

**Puberty Suppression and Transitional Healthcare with Adaptive Youth Services (PATHWAYS). PATHWAYS TRIAL, PATHWAYS CONNECT, and PATHWAYS HORIZON Intensive.**

Overall, a comprehensive study that would be suitable for the intended participants

Positive comments:

- Extensive PPI involvement, including PIS feedback
- Thorough consideration given to address the adverse effects of the drug and investigations
- Comprehensive list of blood tests, clinical examination and mental health assessments
- Reimbursement and compensation provided
- Level 3 Safeguarding procedures ensured
- GP informed
- Inclusive participant selection with the help of interpreters, bespoke formats of information for those who require these services; use of checklist to ensure comprehension of the information provided
- Gillick competence assessed regularly
- Robust personal data handling
- Time given for participants to review the PIS
- Can withdraw from study at any time
- PIS well-written and easy to read, with all the relevant information. Flow chart is very clear.

Questions to clarify:

- Would it be better to be clear in the beginning that this study is for those from 12-16 year old, rather than under 16?
- It is mentioned that side effects of the drugs are documented and addressed promptly, according to GCP, but would be good to know exactly how they will be addressed
- Is mental health support by CAMHS going to be 24/7?
- Fertility option is discussed, is that also involving a clinical psychologist?
- If there are serious side effects, who will pay for compensation?