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**Participant Information Sheet/Consent Form**

**Non-Interventional Study** -*Adult providing own consent*

*Austin Health*

|  |  |
| --- | --- |
| **Title** | The effect of gender-affirming hormone therapy on scalp and facial hair in transgender individuals: a prospective observational study |
| **Short Title** | The effect of gender-affirming hormone therapy on scalp and facial hair in transgender individuals: a prospective observational study |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | NA |
| **Coordinating Principal Investigator/ Principal Investigator** | A/Prof Ada Cheung, Dr Gia Toan Tang |
| **Associate Investigator(s)** | Dr Gia Toan Tang, Dr Ingrid Bretherton, Professor Jeffrey Zajac, Professor Rodney Sinclair |
| **Location**  | Austin Health and Repatriation Campus, Sinclair Dermatology |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you are undertaking gender transition and will be using gender affirming hormone therapy as part of your treatment. The research project is aiming to look at the effects of gender-affirming hormone therapy on scalp and facial hair of transgender individuals.

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

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

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

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to the tests and research that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Transgender individuals may feel that their gender identity and expression is incongruent to the gender assigned to them at birth. They may choose to undergo gender transition, which includes gender-affirming hormone therapy. In a male-to-female transition, they may receive oestrogen therapy and testosterone therapy if they are going for female-to-male transition.

Hair contributes to an individual’s identity and can be an important element of gender expression and perception in society. Gender-affirming hormone therapy can lead to changes in the distribution and pattern of hair. Subsequently, hair diseases can significantly affect an individual’s self-image, intimate relationships and quality of life.

Testosterone and estradiol both influence the cycle of hair growth. They stimulate secondary sexual hair and contribute to post-pubertal sexual dimorphism. In addition, androgens (including testosterone and dihydrotestosterone) can have the opposite effect and produce patterned hair loss on the scalp. Meanwhile, the role of oestrogen is less well established, but estradiol and/or anti-androgens used as feminising hormone therapy tends to reduce body and facial hair and may be protective against scalp hair loss.

Studies looking at changes in hair growth during gender-affirming hormone therapy are limited, particularly in the transgender population. Technological advancement means that we now have the tools to observe these changes at a follicular level. We have access to a high resolution trichoscopic photography to image the scalp, and then analyse hair growth form individual follicles using artificial intelligence technology. Currently, this technology is being updated to be valid for measurements obtained from photographic images of facial regions such as the chin.

The primary aim of this 6-month observational study is to describe the impact of gender-affirming hormone therapy in transgender individuals on hair growth on the scalp and face. We will correlate hair growth and distribution at baseline with baseline hormone levels. We will measure hormone levels, hair growth and distribution at the conclusion of the 6 months observational study.

If we can understand more about the changes that occur in scalp and facial hair, then we can work towards preventing hair loss that may occur during long-term gender-affirming hormone therapy and improve quality of life through interventions. We can also look at how hair growth and distribution is changed when medications are taken to prevent scalp hair loss.

The results of this research will be used by the study doctor Dr Gia Toan Tangto obtain a PhD degree.

This research has been initiated by the study doctor, Dr Ada Cheung.

**3 What does participation in this research involve?**

**3.1 Study Design**

You will be participating in an observational study. This means we will be observing what happens during routine treatment. This study does not involve giving any specific additional treatments. In this study we will be looking at a male to female group (10 participants) and a female to male group (10 participants). The study will go for 6 months.

**3.2 Details of your involvement**

We would need your agreement and signature on the consent form before doing any study assessments. All study assessments will be conducted at Austin Health/Heidelberg Repatriation Hospital/Sinclair Dermatology.

There are 2 visits in the study over the 6-month period.

