



<Local Trust Logo>

# PATHWAYS

**REC Reference: 25/LO/0500**

## Participant Information Sheet

**We would like to invite you to take part in this research called  
PATHWAYS TRIAL**

- Before you decide if you want to take part, it is important you know why the research is being done and what will happen if you take part.
- Please read this information carefully with a parent/caregiver and **take as much time as you need.**
- Write down any questions on the notes page at the end and ask us if there is anything that you do not understand. A doctor will talk to you about the trial and can help answer your questions.
- You can choose to take part or not take part in the trial. If you decide not to take part in the trial, your doctor will continue to take care of you as they have done in the past.
- If you decide to take part in the trial, you can stop at any time without giving a reason.

**If you have any questions about the trial, please contact:**

Study Doctor (**Insert local details**)

Research Nurse (**Insert local details**)



<Local Trust Logo>

## 1. Why are we doing this trial?

Gender incongruence is when a person's gender identity does not match their sex registered at birth. Puberty can be a difficult time for children and young people who have gender incongruence. This is because their body starts to change in ways that don't match how they feel inside.

During puberty the body produces chemicals called sex hormones, like testosterone or oestrogen. These sex hormones act as messengers that tell the body to change. For example, by causing facial or body hair to grow, breasts to develop or the voice to get deeper.

Doctors have sometimes given young people with gender incongruence a treatment called 'gonadotropin releasing hormone analogues (GnRHa)', also known as puberty suppressing hormones or puberty blockers. This treatment stops the body from releasing sex hormones. This means that whilst a young person is on the treatment they will not continue to go through the physical changes normally experienced during puberty. It has official permission (licensing) to be used in younger children who go through puberty when they are too young. It doesn't have official permission for gender incongruence because it hasn't been carefully tested to find all the benefits and possible harms.

Doctors think puberty suppressing hormones may help young people with gender incongruence explore their gender identity without worrying about their body starting to change. Doctors have thought this might help young people to focus more on things that improve their quality of life, like their interests, school, friendships and relationships. But we don't know whether this happens or not when young people take GnRHa.

Doctors and other people have also been worried about possible disadvantages of GnRHa. These include decreased bone strength, making young people more likely to have fractures. But we don't know how likely this is and whether bone strength returns to normal when young people stop GnRHa or go on to other treatments for gender incongruence like cross-sex hormones. Doctors also worry that GnRHa might affect brain development and



<Local Trust Logo>

learning, because this happens when they are given to animals, but we don't know whether this happens when young people take GnRHa for gender incongruence. There might be other benefits and harms from GnRHa doctors are not yet aware of. That is why it is very important to study its effects carefully.

Because there isn't enough evidence about the benefits and harms of GnRHa, doctors in the UK aren't allowed to give this treatment to children or young people with gender incongruence, unless it's part of a research study. This research aims to find out how young people with gender incongruence experience this treatment, by finding out how it affects their quality of life, mental and physical health and how they feel about their bodies and their gender. It will also look at learning and brain development. For all of these areas, the research will look to see if these get better, stay the same or get worse - we won't know until we complete the study.

## **2. Why am I being invited to take part?**

The doctors and other professionals caring for you in the Gender Service will have discussed GnRHa with you and your parents/legal guardians, including the possible advantages and disadvantages. You have been invited to take part in the PATHWAYS TRIAL because you and your parents or legal guardians, your care team and the doctors at the Gender Service think that it might be helpful for you to have treatment with puberty suppressing hormones (GnRHa). The doctors caring for you have checked this opinion with other doctors, called the national multidisciplinary team.

## **3. How will the treatment be tested?**

Usually, when a treatment is used for a new reason, a type of experiment called a randomised controlled trial (RCT) is done to see whether it works well and is safe to use. This means you will be put into one of two groups by chance (like flipping a coin). One group will start the treatment right away, and the other



<Local Trust Logo>

group will start after 12 months. This helps us compare the two groups to see how the treatment works - what is helpful and what are the side effects.

