*<insert local letterhead details>*

<Doctor>

<Practice>

<Street>

<City>

<Postcode>

<Date>

Dear Dr <insert GP/Community Paediatrician name>,

**Re:**

**Name: ……………………………………………………………………………………………………………**

**DoB: ……………………………………………………………………………………………………………**

**NHS No: …………………………………………………………………………………………………………**

**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**

I am writing to inform you that your patient, named above, has agreed to take part in the GHD Reversal Trial. The aim of this study is to assess the safety and effectiveness of discontinuing growth hormone (GH) therapy in children with reversed idiopathic, isolated growth hormone deficiency (I-GHD). I am writing to give you some information about the trial.

Around 500 children are diagnosed with GHD every year in the UK, of whom 75% have I-GHD. Diagnosis of GHD is made by measuring the peak GH concentration in the blood following injection with a stimulating substance. Children are treated with daily GH injections until final height is reached, at an annual cost of between £10,000 and 23,000 per child. However, it is thought that up to 88% of patients have outgrown (reversed) I-GHD when re-tested at final height. Some evidence suggests that this reversal occurs during puberty due to the increase in sex hormone production, and that children whose stimulated GH concentrations are normal in early puberty may reach a final height comparable to that of children without GHD.

We are undertaking a multicentre randomised controlled non-inferiority trial to assess the safety, efficacy, health-related quality of life, and cost effectiveness of discontinuing GH therapy in children with I-GHD, who have a normal GH re-test when they reach established puberty. 138 participants with reversed I-GHD and a normal brain MRI will be recruited over a period of 42 months from 12 UK and 5 Austrian paediatric endocrine centres. Participants will be randomised to either stop or continue their standard GH therapy. All participants will be followed up at 6 monthly trial assessments until final height has been reached. The trial will monitor final height and other growth-related outcomes, bone age and health, biochemistry (peak stimulated GH, serum IGF-1, lipid profile), adverse events, and health economic information in all participants recruited. In addition, a subset of participants will undertake additional qualitative research to ascertain trial acceptability, parent and patient experience of the trial and treatment pathways. The study will receive full UKCRN support.

Your patient has been randomised to the <delete as applicable>:

**Control arm: Continue GH therapy**

The patient should continue on their standard care GH therapy. The normal contraindications and safety precautions for use of this treatment should be adhered to, as per routine care.

**Experimental arm: Stop GH therapy**

The patient should stop their GH therapy.

The GHD Reversal Trial is sponsored by University College London and coordinated by the University of Birmingham Clinical Trials Unit (see address below)

GHD Reversal Trial Office, The University of Birmingham Clinical Trials Unit, College of Medical & Dental Sciences, Institute of Applied Health Research, University of Birmingham, Edgbaston, Birmingham, B15 2TT.

Web address: www.birmingham.ac.uk/GHD

The trial is funded by the National Institute for Health Research Health Technology Assessment programme (NIHR HTA) Ref: NIHR127468 and has been approved by ------- Research Ethics Committee.

If you have cause to see your patient during the course of the trial and want to discuss any aspect of their management e.g. treatment regimen, contra-indications etc., please do not hesitate to contact me on Tel: *<insert responsible clinician telephone number>*. It would be particularly helpful if you could inform me of any adverse events your patient reports to you or any therapy changes you make or wish to make.

Yours sincerely,

*<insert responsible clinician name>*