NHS
South London
and Maudsley
NHS Foundation Trust

KING'S College LONDON

Study Title: PATHWAYS HORIZON

Information Sheet for Parents of Children under 16 years

Ethical Clearance Reference Number: **25/LO/0251**

We would like to invite you and your child to participate in this study called PATHWAYS HORIZON, which forms part of the wider research programme Puberty suppression And Transitional Healthcare with Adaptive Youth Services (PATHWAYS). Before you decide whether or not you and your child want to take part, it is important for you to understand why the research is being done and what it would involve for you and your child. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is this study about?

The purpose of this research is to understand the emotions, health and experiences of young people attending Gender Services in England and how these change (or not) as young people grow up. If we understand what is going well and what is difficult for young people, we can adapt the Gender Services so that they provide better care for everyone.

Why have I been invited?

You received this information because your child has an upcoming appointment with the Gender Service, or they have had an appointment with the Gender Service. We are inviting all young people who attend the Gender Service, and their parents or caregivers to participate in PATHWAYS HORIZON.

Do my child and I have to take part?

No, it is up to you and your child to decide whether you want to take part. Choosing not to take part will not affect the care that your child receives from the Gender Service, or disadvantage them or you in any way. It also won't affect whether your child is able to join any other studies run in the Gender Service, if they are eligible for them.

We advise you to read through this information together with your child and to contact us if you have any questions that may help you to decide.

What will happen to my child and I, if I take part?

If you choose to take part, we will ask you to sign a consent form, to confirm that you agree to participate, and to confirm on behalf of your child that they agree to participate. You will be given a copy of the consent form to keep. We will also ask your child to sign a form, called an assent form, to express that they are willing to participate.

Once your child turns 16, they can provide consent for themselves to take part.

Throughout the study your child will be asked to complete a number of questionnaires. These will ask about:

- Their emotions and behaviours
- How they feel about their gender and body
- Their relationships with others
- Their daily life with friends, family, education and other activities

We also want to find out how you think your child is getting on. As a parent or caregiver, you will also be asked to complete a number of questionnaires. These will ask about:

- Your child's emotions and behaviours
- Your child's daily life with friends, family, education and other activities

The questionnaires will take about 30-40 minutes to complete. You can complete them all at once or take breaks.

You can complete the questionnaires on a computer or tablet. If you or your child would like assistance in completing these questionnaires, we can help you via phone or video call.

After you complete the questionnaires, you or your child might want to talk about your thoughts and experiences. You can email the research team [Insert local PATHWAYS researchers' email] if you or your child would like to discuss your thoughts and experiences with a researcher.

We will ask you and your child to repeat these questionnaires once a year, for up to 5 years. You can tell us how you would like us to contact you (email or phone).

What happens when I have completed the questions?

You and your child will each receive a £20 voucher to thank you for your time. We'll send a £20 voucher each time you complete the annual set of questionnaires.

What are the benefits of participating?

The information you and your child provide will help us to understand how to better support young people at the Gender Service, which we hope will lead to improved care for your child and others in the future.

What are the possible disadvantages of participating?

You or your child may find some questions distressing or difficult to answer. We can discuss this with you if it is helpful. Neither of you need to answer any questions which make you feel uncomfortable.

What else will I be asked about?

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 your child is getting on in everyday life. To reduce the amount of information we need to collect from you directly, we'll seek your consent to:

- Link your data to UK health and education databases, held on secure platforms, once personal details (e.g. names) have been removed.
- Share your data with other researchers who have a valid research question, once personal details (e.g. names) have been removed.

In both these instances, your and your child's identity will always be kept safe. This data will be separated from your personal details and confidential.

We'll also seek your consent to:

- Contact you about other studies in the future.
    - One of those studies is about making a new questionnaire to find out what is most important for young people in the Gender Service.

It is up to you whether you agree to any of the above. You can complete just the questionnaires without agreeing to take part in any other further research.

How will my information be used?

We will need to use information from your and your child's questionnaires and the Gender Service for this research project. People will use this information to do the research or to check your child's medical records to make sure that the research is being done properly. We may need to use information from your child's medical records for this research, to check any other health conditions or diagnoses for example.

This information will include your child's:

- Initials
- Name
- Contact Details (phone number & email address)
- NHS Number

This information will also include your:

- Initials
- Name
- Contact Details (phone number & email address)

People who do not need to know who you or your child are will not be able to see your or your child's name or contact details. Your and your child's data will have a code number instead.

King's College London and South London and Maudsley NHS Foundation Trust (SLaM) are the sponsors of this research and are responsible for looking after your information. We will keep all information about you and your child safe and secure by:

- Following strict guidelines concerning the use and storage of personal information, compliant with the General Data Protection Legislation (GDPR) in UK law, to keep the information that is provided safe and private.
- Unless you give us permission, your and your child's information will not be shared with anyone outside of the research team.

We will inform your child's GP and clinical team of your and your child's involvement in the research. If your answers make us worried about your child's safety, we may contact their care team, but we'll talk to you and your child first.

The research team may be obliged to share information with your child's GP or clinical care team if we think that your child's safety is at risk.

Once we have finished the study, some data will be stored securely, so we can check the results. We will keep the confidential data for up to 25 years.

We may share or provide access to data about you and your child with researchers 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

If this happens, we will only share the data that is needed. We will also make sure you and your child can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if your child has a rare illness, it may still be possible to identify them. 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)

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 and your child's 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.
- 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.

What are my choices about how my information is used?

You and your child can stop being part of the study at any time, without giving a reason, and without their care being affected.

If you or your child would like to stop being part of the study, please tell the team at the Gender Service or one of our researchers.

You have the right to ask us to remove, change or delete data we hold about you and your child for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

Who will know that my child and I are taking part?

Your child's GP will be informed of your and your child's involvement in this research. If your child is under the care of the Children and Young People's Gender Service, the team at the Gender Service will also be informed. The questionnaires you and your child complete are routinely used in the Gender Service. To save you repeating the questionnaires, we will share your responses with the Gender Service, so they can see whether they are helping your child and other young people, unless you tell us not to. If your child is discharged from the Gender Service, we will no longer share your responses with them.

Where can I find out more about how my information is used?

You can find out more about how we use your and your child's information using the following:

- 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 research team:
    - (Insert local PATHWAYS researchers' email)
- by sending an email to the data protection officers:
    - Olenka Cogias, info-compliance@kcl.ac.uk (KCL)
    - Claire Delaney-Pope, informationgovernance@slam.nhs.uk (SLaM).
- by ringing us on: 0207 848 7816

What will happen to the results of this research?

The findings of this research will be presented in internal reports, professional journals and at conferences. We will also publish reports about our findings for the general public and these will be freely available, including on the PATHWAYS website. It will not be possible to identify you or your child from any of the research reports we write. We will send you a newsletter at least twice a year to keep you and your child informed about the study.

Who has reviewed this research and how is it being funded?

This research is being funded by the National Institute for Health and Care Research (NIHR). The research has been reviewed by independent scientists prior to funding it. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by the Health Research Authority (HRA) Research Ethics Committee (Reference: **25/LO/0251**).

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), In the event that something does go wrong, and you or your child 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, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

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