## 4. What will happen if I take part?

### Finding out about the research

The first step is to carefully read this information sheet, take time to think about what you have read and ask any questions. If you want to take part, a doctor will ask you some questions to make sure you understand why the trial is being done, what will happen if you take part, and what might be good or bad about starting treatment with puberty suppressing hormones (GnRHa). You will have already discussed this with your doctors, but it is important that you ask about anything you want to, and that all your questions are answered.

### Agreeing to take part

We will then ask you to write your name on a form to say that you understand the research and what will happen. You will be given a copy of this form to keep.

We will also ask your parent or another adult who looks after you (caregiver) to sign a form to say that they agree for you to take part.

### Finding out which group you are in

A computer programme will pick whether you are in Group 1 or Group 2:

Group 1: This group will start the treatment straight away, called the '**immediate**' group.

Group 2: This group will wait 12 months before starting the treatment, called the '**delayed**' group.



<Local Trust Logo>

A doctor at the Gender Service will tell you which group you have been given. No one in the study will pick their own group, as this needs to be selected at random for the research to work.

## **Treatment**

There are several different drugs that can be used to suppress puberty. The main one we will use in PATHWAYS TRIAL is called Triptorelin. We may use other drugs, or give you Triptorelin in different doses and frequency, depending on how you respond. The other drugs we might use are called Leuprorelin and Goserelin. If we change your treatment, we will discuss it with you and your parents/caregivers first and explain why we think it is a good idea.

The puberty suppressing hormone (GnRHa) is given by an injection. The treatment lasts for 6 months, so you will receive the injection once every 6 months after starting the treatment. A specialist nurse or doctor will explain this to you before you are given the treatment.

Depending on how you feel during the 6 months and how your body has responded, a doctor may suggest you change to an injection that lasts for 3 months or 1 month.

## **Safety checks and scans**

A doctor will ask you and your parent/caregiver some questions about you and your mental health before you start the treatment. We recommend keeping physically active, such as walking and running, while you are in the trial. This will help you to maintain a healthy weight and strong bones.

To make sure it is safe for you to take part, you will need to have some tests and measurements taken at the clinic, including blood and urine tests, your height, weight, heart rate, blood pressure, and a pregnancy test if you were female sex at birth. You will also need to have an electrocardiogram (ECG), which tests your heart's electrical activity by placing sticky patches called electrodes on your skin.



<Local Trust Logo>

These tests may have already been done by your doctor but you may need to repeat them when you are due to start treatment, to make sure it is still safe for you to take part. We will repeat these tests once every 6-months whilst you are taking the treatment. We will repeat the height, weight, blood pressure, and pregnancy test (if applicable) every time you have an injection, and the doctor will ask you about any other medications you are taking and if you have had any side effects.

Before starting the trial a doctor or specialist nurse will have looked at your body to check your physical health and what stage of puberty you are at. This is called a Tanner Stage Assessment. We don't know if the benefits and side effects of GnRHa are the same at all stages of puberty, so we want to find out whether this makes a difference. If you are in the delayed group, you will have this assessment again when you are due to start the treatment.

### **Blood and urine tests**

You'll need to have blood and urine tests during the trial to make sure it's safe for you to keep going. They'll only take about 2 tablespoons of blood and around 1/3 of a cup of urine. The nurses or doctors will label your samples with your name, date of birth, and NHS number to make sure they don't get mixed up. Then, the samples will be sent to the hospital lab, where they'll be tested. After that, the lab staff will check the results to make sure they're right and put them into the hospital system, before destroying the samples. The doctor will then look at them and see how you're doing.

### **Bone imaging**

You will also be asked to have 2 types of bone imaging. The first scan is called a DEXA, or bone density scan. During the DEXA scan you will lie down on a padded table for around 15 minutes whilst a scanner moves over your body. The DEXA scan is important for doctors to know how strong your bones are during the treatment. The second scan is called a bone age X-Ray, which takes a special picture of your left hand. The bone age X-Ray helps doctors to see how your bones are growing.



<Local Trust Logo>

The effects of puberty-suppressing hormones (GnRHa) on foetal (baby in the womb) development and reproductive cells are not yet fully understood. For this reason, it is important to avoid pregnancy during treatment. If you were female at birth and you are or might be sexually active with a person of the opposite sex, you will need to use effective barrier contraception (such as a male or female condom, diaphragm or cervical cap) as a precaution throughout the treatment period to prevent pregnancy and against infections. If you stop puberty suppression, you will need to continue to use this contraception until your periods return. Your doctor or a specialist nurse will be able to discuss alternatives with you.