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

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

* Medical Interview. One of our study doctors will ask about your medical history and any medications you are taking. We can get some of this information from your Austin Health medical record. If you qualify to be on GAHT, a medical script will be given.
* 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.
* Baseline blood test. These are routine blood tests taken from your arm. It is a fasting blood test which means you will be asked not to eat or drink for 8 hours prior to the test (usually done before eating breakfast). We are checking hormone levels, electrolytes, kidney and liver function, vitamin D, bone markers, blood sugar and insulin levels, and cholesterol levels. If there is a chance you may be pregnant, a pregnancy test (β-HCG) will also be done.
* Scalp and facial hair dermatoscope 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 photos of scalp hair at certain regions (vertex, temporal and occipital). Currently, it is being updated to be valid for measurements of hair on the face as well. We have a system called HairMetrix which will allow us to analyse the scalp and facial hairs obtained in the photo and provide accurate details about the total hair count and follicle qualities.

An additional visit will occur at the 6-month mark, and also will take 2 hours consisting of the following:

* Medical interview: One of our study doctors will assess your progress while on GAHT and the biochemistry of bloods taken. We can get some of this information from your Austin Health medical record.
* Physical examination: height, weight, waist circumference, hip circumference, blood pressure and heart rate as well as relevant examinations based on the physiological effect of gender-affirming hormone therapy.
* Baseline hair count, follicular unit type, follicular unit diameter, follicular unit diameter per cm2, quantity of follicular units per cm2, medium hair by follicular count, average hair width, terminal: vellus hair ratio, interfollicular mean distance in the temporal, vertex and occipital region of the scalp as well as the face will be measured using Hairmetrix. You will also be asked to complete the questionnaires about how the quality of your life is affected.
* Blood test: These are routine blood tests taken from your arm. We are checking hormone levels, electrolytes, kidney and liver function, vitamin D, bone markers, blood sugar and insulin levels, and cholesterol levels which are relevant to the changes caused by gender-affirming hormone therapy.
* Scalp and facial hair dermatoscope 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 photos of scalp hair at certain regions (vertex, temporal and occipital). Currently, it is being updated to be valid for measurements of hair on the face as well. We have a system called HairMetrix which will allow us to analyse the scalp and facial hairs obtained in the photo and provide accurate details about the total hair count and follicle qualities.

At this point the study is over and you can continue to attend your usual clinic.

**3.3 How the research will be monitored**

This research is observational so will not affect type of treatment you will receive. The researchers are responsible for monitoring you and your test results and informing both you and your local doctor if any issues arise. This research in accordance with human research ethics committee approval.

**3.4 Access to personal records that may be required**

Medical records may be accessed as part of this study. This may mean accessing medical records from the hospital or other doctors with your consent. This project does not involve any audio or visual recordings. Photography of your scalp and facial hairs will not have any identifiable features.

* 1. **Results of the Study**
* This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.
* All published data will be grouped data, meaning that you will not be individually identifiable.

**3.6 Costs and reimbursement**

*Additional Costs*

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

*Reimbursement*

You will not be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

**3.7 Your local doctor**

If you decide to participate in this research project, the study doctor 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 study visit and a subsequent study visit after a 6- month period. You are under no obligation, and if you change your mind and no longer wish to be involved in the study then this will not affect your ongoing care.

You may be asked not to interfere with normal facial and scalp hair growth a few days prior to the visits, such as refraining from shaving 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. Certain medical conditions that affect hair growth would exclude you from participation in the study but we will make sure that you do not have it before enrolment.

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

**5 Other relevant information about the research project**

This study is conducted at Austin Health and Sinclair Dermatology. Overall, there will be around 20 people who will participate in the study: 10 in the female to male group, 10 in the male to female group.

**6 Do I have to take part in this research project?**

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

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

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Austin Health/Sinclair Dermatology.

**7 What are the alternatives to participation?**

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

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research. However, this research will contribute to our understanding of how sex hormone affects scalp and facial hair and will potentially benefit the transgender community. It will form a foundational understanding that allows us to conduct future research on how to minimise hair loss and improve gender phenotype for transgender individuals commencing on gender-affirming hormone therapy, which may improve their sense of gender identity and quality of life.

