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Participant Information Sheet Interviews

For Young People 16 years & over

*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’s called the Growth Hormone Deficiency Reversal Trial. We call it the **GHD Trial**, for short.

**Why are we doing it?**

The GHD Trial is taking place in 12 hospital trusts across England and 4 sites in Austria. It is important that this research is done as well as possible. To ensure this, our team wants to talk to families who have been invited to take part in the GHD trial. We want to learn more about why young people and their parents or carers take part or choose not to. We are also interested in your suggestions for improvement. This information will help us improve how the rest of the trial is done and lead to better understanding about growth hormone treatment.

**Why are we asking you?**

The GHD trial is taking place in your hospital. We think that you have been invited to take part (by your usual care team). You may have decided to take part or you may have decided not to. Or, you may have started the GHD trial and left it. Whatever your decisions, we would be really interested to hear what you think about it.

**What will the study involve?**

It will involve taking part in an interview. For some people this will involve a single interview. However, if you are taking part in the trial we will invite you to talk to us once more in about 6 months to see how things are going. We would like to speak to young people. We are also asking parents / carers to take part in an interview. Ideally, we would like to interview parents/carers and young people separately, but we can interview families together if that is preferred. We think the interviews will last between 30 and 45 minutes each.

Our research team will contact you to talk about the study and answer any questions that you have. We can then arrange a good time to do the interview. The interview might be face to face (at your house or another suitable place that you choose) or it might be done by telephone, Skype, FaceTime or something similar. This will depend on where you live and your preferences.

If you want to take part, you will be asked to sign a consent form that shows you are happy to take part.

**About the interview**

We will ask you for some brief personal information so we can describe the range of people who have taken part in the study. We will then talk to you about being asked to take part in the GHD trial and what it is like to be taking part or having decided not to take part. It does not matter what your decision was, your views and experiences are just as important to us.

You don’t have to tell us anything that you don’t want to and there are no right or wrong answers.

The interview should feel like a conversation. You don’t have to tell us anything that you don’t want to and there are no right or wrong answers. You can stop at any time. At the end, we will check that you are still happy for us to use the interview as part of the study and answer any questions that you have.

The interview/s will be audio-recorded so we don’t forget anything that was said. We will use a professional company to type-up the recording and then analyse it. All names (and other information that might mean people know who you are) will be removed and the findings will be written up in a report that might include anonymous quotes of things that you have said.

**Do I have to take part?**

No. Taking part in this study is completely your decision.

If you decide to take part, you will be asked to verbally agree to some statements that a researcher will read out and document. Your statements will be audio recorded. This is known as taking verbal consent. You can still change your mind and leave the study at any point, without giving a reason. This will not affect your care in any way. Any information collected from you can be destroyed and removed from the study. This will be possible up until the point that we have combined it with other people’s information and started analysis (usually up to 2 weeks after you have taken part). In all cases, we will explain how your data are being used and demonstrate to you that you will not be able to be identified from the results or any publications resulting from the study.

**What are the possible 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, we know that sharing experiences can sometimes be emotional. You can pause or stop the interview at any time. We can also give you information about people who can support you with your feelings.

**Will my information be kept safe and private?**

Yes, your information will be kept safe and private. The University of Birmingham will act as the data controller for this study. This means that the University is responsible for looking after your information and using it properly. All information that we collect about you will be kept safe and secure according to the General Data Protection Regulations and Data Protection Act. No one will be able to identify you from any reports or publications that result from this study.

If you agree to take part, we will need to keep some information about you (e.g. your signed consent forms and contact details). All data will be kept electronically on secure computer servers at the University of Birmingham. Only the researchers involved in this study will have access to this data and access will be password protected. The only exception to this is the audio-recordings that will be temporarily shared with a professional transcription company that complies with the Data Protection Act, has a confidentiality agreement in place with the University of Birmingham, and uses advanced encryption to transfer and store files. Audio recordings will be destroyed by the transcription company once they have been transcribed, anonymised and checked.

The only times when we cannot keep information private is if we think there is a risk of serious harm to you or others. In this case, the researchers will need to follow Hospital and University Safeguarding Policies and may need to share their concerns with appropriate staff or agencies. There is also the possibility that inspectors may need to look at the data to ensure the study is being carried out properly.

Once we have finished the study, we will keep the data so we can check the results. This 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/](http://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 results of the study?**

The information will be used to improve how we run the trial. This might involve changing the information that we give to young people and their families or changing how we recruit young people and families to the trial.

The results may also be included in the final research report, presented at scientific meetings and published in scientific journals. We will make sure that no-one can be identified from the details presented.

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

This study is sponsored by University College London (UCL) and organised by the University of Birmingham. It is funded by the National Institute for Health Research Health Technology Assessment (project reference: NIHR127468).

**Who has approved the study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Wales Research Ethics Committee 3 (Wales REC 3). It has also been approved by the University of Birmingham Research & Development Department.

**What if there is a problem?**

If there is a problem you should talk to your parents or any of the researchers.

You can also make complaints to Dr Birgit Whitman, Head of Research Governance & Integrity, Research support Group, B Block, Aston Webb Building, University of Birmingham, B15 2TT (email:

researchgovernance@contacts.bham.ac.uk; telephone: 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 to resolve problems.

Now that you have read the information, please think about what you would like to do.

You can contact me if you have any questions and to let us know whether you would like to take part or not. We may contact you again if we haven’t heard back from 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 information**