### **Online questionnaires**

You will be asked to complete some questionnaires. These will ask about:

- Your emotions and behaviours
- How you feel about your gender and body
- Your relationships with others
- Your daily life with friends, family, education and other activities

You can answer the questionnaires on a phone, tablet or laptop, either on your own before you visit the clinic, or during the visit if you prefer. We can also do this with you over the phone or by video call.

We will ask you to do most of these questionnaires once a year (including after the trial ends, for up to 5 years in total) and they will take around an hour to complete.

We will ask you to complete some of these questionnaires more often, 2 will be completed 7 times in total and 1 will be completed 5 times in total.

After you complete the questionnaires, you might want to talk about your thoughts and experiences. There is an option to let us know that you would like a researcher to contact you.



<Local Trust Logo>

Young people might worry that the answers they give could affect whether they stay on GnRHa. We know that young people's emotions and experiences change, depending on what is happening in their lives. Your treatment will not be stopped if you tell us about difficult feelings or experiences.

## **Cognitive assessments**

The cognitive assessments are short puzzles and tasks that tell us about how you learn, think and solve different problems. For example, you might be shown some pictures and after a short break be asked to tell us what you saw, to see what you can remember.

We will ask you to complete them with one of the researchers in clinic, whenever possible on the same day as one of your existing appointments. This will take about 2 hours, but you can have as many breaks as you need.

We will ask you to do these cognitive assessments once a year (3 times in total). You will get a voucher worth £30 every time you complete your cognitive assessments.

## **Continuing the treatment**

**3 months into the trial:** A doctor or researcher will call you to check how you are feeling.

**6 months:** Only if you are in the immediate group, you will visit the clinic for your safety checks, including blood and urine tests. If a doctor is happy for you to continue, you will continue the treatment.

**9 months:** A doctor or researcher will call you, again to check how you are feeling.

**12 months:** You will visit the clinic for your safety checks and scans. If you are in the immediate group, you will only have a bone age X-Ray if the doctor thinks you need to. You will have blood and urine tests as part of the safety checks.



<Local Trust Logo>

If you are in the immediate group and the doctor is happy for you to continue, you will continue the treatment.

If you are in the delayed group, you will also have your Tanner stage assessment. You will have safety checks (blood and urine tests). If the doctor is happy for you to start the treatment, you will start the treatment at this point.

**15 months:** A doctor will call you, again to check how you are feeling.

**18 months:** You will visit the clinic for your safety checks and scans. If the doctor is happy for you to continue, you will continue the treatment. You will have blood and urine tests as part of the safety checks.

**21 months:** A doctor will call you, again to check how you are feeling.

**24 months:** The final clinic visit during treatment is at 24 months, where you will repeat the safety checks and scans to make sure you are still safe and well. You will only have a bone age X-Ray if the doctor thinks you need to.

### **What happens when my treatment in the trial ends?**

When the trial ends, your doctor will talk to you and your parent/caregiver about how you have found the treatment in terms of your quality of life, mental and physical health and your experience of your gender and body. You will discuss the next steps in your care, what your options are, and what you would like to do. These might include staying on GnRHa, stopping the treatment, or going on to another treatment.

It is not possible to know what your treatment plan will look like at the end of the trial, as this will depend on several factors, including your experience of GnRHa, your mental and physical health, and your future preferences. We also do not know whether results from the trial more generally may be showing that there are significant harms from this treatment, which could mean it is not a good idea to stay on GnRHa.



<Local Trust Logo>

If you want to stay on GnRHa and your doctor in the Gender Service agrees that you may continue to benefit from it, your care will be reviewed again by the national multidisciplinary team, who need to agree that you should stay on GnRHa. If they don't agree, they will give you reasons why they think this is not the right ongoing care for you. If they make that decision and your circumstances change so the reasons no longer apply, your doctor can ask for another review of your care.

