted into a vein. A total of about 8-50mLs (about 3 tablespoons) of blood will be taken. Some known risks associated with obtaining blood samples include minor bruising, haematoma (accumulation of blood in the surrounding tissue), swelling, tenderness, and inflammation at the site of blood collection. These risks typically last several days and will completely heal. Blood samples may be analysed after the research trial has completed but will not be kept longer than 3 years after the final clinical research trial report has been completed.

You may be asked not to interfere with normal scalp hair growth a few days prior to the visits, such as refraining from shaving, using hair removal products and/or other hair removal procedures.

To measure your scalp, we will be placing a temporary 1mm dot tattoo on the area of interest on the scalp. The tattooing process will be quick (taking less than 5 seconds) and does not cause any pain. The purpose of the tattoo is to ensure that hair measurements using HairMetrix/TrichoLab are done at the same site on the scalp so that progress photos throughout the clinical trial can be compared to one another. Sometimes, we may need to repeat the tattooing process if the tattoo wears off quicker than expected. The needle cartridges are disposable single-use needles. The ‘1mm’ refers to the diameter of the dot being tattooed and not the depth of the needle. The needles used are small, so it will only imprint ink on the skin surface of the scalp and it is unlikely that it is sharp enough to penetrate the skin or cause bleeding. Furthermore, prior to tattooing, the site of interest will be cleaned with an alcohol wipe

to minimise any risks of infection. No aftercare is required as this is a relatively quick, painless step. Furthermore, as this is done on the scalp and hidden underneath hair follicles, it will not be noticed by people and can only be seen if it is actively searched for. If your hair is very light, we may need to use hair dye to darken the roots in only a small area.

For the photos in the region on the back of your head, we will need to trim a small part of your hair (the area around the size of a 20 cent coin) for TrichoLab and Hair Metrix analysis. This is to ensure consistency and allow us to measure extra parameters in the TrichoLab such as hair rate as by trimming the hair, we can see the tip of the hair and measure how much it has grown along with other properties.

The systems that we are using to measure scalp hair is the Hair Metrix and TrichoLab. They are both non-invasive artificial intelligence technologies that let us analyse magnified pictures of your scalp. We will take images of the top, side and back of your head. As these images are magnified, your identity will remain anonymous. The parameters in HairMetrix are standardised and it allows automatic comparison of different measurements taken over time for each individual. The HairMetrix system allows us to analyse aspects of hair growth from the magnified images that we would not be able to manually, such as the distance between hair follicles, the total amount of hair in each region of the scalp/face and thickness of each individual hair. The TrichoLab system also measures similar parameters but the additional features are that it allows us to do hair-to-hair matching whereas HairMetrix does not. This means that we are able to number the follicles at baseline, and then keep track of it as we take more progress photos. We can then work out whether any new hair growth is from the same follicle or from a different hair follicle nearby and calculate the growth rate of your hair over the clinical trial. Comparing HairMetrix and Tricholab will allow us to identify which artificial intelligence technology will be most useful in the future for research in trans health.

As you are participating in a randomised controlled research trial, it means that we will be providing you with a medication. It will either be minoxidil or placebo (allocated like the toss of a coin). The placebo is a medication with no active ingredients. It looks like the real thing but is not. This research trial has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids research trial team members or participants jumping to conclusions. The research trial is double-blinded, meaning that you and the research trial members will not know which product you received until the end of the research trial.

In the first visit, it will take up to 2 hours and involve the following:

- Medical Interview. One of our research trial team members will ask about your medical history and any medications you are taking. We can get some of this information from your medical record. We will give you a script and you will be provided with either minoxidil or placebo by the pharmacist. You will be given products in a screw top container that may either be the placebo or minoxidil, and you will be instructed to take it twice a day and follow the dosing schedule.
- Physical examination: height, weight, waist circumference, hip circumference, blood pressure and heart rate
- Completing questionnaires about how your hair affects the quality of your life.
- Temporary 1mm dot tattoo on the scalp for scalp hair dermatoscope photos.
- Scalp hair trichogram analysis: This is a tool that is used to look at hairs at a magnified level. It is safe, painless and non-invasive. We will be using the dermatoscope to take magnified photos of scalp hair at certain regions (top, side and back of the head). Magnification allows us to detect hair follicles on the face as well. We have two systems, HairMetrix and TrichoLab, which will allow us to analyse the scalp obtained in the photos and provide accurate details about the total hair count and follicle qualities. In the first visit, we will be able to obtain the baseline hair count and other various parameters.
- Assignment to randomised allocation number
- Dispensing of minoxidil/placebo based on the randomised allocation number

