

GROWTH HORMONE THERAPY GUIDELINES

ENTRY AND EXIT CRITERIA

February 2009

INTRODUCTION

These guidelines are intended to assist specialists in gauging which groups of children are likely to receive growth hormone. In view of the complexity of growth disorders each individual application is thoroughly evaluated to determine the appropriateness of growth hormone therapy, thus fulfilling entry criteria alone does not guarantee that an applicant will receive growth hormone therapy. In determining whether to commence supplying growth hormone, priority is given to the indications in the order in which they are grouped below, with the highest priority given to Category 1.

All queries about these guidelines should be directed to the New Zealand Growth Hormone Committee.

CATEGORY ONE - GROWTH HORMONE DEFICIENT CHILDREN

ENTRY CRITERIA

- Group A.** Growth hormone deficiency with symptomatic hypoglycaemia, or other significant growth hormone deficient sequelae (eg cardiomyopathy, hepatic dysfunction). Growth failure is not a requirement for treatment in these patients. Formal growth hormone testing may not be necessary in the neonatal period. Random growth hormone measurements taken within the first two weeks of life or during spontaneous hypoglycaemia are usually sufficient. In such infants growth hormone values may be higher than seen in groups B and C.
- Group B.** Complete growth hormone deficiency. Defined as a persistent growth velocity <25th percentile and a failure to achieve a peak growth hormone value ≥ 4 $\mu\text{gm/L}$ to two of the conventional growth hormone tests listed below;

- i. IV Arginine (0.5 gm/kg),
- ii. IV Insulin (0.1-0.15 u/kg, symptomatic or biochemical hypoglycaemia {blood glucose \leq 2.5 mmol/L or plasma glucose $<$ 2.2 mmol/L} must be reached),
- iii. PO L-Dopa (0.15 gm/1.73m²),
- iv. PO Clonidine (0.15 mg/m²),
- v. SC/IM Glucagon (0.03 mg/kg)
- vi. Sex steroid priming (Ethinylloestradiol, 40 micrograms/m² in 3 divided doses per day for 2 days, reporting the next day for test) is recommended during late childhood prior to puberty.

Group C. Partial growth hormone deficiency defined as a persistent growth velocity $<$ 25th percentile and a failure to achieve a peak growth hormone value $>$ 7.0 μ gm/L to two of the conventional tests listed above in Group B.

Patients who have been treated for malignancies should be disease free for at least one year. The Committee may in some instances request a longer disease free interval if the particular malignancy commonly recurs after several years disease free. Patients with treated non-malignant CNS tumours who have complete growth hormone deficiency may not need to wait one year before application is made.

EXIT CRITERIA

Only one criterion needs to be fulfilled to stop growth hormone therapy.

1. Achievement of height compatible with genetic potential.
2. Bone age of \geq 14 years (female) or \geq 16 years (male) and the growth velocity $<$ 2cm/yr as calculated over six months.
3. Patient chooses to stop growth hormone therapy.
4. A malignancy that develops after growth hormone therapy was commenced.
5. A serious adverse reaction or complication that either the patient's specialist or New Zealand Growth Hormone Committee considers is likely to be attributable to growth hormone treatment.

CATEGORY TWO - TURNER SYNDROME

Turner Syndrome priority ranks ahead of all other disorders characterised by short stature not due to Growth Hormone deficiency as these girls have been clearly shown to demonstrate an improvement in final height with growth hormone therapy.

ENTRY CRITERIA

1. Turner Syndrome with a poor growth velocity (<25th percentile for normal girls), over 6-12 months. Older girls with short stature and limited growth potential may be considered without growth velocity data.

This group does not include Noonan Syndrome (see Category Three).

EXIT CRITERIA

Only one criterion needs to be fulfilled to stop growth hormone therapy.

1. Bone age ≥ 14 years and growth velocity < 2.0 cm/yr calculated over six months.
2. Growth velocity below the mean for age (based upon Ranke's Turner Syndrome growth velocity charts) or growth velocity < 2.0 cm/yr as calculated over a six month interval.
3. Patient chooses to stop growth hormone therapy.
4. A malignancy that develops after growth hormone therapy was commenced.
5. A significant adverse reaction or complication that either the patient's specialist or New Zealand Growth Hormone Committee considers is likely to be attributable to growth hormone treatment.