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

While this research does not involve any interventional treatment, you may be receiving gender-affirming hormone therapy that cause side effects. You may have none, some or all of the effects as explained by your doctor, and they may be mild, moderate or severe. If you have any of these side effects, explained to you, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptom that you get. Many side effects go away shortly after stopping a medication. 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 participation in the study. Your study doctor 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 gender affirming hormone therapy on the unborn child and on the newborn baby are unclear. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project.

If you do become pregnant or father a child whilst participating in the research project, you should advise your study doctor immediately. Your study doctor may withdraw you from the research project and advise on further medical attention should this be necessary. You cannot continue in this study if you become pregnant.

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

Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

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 full clinical examination. The photos will not be used to help diagnose, treat or manage a particular condition. On rare occasions, the specialist 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.

**10 What will happen to my test samples?**

A mandatory part of participation in this study is the collection of blood samples. Your blood samples will be analysed by Austin Health or an equivalent pathology service on the day that blood is collected from you and then these samples will be discarded within 14 days. The results of these tests will go into your Austin Health medical record and also be collected separately in your study file.

**11 What if new information arises during this research project?**

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

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

**12 Can I have other treatments during this research project?**

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

It may also be necessary for you to take medication during or after the research project 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 your doctor about this possibility.

**13 What if I withdraw from this research project?**

If you decide to withdraw from this research project, 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 project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

**14 Could this research project be stopped unexpectedly?**

It is unlikely that this research project would be stopped unexpectedly.

**15 What happens when the research project ends?**

At the conclusion of this study, you will be invited to have ongoing monitoring and management as part of your standard routine care.

The results of the study 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 study 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 study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential 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 – Austin Health. Your paper and electronic data will be stored for 15 years following completion of this study. 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 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 project.

Your health records and any information obtained during the study 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 study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project 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 project 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 study 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 project.

Any information obtained for the purpose of this research project 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 project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. 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 project is being conducted by the names listed at the top of the first page. This research is not commercially nor pharmaceutically funded and Austin Health is unlikely to benefit financially from this research project.

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

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

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

**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**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the following primary study doctor:

**Clinical contact person 1**

|  |  |
| --- | --- |
| Name | Dr Gia Toan Tang |
| Position | Principal Investigator |
| Telephone | 03 9496 5000 |
| Email |  |

**Clinical contact person 2**

|  |  |
| --- | --- |
| Name | Dr Ada Cheung |
| Position | Principal Investigator |
| Telephone | 03 9496 5000 |
| 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 | Complaints Contact Person |
| Position | Office of Research |
| Telephone | 03 9496 4090 |
| Email | ethics@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 HREC |
| HREC Executive Officer | Chelsea Webster |
| Telephone | 03 9496 3248 |
| Email | ethics@austin.org.au |

**Reviewing HREC and Local HREC Executive Officer details**



**Place Patient Label Here**

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | The effect of gender-affirming hormone therapy on scalp and facial hair in transgender individuals: a prospective observational study |
| **Short Title** | The effect of gender-affirming hormone therapy on scalp and facial hair in transgender individuals: a prospective observational study |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | NA |
| **Coordinating Principal Investigator/ Principal Investigator** | Associate Professor Ada Cheung/ Dr Gia Toan Tang |
| **Associate Investigator(s)** | Dr Gia Toan Tang, Dr Ingrid Bretherton, Professor Jeffrey Zajac, Professor Rodney Sinclair  |
| **Location**  | Austin Health and Repatriation Campus |

**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 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 project without affecting my future health care.

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

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

I understand that, if I decide to discontinue the research project 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.

**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 formWitness to the informed consent processName (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. |

**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.



**Place Patient Label Here**

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | The effect of gender-affirming hormone therapy on scalp and facial hair in transgender individuals: a prospective observational study |
| **Short Title** | The effect of gender-affirming hormone therapy on scalp and facial hair in transgender individuals: a prospective observational study |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | NA |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Ada Cheung/Dr Gia Toan Tang |
| **Associate Investigator(s)** | Dr Gia Toan Tang, Dr Ingrid Bretherton, Professor Jeffrey Zajac, Professor Rodney Sinclair  |
| **Location**  | Austin Health and Repatriation Campus |

**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.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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*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.*

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**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.