Study Title: PATHWAYS HORIZON

Information Sheet for Parents of Young People 16 years and older

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

We would like to invite you 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 want to take part, it is important for you to understand why the research is being done and what it would involve. 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 young person 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 I have to take part?
No, it is up to you whether you want to take part. Choosing not to take part will not affect the care that your young person receives from the Gender Service, or disadvantage them or you in any way.

What will happen 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. You will be given a copy of the consent form to keep.

As a parent or caregiver, you will be asked to complete a number of questionnaires. These will ask about:

- Your young person's emotions and behaviours
- Your young person'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 would like assistance in completing these questionnaires, we can help you via phone or video call.

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

We will ask you 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 will 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 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 young person and others in the future.

What are the possible disadvantages of participating?
You may find some questions distressing or difficult to answer. We can discuss this with you if it is helpful. You don't have 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 young person 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 young person'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:

- Share your questionnaire responses with your young person's Gender Service, as this could advise them on how to deliver better care for your young person and may help them to understand whether they are appropriately supporting young people.
- 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 questionnaires for this research project. People will use this information to do the research or to check your records to make sure that the research is being done properly.

This information will include your:

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

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

King's College London and South London and Maudsley NHS Foundation Trust are the sponsors of this research and are responsible for looking after your information. 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 Legislation (GDPR) in UK law, to keep the information that you provide safe and private.
- Unless you give us permission, your information will not be shared with anyone outside of the research team.

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

The research team may be obliged to share information with your young person's GP or clinical care team if we think that your young person'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 young person 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 young person can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if your young person 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 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 can stop being part of the study at any time, without giving a reason, without your young person's care being affected.

If you would like to stop taking part in the study, please tell the team at the Gender Service.

You have the right to ask us to remove, change or delete data we hold about you 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.

Where can I find out more about how my information is used?
You can find out more about how we use your 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 848 781

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 from any of the research reports we write. We will send you a newsletter at least twice a year to keep you 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 young person 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.