- Giving you instructions on the dosing schedule of the medications and instruction on the adherence diary

At week 24, blood samples may be collected to measure blood levels of low-dose oral minoxidil. Additionally, at week 0, 12 and 24 visit, you will be asked to complete the questionnaires again regarding how your hair is affecting the quality of your life. We will check your routine blood tests that will be taken by an external pathology service (i.e. Dorevitch Pathology) as part of your ongoing care at week 0, 12 and 24.

We will provide the medication to you at week 0 and then every 6 weeks. However, if you remain well with no significant side effects, we may be able to provide you with 3 months worth of medication at week 12 to continue until the end of the trial.

At the end of the 24 week/24+3 week visit, your participation in the research trial is over and you can continue to attend your usual clinic. You will only be informed of whether you received minoxidil or placebo once the entire research trial is completed.

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

You will not be reimbursed for travel, parking, meals and or other expenses associated with the research trial visit.

If you decide to participate, the research trial team member, with your consent, will inform your local doctor. We encourage your local doctor to continue to be involved in your care.

4 What do I have to do?

Participants are asked to attend an initial research trial visit at week 0 on Monday and Thursday and subsequent visits at week 6 and week 12, then Monday and Thursday on Week 24. You are under no obligation, and if you change your mind and no longer wish to be involved in the research trial then this will not affect your ongoing care.

You may be asked not to interfere with scalp hair growth a few days prior to the visits, such as refraining from shaving, using hair removal products and/or other hair removal procedures.

There are no other lifestyle or dietary restrictions. If you are a blood donor, you will be able to continue to donate blood. You will continue to take all your regular medications as recommended by your treating doctor. Certain medical conditions that affect hair growth, or prevent you from receiving minoxidil, would exclude you from participation in the research trial and these will be screened for before enrolment.

Since we will be collecting blood samples at your week 24 visit to analyse how your body absorbs, metabolises and removes minoxidil, it is important that on your appointment that week you **DO NOT** take your dose at home.

As minoxidil is teratogenic, it is important that you do not become pregnant during this clinical trial. Furthermore, you must not be breastfeeding. If you are actively trying to conceive or breastfeeding you must not take part in this research trial.

We will also ask you about possible side-effects of minoxidil. Common side effects include low blood pressure, fast heart rate and fluid retention causing shortness of breath, dizziness and leg swelling. You can write this down in your adherence diary. You will be informed of the side effects of minoxidil before your participation. If you have any concerns, please seek medical attention and inform the research trial team members. If you need to commence any new medications while the trial is being conducted, please let the research trial doctor know.

It is your responsibility to inform the research trial team members immediately if there are any issues or concerns during research trial visits or tests performed, as we can assist you with these issues.

The schedule of this research trial is as shown in the following pages:

Research trial schedule/visits.

Assessment/Procedure	Screening (+/- 14 days from routine standard care initial consult)	Visit 1 (week 0)	Visit 2 (week 0+3)	Visit 3 (week 6)	Visit 4 week (week 12)	Optional, week 12+3	Week 18 – only if necessary	Visit 5 (Week 24)	Visit 6 (Week 24+3)
Demographic information and eligibility: **- Inclusion/exclusion criteria** **- Height and weight** **- Medical History** **- Concomitant medications** **- Comorbidities**	**X**	**X**							
Informed consent	**X**	**X**							
Review of bloods done or be taken as part of routine care with their specialist		**X**			X			X	
Clinical assessments	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Randomisation and allocation		**X**							
Commencement + continuation of testosterone		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**

DLQI/modified WAA-QOL		**X**			X			**X**	
Research trial medication dispensing, administration and accountability			X	X	X		X (if only dispensed for 6 weeks)		
Hair measurements: **- Scalp temporary tattoo** **- Scalp macrophotography** **- Trichogram** -Hair clipping and dyeing		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Dispense adherence diary		**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**
Minoxidil pharmacokinetics analysis								**x**	

5 Other relevant information about the research trial

This research trial is conducted by Austin Health/The University of Melbourne with hair analyses done at Sinclair Dermatology. Overall, there will be at least 20 participants in the research trial where we aim to have at least 10 trans people using testosterone in each of the minoxidil group and the placebo group.

