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Participant Information Sheet Interviews

For parents/carers

*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 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 hospitals 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 and your child have been invited to take part (by your usual care team). You may have decided to take part or chosen 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 a parent / carer or both parents / carers. We are also asking children 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 anticipate the interview(s) 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 will also check if your child is happy to take part and arrange a time to contact them directly to discuss their own interview. Interviews will take place at a time that is convenient for you and might be face to face (at your house or another suitable place that you choose) or 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 ask you about being invited to take part in the GHD trial and why you have made your decision to take part or not. It does not matter what your decision was; your views and experiences are just as important to us.

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 we will analyse it. All names (and other identifiable data) will be removed from the transcription and the findings will be summarised in a report that might include anonymous quotes.

**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 sign a consent form. However, you can still change your mind and leave the study at any point, without giving a reason. This will not affect your child’s 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 data 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 benefits and risks of taking part?**

We do not expect there to be any risks and some people who take part in research say it is interesting. However, there are no other direct personal benefits. The information gained will help improve the trial and provide better information about treating Growth Hormone Deficiency. We know that sharing experiences can sometimes be emotional. You can pause or stop the interview at any time and we will have information concerning support services should you wish to be signposted to these.

**Will my information be kept confidential?**

Yes, your information will be kept confidential. 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 kept safe and secure according to the General Data Protection Regulation 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 identifiable 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 these 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. At each point, your information will be securely stored and we will use advanced encryption to safely transfer files.

The only times when we cannot keep information confidential 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 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/](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](mailto: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 the main trial procedures. This might for example involve recommendations to change the information that we give to families. The anonymised findings may also be included in the final research report, presented at scientific meetings and published in scientific journals. Care will be taken to ensure that individuals cannot be identified from the details presented. If you wish to receive a summary of the research findings we will share this with you towards the end of the study.

**Who has reviewed 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).

**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 Programme (project reference: NIHR127468).

**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 or I want to complain?**

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.

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

Please feel free to contact the study team 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, [inset 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