Questions:

I would be grateful if the Department of Health (NI) could provide the following information relating to the forthcoming NHS clinical trials involving puberty-suppressing hormones (GnRHa) for children and young people.

1. Participation of N. Ireland

    a) Has the Department of Health (N. Ireland) agreed to allow children or young people from N. Ireland to participate in the NHS-approved clinical trials of puberty-suppressing hormones?
    b) If so, please confirm the date this decision was made and provide any documentation, ministerial submissions, or internal communications outlining the basis of that decision.

2. Service involvement

    a) Which N. Ireland health bodies or clinical services (e.g., HSC Trusts, the Regional Gender Identity Service, Community Paediatrics, CAMHS, etc.) have been asked to participate, support, or facilitate referrals into the trial?
    b) Please confirm whether any NI-based clinicians or services have formally agreed to participate, and provide any correspondence relating to this.

3. Eligibility and screening for NI participants

    a) Has the Department produced any guidance, criteria, risk assessments, safeguarding protocols, or consent frameworks specific to N. Ireland regarding the enrolment of minors into these clinical trials?
    b) If such documents exist, please provide copies.

4. Anticipated age groups

    Please confirm whether children as young as 10 years old may be referred from N. Ireland into these trials, and provide any documentation or guidance held by the Department relating to minimum or maximum ages for NI participants.

5. Funding and operational arrangements

    a) Will the Department of Health (NI) fund or provide resources for NI participants taking part in the trial (travel, clinical appointments, follow-up care, etc.)?
    b) Please provide any financial or operational planning documents relating to N. Ireland's involvement.

6. Communications and ministerial briefings

    Please provide copies of:

    a) Any ministerial briefings, internal memos, emails, or policy papers that refer to N. Ireland's participation in the puberty-blocker trials.

b) Any communications between the Department of Health (NI) and the Department of Health and Social Care (England), NHS England, the Health Research Authority, or trial coordinators (e.g., King's College London) regarding trial access for NI residents.

7. Public statements vs. internal planning

   If the Department has stated publicly that children in N. Ireland will have "equitable access" to these trials, please provide the internal documents that clarify:

   a) What "equitable access" is intended to mean in practice;
   b) Whether NI expects to refer participants;
   c) Whether any assessment has been carried out on the impact of participation on NI services.

Response:

1.
   a) The Department of Health (DOH) has agreed to participate in the Proposed Puberty Suppressing Hormones (PSH) Study.
   b) Please see appendix 1 through 2 attached. Some of the information in the document has been redacted. The reason for this decision and the applicable exemption in this instance is set out in appendix 3.

2.
   a) The Regional Gender Identity Service will participate in the PSH study and referrals will be made through them.
   b) I refer you to appendix 4 attached. Some of the information in the document has been redacted. The reason for this decision and the applicable exemption in this instance is set out in appendix 3.

3.
   a) The National Providers Network for England and Wales has produced clinical guidance for the assessment of suitability for puberty suppressing hormones.
   b) SPPG do not hold this information.

4. To take part in the PATHWAYS TRIAL, young people will need to have a diagnosis of gender incongruence according to the World Health Organization's diagnostic manual, the ICD-11. They will have experienced gender incongruence that has persisted for more than two years, and have participated sufficiently in other forms of care for gender incongruence. A young person's clinical eligibility will then be considered by both their clinical care team and by the National Multi-Disciplinary Team (NMDT). The NMDT is a group of senior clinicians from the Children and Young People's Gender Service who ensure that decisions about eligibility are made consistently across clinicians and services. The team reviews information about each young person's psychosocial and physical health, education, and safeguarding to make sure eligibility is assessed comprehensively. There is no younger age cutoff, in line with the High Court decision Bell v Tavistock. However, all young people will need to demonstrate informed assent, which will make it very unlikely that younger children are eligible.

5.

a) NHS England has commissioned and funded the study as part of a wider research programme in partnership with the National Institute for Health and Care Research (NIHR). The research and treatment costs for NI participants will be borne by DOH. The current research team will use central resources to manage data analysis.
b) There are no such documents at present.

6.

a) Please see attached appendices 5 through 9. Some of the information in the document has been redacted. The reason for this decision and the applicable exemption in this instance is set out in appendix 3.
b) Please see attached appendices 10 through 12. Some of the information in the document has been redacted. The reason for this decision and the applicable exemption in this instance is set out in appendix 3.

7.

a) When NI joins the study, the conduct of the trial will be exactly the same for NI participants, from the stage of considering eligibility through to care within the protocol. If NI participants wish to take part in CONNECT (the brain imaging study) additional funding to come to London would be required from NI.
b) Yes, if participants meet the criteria they will be considered for referral.
c) No.

Appendices may be requested from the Information Management Branch (IMB) if required at the following address:

- *FOI@health-ni.gov.uk*

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