This clinical trial is a follow-on trial from our pilot research trial, which looked at the effect of gender affirming hormone therapy on hair pattern changes in trans and gender-diverse people assigned female at birth over 6 months.

6 Do I have to take part in this research trial?

Participation in any research trial 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 trial 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 Austin Health/Sinclair Dermatology.

7 What are the alternatives to participation?

You do not have to take part in this research trial to receive treatment at this hospital. Other options are available; these include continuing with your standard treatment. Your research trial team member will discuss these options with you before you decide whether or not to take part in this research trial. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research. In this research trial, we may find results that suggest that minoxidil is effective in promoting hair growth if you were allocated in the minoxidil treatment group, but it does not mean that you will not experience hair disorders in the future. Other possible benefits may include improving clinical guidelines for minimising hair loss in trans people on testosterone therapy. It will also contribute to our understanding of how testosterone affects scalp hair and may potentially benefit the trans community. It will form a foundational understanding that allows us to conduct future ethically approved research on how to minimise hair loss and results from the research trial may impact quality of life for trans individuals assigned female at birth commencing testosterone therapy.

9 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 despite the minoxidil dose being a very low dose in this clinical trial.

If you have any of these side effects, or are worried about them, talk with your research trial team member. Your research trial team member will also be looking out for side effects.

The side effects of minoxidil are listed below. However, the doses that we are using to manage hair loss is much lower than the dose that minoxidil is used to treat high blood pressure.

Therefore, we do not anticipate that you will experience any of the side effects at the doses given to you, and if you do have side effects, they may not be severe. However, if you do

experience side effects and it concerns you, talk to your research trial team member. When you stop taking the minoxidil and it is cleared out of your system, it is likely that your hair loss may progress and worsen again.

Very common side effects (More than 1 in 10 people)	Other common side effects (May affect up to 1 in 10 people)	Very rare side effects (May affect up to 1 in 1000 people or frequency cannot be estimated from available data)
• Feeling dizzy or faint, especially when you stand up • Your body retaining more water than normal, you may notice your legs getting puffy, or that you have put on weight • Feeling more tired, wheezy, short of breath, especially if you already have a weak heart • Chest pains, especially for the first time, or worse chest pains if you have had angina or heart attacks before. • Initial worsening of hair loss before hair growth	• Increased heart rate, • Inflammation of the lining surrounding the heart, abnormal electrocardiogram • Increased hair growth • Hair colour changes • Accumulation of fluid around the heart • Compression of the heart due to build-up of fluid	• Decreased white cell counts • Decreased blood platelets which increases risk of bleeding or bruising • Serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome) • Inflammation and blistering of the skin • Reduced kidney function • Gastrointestinal disorders • Accumulation of fluid between the layers of tissue lining the lungs and chest cavity • Breast tenderness

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your research trial team member 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 research trial team member may need to stop your treatment. Your research trial team member will discuss the best way of managing any side effects with you.

If your participation in this research uncovers a medical condition of which you were unaware of, we will support you in accessing appropriate information and management.

The effects of sublingual minoxidil on the unborn child and on the newborn baby are not known. It is important that research trial participants are not pregnant, trying to get pregnant or breastfeeding and do not become pregnant during the course of the research trial. As part of routine care, your doctor may have advised you that you cannot be pregnant when on testosterone. It is important you continue to follow this advice while participating in this clinical research trial. You cannot continue in this research trial if you become pregnant. If you do become pregnant in the research trial, you should advise your research trial team member immediately. Your research trial team member may withdraw you from the research trial and provide advice on further medical care.

If you become upset or distressed as a result of any part of your participation in the research, the research trial team member will be able to assist in arranging counselling or other appropriate support with your usual treating doctor.

Furthermore, if you are distressed by the questions in the questionnaire regarding how hair loss is affecting the quality of your life, please inform the research trial team member so that support can be provided.