If you stay on GnRHa, your care will need to be reviewed by the national multidisciplinary team every year while you are on it, to check it is still the right treatment for you.

**Figure 1** on page 9 shows what will happen in the immediate start group.  
**Figure 2** on page 10 shows what will happen in the delayed start group.

### Long-term follow-up

**36 months:** We would like to understand your experience long-term and see how you are doing after receiving treatment. Whatever your treatment decision at the end of the trial, we will ask you to complete the full set of questionnaires again and to visit the clinic for a DEXA Scan at 36 months.

**48 months:** The final clinic visit is at 48 months, where we will ask you to have a DEXA Scan and complete the final set of questionnaires.

As much as possible, we will arrange your visits for when you are coming to see the specialist nurse or doctors to review your treatment. If that isn't possible, we can be flexible when arranging study visits to find a date and time that suits you best. If you arrange a visit and you can no longer make it, that is ok, we can arrange another time for you.



<Local Trust Logo>



We will reimburse your costs for attending research appointments, including your and your parent/caregiver's travel and meals on days when you have a cognitive assessment.



<Local Trust Logo>

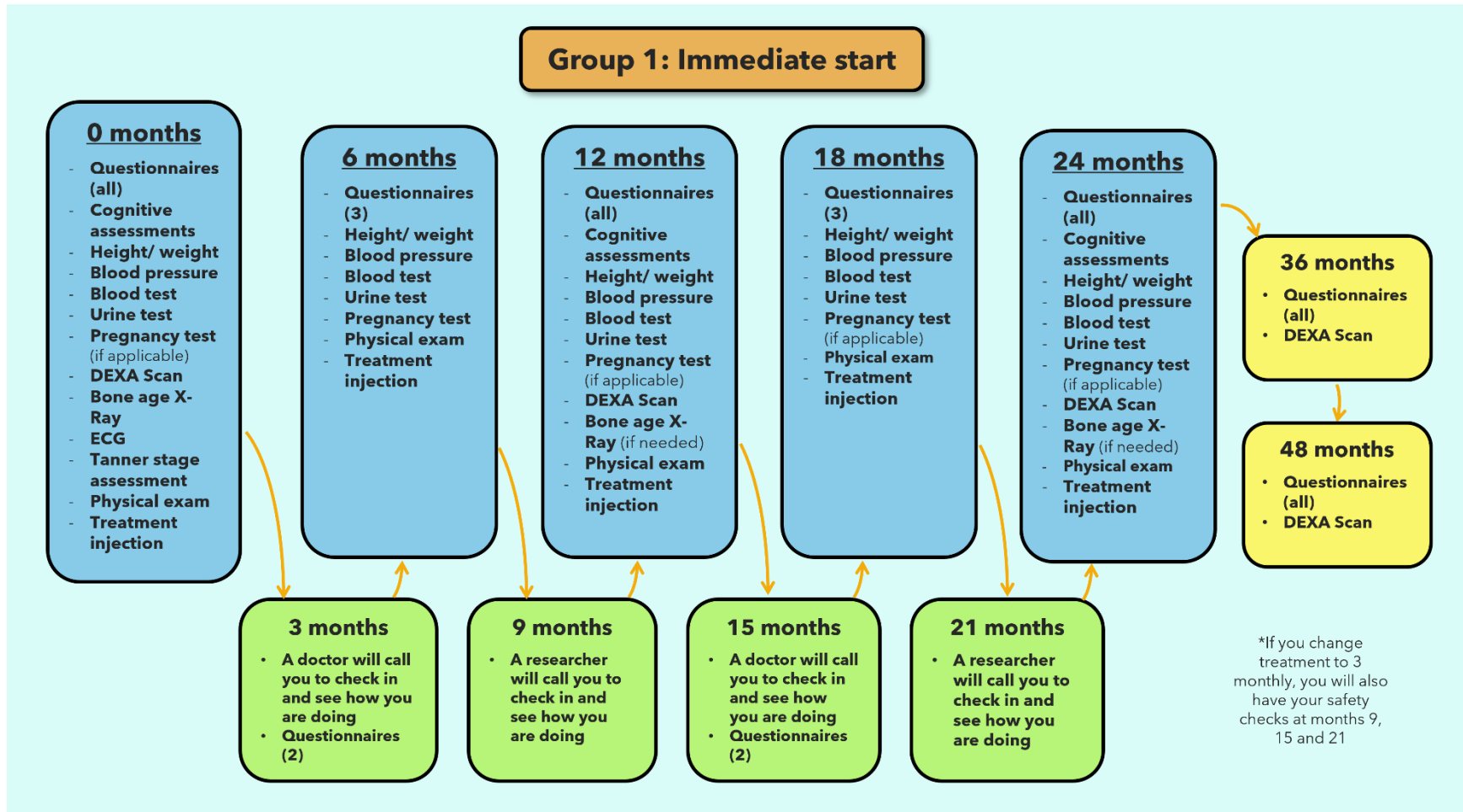


Figure 1- A flowchart showing what will happen in the immediate start group



<Local Trust Logo>

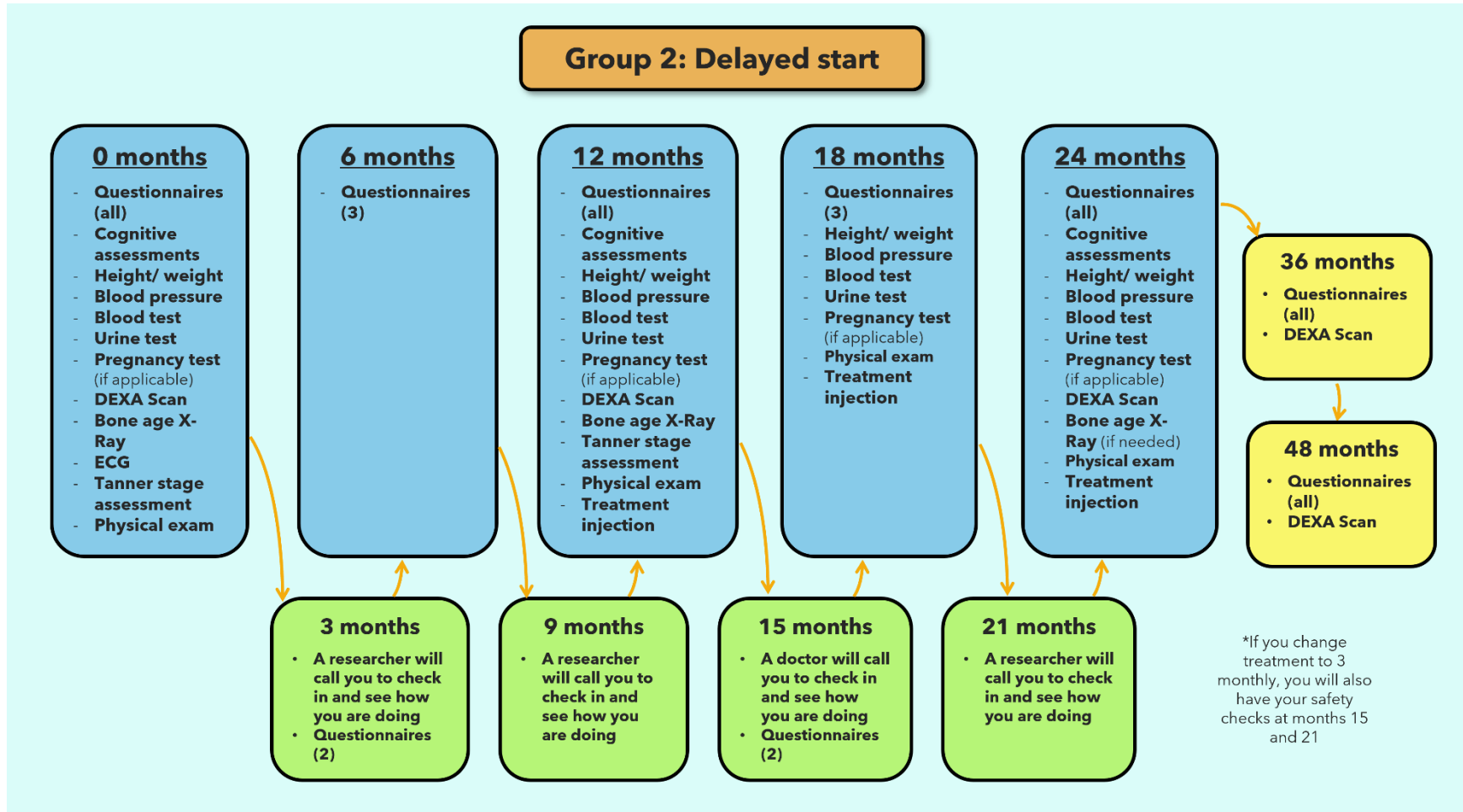


Figure 2- A flowchart showing what will happen in the delayed start group



<Local Trust Logo>

## 5. What might be good about taking part?

We do not know whether the treatment may help you.

By taking part in this study, you may help us learn more about what children and young people with gender incongruence find good or not so good about puberty suppressing hormone (GnRHa) treatment. This information might help young people, parents and doctors in the future make decisions about this treatment.

