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**Young Person 16-18 Years Consent Form**

**The Growth Hormone Deficiency Reversal Trial: Effect on final height of discontinuation vs continuation of growth hormone treatment in pubertal children** **with isolated growth hormone deficiency – A non-inferiority randomised controlled trial**

**Trial No.:**

**iXi iXi iXi iXi**

**Site name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Please initial inside each box at the end of each row***

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| --- | --- | --- |
| 1 | I confirm that I have read and understood the information sheet, dated  \_ \_ / \_ \_ \_ / \_ \_ \_ \_, version number \_\_\_.\_\_\_ for The GHD Reversal Trial. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. |  |
| 2 | I agree that my participation in this study is voluntary and that, if I take part, I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. |  |
| 3 | I agree that if I decide to withdraw from the trial any information that has already been analysed cannot be withdrawn. I understand that as part of the withdrawal process, I will be contacted by a member of the study team and given the options described in the above participant information sheet about what other data can be collected from me, what happens to that data, and that my response will be recorded on a withdrawal form. |  |
| 4 | I agree that my hospital research team can provide a copy of my consent form, and relevant personal information, including my name, date of birth, height, weight, blood test results, results of X-ray analysis, quality of life questionnaire data, and other relevant details of my medical history (e.g. medication and healthcare facility visits) to the researchers based at the University of Birmingham for use in the GHD Reversal Trial. |  |
| 5 | I agree that relevant sections of my medical notes and data collected during the trial may be looked at by individuals from The GHD Reversal Trial team at The University of Birmingham Clinical Trials Unit. |  |
| 6 | I agree that collaborators of the GHD Reversal Trial, and authorised representatives from the study Sponsor (University College London), regulatory authorities and my NHS trust can access my data where relevant such as my taking part in this research and safety monitoring. |  |
| 7 | ***For female participants only:***  In the event of myself becoming pregnant during the trial I agree for the pregnancy to be monitored for the purposes of the trial. |  |
| 8 | I agree to my GP being informed of my participation in The GHD Reversal Trial. |  |
| 9 | I agree that my data will be anonymised and used in combination with that of others to produce research outputs such as reports, presentations, publications and websites connected to the GHD Reversal Trial. I understand that I will not be individually identified in any publicly available output. |  |
| 10 | I understand that the information collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. |  |
| 11 | I agree to having blood samples taken and being used as detailed in the above participant information sheet. |  |
| 12 | I agree for a copy of my hand X-rays taken as part of the trial, to be securely sent from my hospital to Great Ormond Street Hospital in London (for UK based patients) or to Kepler Universitätsklinikum in Linz (for Austria based patients) for central analysis for the purposes of the study.  I understand that the copy of this X-ray will be securely deleted 60 days after its receipt at Great Ormond Street Hospital (for UK based patients) or Kepler Universitätsklinikum (for Austria based patients). |  |
| 13 | I agree that some anonymous information collected from me for the GHD Reversal Trial may be shared and/or made publicly available for other researchers to support other research in the future. |  |
| 14 | I agree to my taking part in The GHD Reversal Trial. |  |
| **Optional Consent Item -** Please initial inside the box if you agree to the following optional consent item. This will not affect your eligibility to take part in the trial. | | |
| 15 | I agree that I may be contacted by the research team in the future regarding further research that is linked to this study. |  |

***Name of Young Person****:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature of Young Person****:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Date*** *(dd/mmm/yyyy):* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Name of Person taking Consent****:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature****:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Date*** (*dd/mmm/yyyy):* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If an interpreter has translated this form they should countersign here to certify that they have translated fully and accurately.

***Name of Translator****:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature****:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Date*** *(dd/mmm/yyyy):* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

When completed: 1 for young person, 1 (original) for Investigator Site File, 1 to keep in medical notes and 1 sent to BCTU.