CATEGORY THREE - SHORT STATURE WITHOUT GROWTH HORMONE DEFICIENCY

ENTRY CRITERIA

The following four criteria must be met:

1. Height shorter than 3 standard deviations below the mean for age.
2. Absence of severe chronic disease (including recognised skeletal dysplasias).
3. A growth velocity < 25th percentile over ≥ 1 year.
4. Where bone age is markedly delayed, height in relation to bone age may be considered.

EXIT CRITERIA

1. Growth velocity fails to increase by at least 2cm/yr following at least a six month trial of growth hormone in those who do not have complete growth hormone deficiency.
2. A growth velocity in the second and subsequent years of treatment in non growth hormone deficient patients that consistently falls below the 50th percentile.
3. Bone age of >14years (female) or >16 years (male) and the growth velocity <2cm/yr as calculated over six months.
4. An increase in bone age that exceeds the increase in height age in non-growth hormone deficient patients with very delayed bone ages.
5. A malignancy that develops after growth hormone therapy was commenced.
6. A serious adverse reaction or complication that either the patient's specialist or New Zealand Growth Hormone Committee considers is likely to be attributable to growth hormone treatment.

CATEGORY FOUR - SHORT STATURE DUE TO CHRONIC RENAL INSUFFICIENCY INCLUDING DIALYSIS

Growth retardation is one of the most important consequences of renal insufficiency in children. Nearly half of the children in whom chronic renal disease develops before the age of 15 years have final heights of more than 2.5 SD below the mean.

To address this problem, several investigators have studied the effects of growth hormone therapy in these children. Three studies including one double-blind, placebo controlled trial, have examined the effects of growth hormone in children with Chronic Renal Insufficiency (CRI) receiving medical management and one study has examined its effects in children with end stage renal disease undergoing dialysis.

In each study, growth hormone therapy was found to increase growth rate significantly. This increase was not accompanied by an undue rate of bone age advance, suggesting an improvement in final height potential for these children, but no studies of sufficient length have been reported to allow for the unambiguous determination of the effect of growth hormone on final height. Nevertheless, growth hormone is approved by the FDA for the use in children with CRI prior to renal transplant. However, to benefit from growth hormone therapy, children with CRI must be in good metabolic control and maintain adequate nutritional intake.

Limited final height data is now available for Growth Hormone therapy in children with CRI and demonstrates preservation of predicted final height. Without therapy there is a marked attenuation of the pubertal growth spurt and considerable loss of final height greater than would be expected from prepubertal growth.

Growth Hormone therapy appears to be safe in children with CRI. No long-term changes in serum insulin or glucose levels or adverse effects on creatinine clearance have been reported; however, a disturbing increase in serum creatinine levels has been observed in some children. Therefore, careful monitoring of renal function is mandatory in children with CRI receiving growth hormone and therapy should be reconsidered if there is an otherwise unexplained decrease in renal function. **Excerpts from recommendations made by the Lawson Wilkins Society for Paediatric Endocrinologists. 1995).**

Several correlations with CRI/ESRF and height SDS have been made. As expected there is a linear correlation between loss in height SDS and increasing creatinine. Younger age also

results in greater loss in height SDS. Importantly, following renal transplantation children <6 years of age often exhibit acceleration in height velocity, whereas those older do not.

The safety data using growth hormone therapy is CRI and ESRF and post transplantation remains encouraging. There is no association between growth hormone use and the risk of rejection. There is also no evidence of an accelerated decline in renal function, lymphoproliferative disease or renal malignancy. There may be an increased risk of developing diabetes mellitus, probably due to a combination of side effects from tacrolimus, glucocorticoids and other immunosuppressive agents superimposed on the well known insulin resistance of growth hormone. Tacrolimus and similar medications have been demonstrated to cause both insulin resistance and beta cell failure and glucose intolerance with these medication and growth hormone is not unexpected.