## 6. Risks or possible risks of taking part in the study

Taking part in this study means you will receive medicines called puberty blockers (GnRH analogues). These medicines are already used for other conditions, like early puberty, and most side effects are mild and go away when treatment stops. Common short-term effects include headaches, hot flushes, tiredness, mood changes, and soreness where the injection is given. Some people may feel more anxious or low in mood, so we will check in with you regularly about how you are feeling.

There are also some less common but important risks. These medicines can affect your bones by slowing down bone strength development. We will monitor your growth and bone health during the study. Rarely, a condition called idiopathic intracranial hypertension (IIH) can happen, which causes severe headaches, vision problems, or ringing in the ears. If you notice these symptoms, you must tell your doctor straight away. There is also a very small chance of changes in heart rhythm, especially if you take certain other medicines, so we will check your health history and may do an ECG (heart tracing) if needed.

Some risks may not show up until later in life. These include possible effects on:

- Fertility (your ability to have children in the future if you go on to have cross sex hormones like testosterone or oestrogen). It is important that



<Local Trust Logo>

you talk to the doctors in the clinic about the options you have for your fertility for the future. These choices would include being referred to a fertility specialist to discuss storing eggs or sperm.

- Bone health (risk of weaker bones or fractures later)
- Sexual development and function
- Memory and thinking skills (we do not yet know if there is an effect)

Because these changes can take years to appear, we will ask for your parent's/legal guardian's permission and your agreement to keep in touch after the main study ends and, if you agree, link to your NHS health records. This helps us understand the long-term effects and keep you safe. You can say no to this and still take part in the main study.

