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**The Growth Hormone Deficiency Reversal Trial: Qualitative Study (audio-recording trial discussions and contact for later interview)**

**Participant Information Sheet - Young People (16 years & over)**

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| --- | --- | --- | --- | --- |
| **An invitation to take part in research** |  |  | **Use of personal data** | |
| * We would like you to take part in a research study. * Before you decide whether to take part, it is   important that you understand why the research is  being done and what it will involve.   * Please take time to read the following information   carefully and feel free to discuss it with others.   * You are free to decide whether or not to take part. * Ask us if anything is not clear or if you would like   more information. |  |  | * We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. * Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. | |
| **Important things to know** |  | | | * At the end of the study we will save some of the data in case |
| * This study is part of a larger project about   treatment for young people who were previously  diagnosed with growth hormone deficiency.   * We want to understand what it is like to be invited   to take part.   * To do this, we need to audio-record the   conversations where young people and their families  are invited to take part.   * We also need to interview young people. * This information will help us to improve our   research processes and get more useful findings.   * We would like you to take part in both of these   activities (but you can choose just one if you prefer).   * Taking part is optional and you can stop at any time. |  | | we need to check itand for future research. We will make sure no-one can work out who you are from the reports we write.   * The information pack tells you more about this.   **How to contact us**  If you have any questions about this study, please contact [insert name] at [insert email] or on [insert phone] | |

**Terms used in this leaflet:**

**Trial or research trial** – this is the main research project that is looking at the best ways to treat growth hormone deficiency.

**Study or qualitative study** – this is work that we are doing to learn what it is like to take part in a trial. A ‘Qualitative’ study is one that collects spoken or written data (rather than numbers) and in this case we are talking about audio-recordings and interviews.

1. **Why are we doing this study?**

The Growth Hormone Deficiency Reversal Trial is taking place in 12 hospital trusts across England and 4 sites in Austria. It is called the **GHD Trial** for short.

We think that it is important that patients and their families are given the best information to help them make decisions about whether or not to take part. To do this, we want to learn more about how information is given and what it is like for children, young people and their families to be asked to take part, and why they take decisions to take part or not.

We also want to understand what it is like to be involved in the GHD Trial.

This information will help us improve how the trial is done and lead to better understanding about treatment for growth hormone deficiency.

**2. Why have I been invited?**

You have been invited to take part because the GHD Trial is taking place in your hospital or place of care. Your clinical team is inviting families to take part and we believe that you are one of them. As such, we think you are well placed to get involved in the qualitative study.

**3. What does taking part involve?**

There are two ways to take part. We would like you to do both of these, but you can do one if you prefer.

1. Give us permission to record the discussion that you have with your doctor or nurse when they give you information about the GHD Trial. This will use audio-recording (voice only).
2. Give us permission to contact you at a later date to invite you to take part in a confidential (private) interview at an appropriate time and place of your choosing. This could be face-to–face, telephone or use a communication tool like Skype.

It does not matter whether you decide to take part in the research trial or not. Your views and experiences are just as important to us.

**4.** **More information about the study**

**What will happen if I take part?**

1. If you agree to take part in the audio-recording – a doctor or nurse will check that you are happy for us to record your conversation about the trial. If you are happy, they will use a small digital audio-recording device to record the conversation. You can stop the recording at any time and 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. It you are happy, the recording will then be sent to researchers at the University of Birmingham who are running this part of the study. They will use a professional company to type-up the recording and then they will analyse it. All names (and other identifiable data) will be removed and the findings will be written up in a report that might include some of the things that you said. No-one will be able to tell who said those words.
2. If you agree to being contacted about interviews – we will ask for your contact details. We will send you an interview study-pack at a later date – by post or email depending on how you would like it. This will include a detailed information sheet for you. We will ask you to decide whether or not you want to take part (and arrange an interview if relevant). We anticipate the interview(s) will last between 30 and 45 minutes.

**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, please tell us if you are worried about any aspect of taking part and we will make sure that you receive appropriate support.

**What information will you collect?**

Information collected as part of the study will include:

* your name and signature on the consent form – this is the form you will sign if you decide to take part in the audio-recording of your conversation about the trial
* contact details so that we can send you more information about an interview
* personal information to describe the range of people who take part (e.g. how long you have been using the hospital)
* audio-recordings of your conversation about the trial

**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 Regulation and Data Protection Act. No one will be able to identify you from any reports or publications that result from this study.

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.

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 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/](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](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 name and 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.

**Do I have to take part?**

No. Taking part in this study is completely your decision. Please take your time to read the information carefully and talk to your parents or any other adult that you trust if you want to.

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 care in any way. We will do our best to remove and destroy your data from the study if this is what you want. This will be possible up until the point that we have combined it with other data and started to analyse it (usually 2-weeks after you have taken part). In this case, we will explain how your data is being used and the steps we have taken to make sure that you cannot be identified from the results or any publications resulting from the study.

If you decide not to take part, we would value your feedback about the reasons. This will help us improve how we conduct research in the future. It is your choice whether you tell us a reason or not. Anything you do tell us will be kept private.

**What will we do with the results of the study?**

The information will be used to improve how we run the main trial. This might involve changing the information that we give to young people and their families, or it might mean more staff training.

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).

**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.

**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).

**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.

**5. What should I do next?**

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.

[insert photo]

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**