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Participant Information Sheet

Audio & Contact

For young people aged under 16 years

*The Growth Hormone Deficiency Reversal Trial – Qualitative Study*



This study is part of a bigger project that is looking at the best ways to treat young people who have been previously diagnosed with Growth Hormone Deficiency. It is called the **GHD trial**, for short.

**Why are we doing it?**

We want the GHD trial to work really well. As part of this we are finding out what makes families want to be involved or not. This is called a qualitative study. This information will help the team doing the GHD trial to improve how they do their research. This will ensure that the results are really useful.

**Why are we asking you?**

The GHD trial is taking place in your hospital. We think that you and your parents/carers will be invited to take part (by your usual care team).

**What will the qualitative study involve?**

It will involve two things. We hope you will do both, but you can do just one if you prefer.

1. We would like to audio-record the conversation that happens when you and your parents/carers are invited to take part in the GHD trial.
2. We would like to contact you and your parents/carers at a later date to see if you would like to take part in an interview(s). We think the interview(s) will last between 30-45 minute. This invitation pack will be sent to your parents/carers, with information included for you.

**If you give us permission to record your conversation:**

1. A doctor or nurse will check that you are happy to take part and answer any questions that you have.
2. They will ask you to sign an ‘Assent’ form to show you are happy to take part. Your parents will also be asked to sign ‘Consent’ forms to show they are happy for you and them to take part.
3. The doctor or nurse will switch on a digital audio recorder that will record your voice.
4. The recording will be sent to researchers at the University of Birmingham, typed-up and analysed.

**If you give us permission to contact you about an interview:**

1. We will ask your family for contact details.
2. At a later date, we will send your family an interview pack (by post or email).
3. This will include a leaflet for you and tell you everything about the interview.

**Do I have to take part?**

No - it is your choice whether you want to take part and you can change your mind at any time.

**What do I do if I don’t want to take part in the study anymore?**

It’s ok to change your mind. Just tell your parents/carers or the researchers that you don’t want to take part anymore. You don’t have to give us a reason.

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.

**What are the pros and cons of taking part?**

* Pros: Some people who take part in research say it is interesting. However, there is no other benefit for you. The information may help improve care for other young people in the future.

 Cons: We hope that taking part will be a good experience, and we don’t expect that taking part will harm you. However, please tell us if you are worried about any aspect of taking part and we will make sure that you some appropriate support.

**Will my information be kept private?**

All of your information will be kept private. No one will know you have taken part in the study unless you decide to tell them. We might use some of your words in our reports, but these will not include your name or anything else that could identify you.

All of your information will be kept electronically on secure computer servers at the University of Birmingham. Only the researchers involved in this study will have access to your information and access will be password protected. The only other person who will see your information is the professional who writes up your information from the recording of our interview and takes your name out. They have agreed to keep your information private, not share it with anyone except the researchers and delete their copy of the recording once they have finished writing it up.

If you agree to take part, we will need to keep some identifiable information about you (e.g. your signed consent forms and contact details).

The only times when we cannot keep information private is if we think you or someone else may be in danger. This might mean telling other people who are responsible for keeping children and families safe.

Once we have finished the study, we will keep some of the data so we can check the results. Data will be held on a secure computer at the University of Birmingham for 10 years.

You can find out more about how we use your information:

* at [www.hra.nhs.uk/information-about-patients/](https://bham.sharepoint.com/sites/GHDReversalTrial-Research/Shared%20Documents/General/Qualitative%20Research%20Documentation/www.hra.nhs.uk/information-about-patients)
* at https://understandingpatientdata.org.uk/introducing-patient-data
* by asking one of the research team
* by contacting the Sponsor’s (University College London) Data Protection Officer: data-protection@ucl.ac.uk

**How will we use information about you?**

We will need to use information from you for this research project.

This information will include your and name contact details. Qualified people will use this information to do the research or to check your records to make sure that the research is being done properly.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

**What will we do with the information?**

The information will be written up by a professional company and fed back to the GHD trial team to improve their research. We may also talk about the findings at meetings or publish them in medical journals. They may also be shared on social media or in newspapers. We will make sure that no one can be identified from these.

**Who has reviewed the study?**

The study has been checked by a Research Ethics Committee. This is a group of people who examine research to make sure it is safe for the people who take part.

**Who is organising and funding the study?**

The study is sponsored by University College London (UCL) and organised by the University of Birmingham. It is being paid for by the National Institute for Health Research Health Technology Assessment

**What happens if something goes wrong?**

The risk of participants suffering harm as a result of this study is minimal. However, the Sponsor has a Public Liability Policy which provides cover for legal costs and compensation claims if you believe that you have been harmed in any way by taking part in the research study.

**What if there is a problem?**

If you have any concerns or complaints about any aspect of the study you can contact me - [insert name] – on [insert tel. no.] Mon to Fri: 9:00-17:00 or [insert email address].

Alternatively, you can contact the Qualitative Project Lead - Dr Jonathan Mathers - on 0121 414 6024, j.m.mathers@bham.ac.uk.

Complaints can also be made to Dr Birgit Whitman, Head of Research Governance & Integrity, Research support Group, Aston Webb Building, University of Birmingham, B15 2TT (researchgovernance@contacts.bham.ac.uk; 0121 4158011).

General advice about taking part in research can also be discussed with the hospital PALS Office (Patient Advice and Liaison Service – [insert PALS contact details]). They can offer independent and confidential advice, and help resolve problems.

1. Please have a think about the study and discuss it with people that you trust.

1. Please let us know if you are:
* Interested in taking part
* Need more information
* Have any questions
1. You can also ask your parents/carers to contact us for you.

**If you want to ask us anything:**

You can contact me, [insert name or team]. This is my picture above. I am [insert role] and will reply as soon as possible.

**Email:** XXXXXXXXX

**Phone:** XXXXXX

**Text:** XXXXX

**FaceTime:** XXXXX

Thank you for reading this leaflet