You can stop taking part at any time. If you do, we will ask if we can still collect information about your health to help make the study results useful for others.

## **7. What might not be good about taking part?**

Whilst on the treatment, you might notice changes to your body or how you feel. You might feel more sad or anxious, or struggle to sleep. You might feel sick or have an allergic reaction to the treatment, but this is less likely.

A doctor or nurse will talk to you regularly over the phone and at the clinic to check if you are having any of these side effects, but **if you feel unwell at any point, please tell your parent/caregivers and let the doctor know on [insert local telephone number]**.

If you take part in this study you will have DEXA scans of your spine and hips and x-rays of your Left Hand/Wrist. Some of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.



<Local Trust Logo>

We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance of this happening to you.

When answering the questionnaires, you might find some questions upsetting or difficult to answer. We can discuss this with you if it is helpful. Remember that telling us questions are difficult or upsetting will not change your treatment in the trial.

Taking a blood sample is usually safe but there are a few things that could happen:

- Feeling a little pain when the needle goes in (like a small pinch)
- Bruising or a small bump where the needle was
- Bleeding, but usually this is small and stops quickly
- Feeling dizzy or faint, especially if you are nervous about the needle or blood
- Infection, but this is very rare and the hospital staff keep things clean to prevent this from happening

If you feel unwell at all following the blood test, please tell a nurse or doctor right away.

It may not always be possible to arrange your clinic visits outside of school hours, however, we will do our best to schedule your appointments in a way that minimises any disruption to your education.