The photos of scalp and scalp hairs we are taking are for research purposes. They are not intended to be used like scans taken for a clinical examination. The photos will not be used to help diagnose, treat or manage a particular condition. On rare occasions, the research trial team may find an unrelated condition or unexpected findings. If this happens, we will contact you to talk about the findings. We cannot guarantee that we will find any/all unusual features. The photos of your scalp and facial hair will be obtained using dermatoscope, which is harmless and non-invasive.

As part of your standard routine care, you may have been asked by your doctor to collect blood tests at a pathology provider, and you may have been informed that it will cause only some temporary discomfort. Blood tests performed during this research research trial will be no different.

10 What will happen to my test samples?

As part of standard routine care, you may be required by your doctor to have bloods collected at an external pathology service. Blood tests for analysis of plasma concentration of low-dose oral minoxidil will also be analysed by an external pathology service. The results of these tests will be accessed by your doctor and research trial team members as part of your routine care and will be documented in your research trial file. The blood samples specifically for analysing plasma concentration of low-dose oral minoxidil will be de-identified and be stored up to 3 years for further analysis of minoxidil pharmacokinetics. However, after that, it will then be discarded.

11 What if new information arises during this research trial?

Sometimes during the course of a research trial, new information becomes available about the treatment that is being studied. If this happens, your research trial team member will tell you about it and discuss with you whether you want to continue in the research trial. If you decide to withdraw, your research trial team member will make arrangements for your regular health care to continue. If you decide to continue in the research trial you will be asked to sign an updated consent form.

Also, on receiving new information, your research trial team member might consider it to be in your best interests to withdraw you from the research trial. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research trial?

Whilst you are participating in this research trial, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell the research trial 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 research trial team member about any changes to these during your participation in the research trial. Your research trial team member should also explain to you which treatments or medications need to be stopped for the time you are involved in the research trial.

It may also be necessary for you to take medication during or after the research trial to address side effects or symptoms that you may have. You may need to pay for these medications and so it is important that you ask the research trial team or your local doctor about this possibility.

13 What if I withdraw from this research trial?

If you decide to withdraw from this research trial, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research trial, the research trial team member and relevant research trial 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 trial can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research trial results. If you do not want them to do this, you must tell the research trial team member.

14 Could this research trial be stopped unexpectedly?

This research trial may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
• Unacceptable side effects
• The drug/treatment/device being shown not to be effective
• The drug/treatment/device being shown to work and not need further testing
• Decisions made by local regulatory/health authorities.

15 What happens when the research trial ends?

At the conclusion of this research trial, you will have ongoing monitoring and management as part of your standard routine care from your usual treating doctor.

You will be informed whether you have received minoxidil or placebo only after the research trial is complete. Minoxidil will be available after your participation in the research finishes, but you will need to see a treating doctor for prescription at your own cost. The sublingual minoxidil used in this research trial, including the doses used, can be obtained through a prescription. The drug can be obtained from any compounding pharmacy. However, as it is a compounded medication, the cost will vary depending on where it is received and it is best to speak with your treating doctor about this.

The results of the research trial may be published in academic journals. You will not be identified in these publications. The research staff can let you know the results of the research trial when they are available.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the Consent Form, you consent to the research trial team member and relevant research staff collecting and using personal information about you for the research trial. Any information obtained in connection with this research trial that can identify you will remain confidential and securely stored. Only the researchers named above will have access to it and it will only be disclosed with your permission. Electronic information such as this will be stored on a password protected computer system on a server at The University of Melbourne. Your paper and electronic data will be stored for 15 years following completion of this research trial. At the end of 15 years, any information that does not also form part of your Austin Health medical record will be permanently destroyed (deleted or shredded).

Information about you may be obtained from your health records held at this and other health services including your GP clinic 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 your participation in this research trial.

Your health records and any information obtained during the research trial are subject to inspection (for the purpose of verifying the procedures and the data) by the Australian Government's Therapeutic Goods Administration (TGA), or Austin Health Human Research Ethics Committee, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant research trial personnel and regulatory authorities as noted above.

