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**The Growth Hormone Deficiency Reversal Trial: Qualitative Study**

Participant Information Sheet for Professionals

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| **An invitation to take part in research** |  |  | **Use of personal data** |
| * Thank you for taking the time to read about this 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.
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| **Important things to know** |  |  | * At the end of the study we will save some of the
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| * This study is one part of a randomised controlled trial that is examining the withdrawal of growth hormone treatment in children and young people.
* It will focus on the initial phase of the trial and examine if the recruitment processes are working as intended.
* To do this, we need to audio-record consultations where patients and their parents/carers are invited to participate.
* We also need to interview recruiting staff.
* The findings will be used to optimise recruitment processes in the main trial.
* We would like you to take part in both activities, (although you can choose to do one, if preferred).
* Participation is optional and you can stop taking part at any time.

  |  |  | Data in case we need to check it and 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]  |

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. We know that recruitment for trials can sometimes be difficult and problems may not be evident until a trial is underway. Our team is therefore undertaking qualitative research at the start of the trial to identify factors that may affect participant recruitment and retention. The aim is to use this information to improve recruitment processes for the main trial.

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

It is really important to understand the recruitment process from the perspectives of everyone involved. This includes the health professionals who are recruiting families, and the patients and parents/carers who are approached to take part.

We have invited you to take part because the ‘Growth Hormone Reversal Trial’ is taking place in your Trust and we believe you are involved in recruiting participants. As such, we think you are well placed to help us understand how the recruitment processes are working.

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

If you decide to take part, you will be asked to give your consent for two research activities:

1. **To audio-record the discussion** you have about the GHD trial with patients and their parents/carers who have already provided their consent to do so.
2. **To participate in a one-off confidential interview.** During the interview you will be asked about your experience of recruiting to the GHD trial, including your views of the GHD trial and how recruitment processes work in practice. We anticipate the interview will last between 30 and 45 minutes

Please note that the audio-recordings and interviews are not assessing your competency or performance. We are interested in the ease and feasibility of the processes that you are asked to use and the factors that influence participant decision-making about the trial. This will help us work out how processes can be improved in the main trial. We are also conducting interviews with patients and their parents/carers.

1. **More information about the study**

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

1. If you consent to audio-record discussions about the trial you will be supplied with an encrypted digital audio recorder and shown how to use it. We will ask you to record all discussions where families have consented. You will then be asked to securely upload the recording so that the research team at the University of Birmingham have access to them. Digital audio recorders will need to be kept in a locked filing cabinet when not being used and recorded discussions deleted from the recorder once these have been uploaded.
2. If you consent to an interview, this will take place at an appropriate time and place that is convenient to you (e.g. workplace) and is unlikely to last more than an hour. If may be necessary to arrange a telephone or Skype interview depending on where you are located. At the start of the interview, we will go through the information sheet once more, answer any questions that you have and re-confirm your consent. We will ask you for some brief personal information (e.g. professional role, previous research experience) so we can describe the range of people who have taken part in the study. The interview will be audio-recorded so we have an accurate record of what is said. It will then be transcribed with all names (and other identifiable data) removed and then analysed by the researchers. The findings will be summarised in a report, which might include anonymous quotes from the interviews.

**What are the possible risks and benefits of taking part?**

We do not expect there to be any risks. There are also no direct personal benefits. However, the information gained may help improve recruitment to the main trial which will in turn provide better information about treating Growth Hormone Deficiency.

**What information will you collect?**

Information collected as part of the study will include:

* your name and signature on the consent form,
* contact details,
* personal information to describe the range of participants (e.g. job title, XXX),
* audio-recordings of your consultations regarding the trial and interview.

**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 be kept safe and secure according to the General Data Protection Regulation and Data Protection Act. You will not be identifiable in 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 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. 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

**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, you are under no obligation to take part.

If you decide to take part, you will be asked to sign a consent form. However, you can still change your mind and withdraw from the study at any point, without giving a reason. If you withdraw, you will be asked whether you want your data to be included in the study or removed. Our ability to remove data will depend on when you leave. For interviews, we can remove all of your data if you withdraw (a) before, (b) during, or (c) 2-weeks after your interview. It will not be possible to remove all of your data after this point. We are also unable to remove your data from consultation audio-recordings. This is because your data will be integrated with patient/parent data. We will, however, remove your identifiable data by destroying your interview recording and removing any personal details from our study files (e.g. name, job title). We will also try to remove any anonymous quotes that we have used from you in any reports or publications, (although this will not be possible if you withdraw after the documents have been submitted).

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

The information will be used to develop strategies to optimise recruitment in the main trial. This might involve recommendations to change patient information packs, standard operating procedures or training for recruiting staff. It might also suggest changes to the trial design (e.g. adding additional recruitment sites). 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.

**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).

**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 research studies.

**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).

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

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.

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| --- | --- |
| [Insert Name, position and contact details] |  |

**Thank you for reading this information**