## **8. Do I have to take part? What if I change my mind?**

No, it is up to you and your parents/legal guardians whether to take part or not. If you change your mind about taking part, you can stop the research at any time, without giving a reason. If you decide you want to stop taking part, your care in the Gender Service or anywhere else will not change in any other way. If you want to stop taking GnRHa, your doctors will talk with you and your parents/legal guardians about other treatment choices you have.



<Local Trust Logo>

To stop taking part in the study, please email the research team (**insert local PATHWAYS researchers' email**) or contact your Gender Service.

## **9. Who is organising and funding the trial?**

This project (NIHR167530) is funded by the National Research Collaboration Programme, an NHS England and National Institute for Health and Care Research (NIHR) partnership. The research was reviewed by independent scientists before this funding was given. The views expressed are those of the author(s) and not necessarily those of NHS England, NIHR or the Department of Health and Social Care.

The PATHWAYS TRIAL is co-sponsored by King's College London (KCL) and South London and Maudsley NHS Foundation Trust (SLaM). The trial is coordinated by the King's Clinical Trials Unit (KCTU) and monitored by the Kings Health Partners Clinical Trials Office (KHP-CTO), to ensure the trial is being done properly, in line with regulations.

## **10. Is the trial ethical?**

All research in the NHS is looked at by a group of people, called a Research Ethics Committee (REC), before the study begins, to make sure it is safe and fair for the people taking part. This research has been approved by the Health Research Authority (HRA) and given a favourable opinion by an NHS Research Ethics Committee.

The research is also overseen by two committees, a Data Monitoring Committee (DMC), and a Programme Steering Committee. These committees are made up of people who are independent from the research team and the funders, and are separate to the HRA and REC. The DMC will check the data and highlight any concerns in relation to the quality of data (such as the amount of missing information) and any concerns about the safety or well-being of participants. The Programme Steering Committee will include at least



<Local Trust Logo>

two lay members with lived experience, as well as scientists, and will advise of the study progress overall.

## **11. How will my personal information be used?**

We will need to use information from you and your medical records for this research project.

This information will include your:

- Initials
- Name
- Date of Birth
- Sex Registered at Birth
- Contact Details (phone number & email address)
- NHS Number

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who don't need to know who you are will not be able to see your name or contact details. Your data will have a unique code number instead.

King's College London and SLaM NHS Trust are the sponsors of this research.

King's College London and SLaM are responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- Non-commercial research organisations
- Higher education institutions (universities)
- Healthcare assessment providers

We will keep all information about you safe and secure by:

- Following strict guidelines concerning the use and storage of personal information, compliant with the General Data Protection Regulation



<Local Trust Logo>

(2018) and the Data Protection Act (2018) in UK law, to keep the information that you provide safe and private.

- Unless you give us permission, your information won't be shared with anyone outside of the research team.

If we are worried about your safety, we may contact your clinical care team or GP, but we'll talk to you first.

- At the start of the trial, you will be given a unique code number or participant identification number (PIN). Your research data will be stored under this unique number.
- Only members of the research team who need to know who you are will be able to see your personal details (name, email address and/or phone number).
- Your research data will be stored under a secure server. The secure server will be password-protected and only authorised members of the local trial team, staff at KCTU, KCL, and KHP-CTO will be given access.
- During the trial, authorised staff outside of your care team will need to see information about you and view your personal and medical records. This is done to check the trial is being done properly.
- Your data will be processed so you cannot be directly identified from it.

## **12. International transfers**

We may share or provide access to data about you with researchers outside of the UK. If you would like to find out where and how your data will be used outside of the UK, here is some more information:

Your data may be used outside of the UK for research related purposes to:

- Conduct collaborative research
- Create larger combined datasets for further analysis
- Maximise the impact of the research
- Improve the quality of research in this area globally



<Local Trust Logo>

- Set up your profile on Q-interactive for completing cognitive assessments

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

- Non-commercial research organisations
- Higher education institutions (universities)
- Healthcare assessment providers

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- Some of the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK.
- We use specific contracts approved for use in the UK which give the same level of protection to personal data it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/>
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We make sure other organisations have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.