It is anticipated that the results of this research trial will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be presented in such a way that you cannot be identified, except with your permission. This is because results will be published in aggregate only and include no features that could identify any individual participant. Information about your participation in this research trial may be recorded in your health records.

In accordance with the Australian and/or Victorian privacy Laws and other relevant laws you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research trial team member named at the end of this document if you would like to access your information. Information about you may be obtained from your health records held at this and other health services 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 your participation in this research trial.

Any information obtained for the purpose of this research trial and for future research 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.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research trial, you should contact the research trial 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. You can also speak to a consumer liaison officer at the Centre for Patient Experience by calling (03) 9496 3566.

18 Who is organising and funding the research?

This research trial is being conducted by researchers listed at the top of the first page. This research is not commercially nor pharmaceutically funded and Austin Health/The University of Melbourne will not benefit financially from this research trial. Associate Professor Ada Cheung receives funding from the National Health and Medical Research Council.

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

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value, the research trial team members or their institutions, there will be no financial benefit to you or your family from these discoveries.

The medications used in this trial are the sublingual minoxidil tablets and placebo tablets. Professor Sinclair is the sole Director and Shareholder of Samson Clinical and Dr Rodney Sinclair Pty Ltd, trading as Sinclair Dermatology. He is the inventor of oral minoxidil tablets for the treatment of male-pattern hair loss (Patent 2011100917, 26, July 2011). No other member of the research team will receive a personal financial benefit from this research trial (other than their ordinary wages). On manuscript publication, as well as oral and poster presentations, this conflict of interest will be declared. Data custodian for this clinical trial will be under the research staff of Trans Health Research Group at The University of Melbourne and not Sinclair Dermatology. Furthermore, data analyses will be done by Trans Health Research Group statistician and the main research staff of the clinical trial (A/Prof Ada Cheung and Dr Gia Toan Tang).

19 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 Austin Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

Clinical contact person 1

Name	Mrs Kylie King
Position	Study investigator
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Clinical contact person 2

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Telephone	03 9496 2260
Email	adac@unimelb.edu.au

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

Complaints contact person

Name	Manager, Office for Research
Position	Office of Research
Telephone	03 9496 4090
Email	research@austin.org.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 name	Austin Health Human Research Ethics Committee.
HREC Executive Officer	Manager, Office for Research
Telephone	03 9496 4090
Email	research@austin.org.au

Consent Form - *Adult providing own consent*

Title	The effect of low-dose oral minoxidil in in transgender and gender-diverse individuals assigned female at birth with androgenic alopecia while on testosterone: A double-blinded, placebo-controlled randomised trial
Short Title	The effect of minoxidil in trans people with androgenic alopecia while on testosterone
Protocol Number	1.4
Project Sponsor	The University of Melbourne
Coordinating Principal Investigator/ Principal Investigator	A/Prof Ada Cheung
Associate Investigator(s)	Dr Gia Toan Tang, Professor Rodney Sinclair, Mrs Kylie King
Location	Austin Health ,Sinclair Dermatology

Consent Agreement

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 The University of Melbourne 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 research trial without affecting my future health care.

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

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form
See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9.A legally acceptable representative may be a witness*.
Witness to the informed consent process
Name (please print) _____

Signature _____ Date _____
* Witness is not to be the Investigator, a member of the research trial team or their delegate. 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.

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.

Name of Participant (please print) _____

Signature _____ Date _____

For participants unable to read the information and consent form
Witness to the informed consent process
Name (please print) _____
Signature _____ Date _____
* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

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 - *Adult providing own consent*

Title	The effect of low-dose oral minoxidil in in transgender and gender-diverse individuals assigned female at birth with androgenic alopecia while on testosterone: A double-blinded, placebo-controlled randomised trial
Short Title	The effect of minoxidil in trans people with androgenic alopecia while on testosterone
Protocol Number	1.4
Project Sponsor	The University of Melbourne
Coordinating Principal Investigator/ Principal Investigator	A/Prof Ada Cheung
Associate Investigator(s)	Dr Gia Toan Tang, Professor Rodney Sinclair, Mrs Kylie King
Location	Austin Health, Sinclair Dermatology

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, my relationship with those treating me or my relationship with Austin Health/Sinclair Dermatology.

Name of Participant (please print) _____

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.