<Local Trust Logo>

- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators if there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: <https://ico.org.uk/for-organisations/report-a-breach>

### **13. How will information about me be used after the study ends?**

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

- We will keep your study data for a maximum of 25 years. The study data will then be fully anonymised and securely archived or destroyed.

### **14. Will the research find anything important for my health?**

During the course of this research project, previously unsuspected clinical findings about you could be revealed. In the event that significant findings are revealed, a doctor will inform your GP and the study team. Where necessary, your local Gender Service and paediatric team will be informed, and there will be a discussion of the findings with you and your parent/caregiver to determine whether any further onward referrals are needed. A summary of the results of your scans will be sent to you GP and you will also receive a copy.

### **15. What are my choices about how my information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the trial. We might not always be able to do this if it



<Local Trust Logo>

means we can't use your data to do the research. If so, we'll tell you why we can't do this.

If you agree to take part in this study, you'll have the option to take part in future research using your data saved from this study.

We're interested in finding out how you're getting on in everyday life. To reduce the amount of information we need to collect from you directly, we'll seek your parent or guardian's consent to:

- o Link your data to UK health and education databases, held on secure platforms.
- o Share your data from the trial with other research groups in the future.

In both these instances, we would only share information about the trial and not information that could identify you (e.g. your name or contact details). Your identity will always be kept safe.

Please discuss this with your parent or guardian and let them know your views. You don't have to agree to either of these, but it may help other young people with gender incongruence in the future.

## **16. Where can I find out more about how my information is used?**

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- our leaflets: <https://slam.nhs.uk/personal-information-gdpr>,  
<https://www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research>
- by emailing your local PATHWAYS research team:
  - o (Insert local PATHWAYS researchers' email)
- by sending an email to the data protection officers:
  - o Olenka Cogias, [info-compliance@kcl.ac.uk](mailto:info-compliance@kcl.ac.uk) (KCL)



<Local Trust Logo>

- o Claire Delaney-Pope, [informationgovernance@slam.nhs.uk](mailto:informationgovernance@slam.nhs.uk) (SLaM).
- by ringing us on **0207 848 7816**

## 17. Who will know I am taking part?

We will need to let your GP know that you are taking part in this trial as it is important for your healthcare. The researchers running the study and the team at the Gender Service will also know that you are taking part.

We'll share the information you give us during the study with the Gender Service, so they can see whether they are helping you and other young people, unless your parent or guardian tells us not to.

## 18. What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (**Insert local PATHWAYS researchers' email**). If you remain unhappy and wish to complain formally, you can do this through the local Patient Advice and Liaison Service (PALS) on tel: (**insert local PALS tel**), email: (**insert local PALS email**).

If something does go wrong, and you are harmed during the research, you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

## 19. What will happen to the results of the trial?

The findings of this research will be presented in internal reports, professional journals and at conferences. We will also publish our results in a way that is easy for the public to understand and make these available to everyone, including posting on the PATHWAYS website. We will send you a newsletter at



<Local Trust Logo>

least twice a year to keep you informed about the study. Our patient advisory groups will help us to share the results in the best way.

It will not be possible to identify you from any of the research reports or publications we write.

## **20. Other studies you may be asked to take part in**

You may be given information about a study called PATHWAYS CONNECT, which is a study looking at how the brain develops in some of the young people taking part in PATHWAYS TRIAL. You might also be asked whether you want to take part in PATHWAYS Voices, where young people attending Gender Services talk with a researcher about their experiences of care in the Gender Services.

It is up to you and your parent/caregiver whether you take part in PATHWAYS CONNECT or PATHWAYS VOICES. If you decide not to take part, your care at the Gender Service will not change and it won't affect your treatment in the PATHWAYS TRIAL.

## **21. Who can I talk to about the trial?**

You can ask any questions you have about the trial at any time by contacting:

[name of responsible person at site]

[address of site] Tel: [xxxxxxxxxxxx]

If you would like more information about participating in research, please contact:

[Name of local PALS]

Tel: [xxxxxxxxxxxx] Email: [email address if applicable] Website: [website if applicable]



<Local Trust Logo>

---

**Thank you for reading this information sheet and for considering  
taking part in this research**