ENTRY CRITERIA

1. Short stature (Height shorter than 2SDS below the mean) with poor growth velocity (<25th percentile over 6-12 months). Where bone age is markedly delayed absolute height and growth velocity in relation to bone age may be considered.
2. A GFR $\leq 30\text{ml/min}/1.73\text{m}^2$ as measured by the Schwartz method –
(Ht (cm)/plasma creatinine ($\mu\text{mol/L}$) $\times 40 =$ corrected GFR ($\text{ml/min}/1.73\text{m}^2$)) in a child who may or may not be receiving dialysis.
3. The patient must be metabolically stable as determined by the New Zealand Growth Hormone Committee.
4. Absence of any other severe chronic disease.
5. The patient must be under the supervision of a specialist with expertise in renal medicine.

EXIT CRITERIA

1. Growth velocity fails to increase by at least 2cm/yr following at least a six month trial of growth hormone.
2. A growth velocity (adjusted for bone age/pubertal status if appropriate) in the second and subsequent years of treatment that falls below the 50th percentile.
3. Bone age of > 14 years (female) or > 16 years (male) and the growth velocity <2cm/yr as calculated over 6 months.
4. An increase in bone age that exceeds the increase in height in non-growth hormone deficient patients with very delayed bone ages.
5. Significant biochemical or metabolic deterioration.

6. A malignancy that develops after growth hormone therapy was commenced.
7. A significant adverse reaction or complication that either the patient's specialist or New Zealand Growth Hormone Committee considers is likely to be attributable to growth hormone treatment.
8. Renal transplantation. Cessation of growth hormone therapy immediately prior to the transplant. Recommencement of growth hormone will occur based on the criteria below.

ENTRY CRITERIA FOR RENAL TRANSPLANTATION

1. On growth hormone prior to renal transplantation

Abbreviated re-application using a serial data sheet will be needed before growth hormone therapy can be reinstated.

- i. Children 6 years or younger must have demonstrated a growth velocity <50th percentile in the 6 months following prednisone reduction to <5mg/m²/day, or to alternated day steroids.
- ii. In children older than 6 years growth hormone can be reinstated when prednisone dose is reduced to <5mg/m²/day, or to alternate day steroids.

2. No prior growth hormone therapy

- i. Short stature (Ht shorter than 2SD below the mean) with poor height velocity (<25th percentile over 6-12 months). Where bone age is markedly delayed absolute height and growth velocity in relation to bone age may be considered.
- ii. The patient must be metabolically stable as determined by the New Zealand Growth Hormone Committee.
- iii. Absence of any other severe chronic diseases
- iv. The patient must be under the supervision of a specialist with expertise in paediatric renal medicine.

EXIT CRITERIA

1. Growth Velocity fails to increase by at least 2cm/yr following at least a six month trial of growth hormone.
2. A growth velocity (adjusted for bone age/pubertal status if appropriate) in the second and subsequent years of treatment that falls below the 50th percentile.
3. Bone age of ≥ 14 years (female) or ≥ 16 years (male) and the growth velocity $< 2\text{cm/yr}$ as calculated over six months.
4. An increase in bone age that exceeds the increase in height in non-growth hormone deficient patients with very delayed bone ages.
5. Significant biochemical or metabolic deterioration.
6. A malignancy that develops after growth hormone therapy was commenced.
7. A significant adverse reaction or complication that either the patient's specialist or the New Zealand Growth Hormone Committee consider is likely to be attributable to growth hormone treatment.
8. Diabetes mellitus that does not resolve with manipulation of immunosuppressive therapy.

Notes:

- a) Because of the recognised association in increased mortality in very unwell patients taking growth hormone treatment, the Growth Hormone Committee recommends the growth hormone treatment be temporarily suspended during any period of prolonged illness.
- b) An HBA1c and fasting glucose is required prior to starting and following 3 months of growth hormone therapy.

CATEGORY FIVE PRADER-WILLI SYNDROME

ENTRY CRITERIA

In children with Prader-Willi Syndrome, funding for growth hormone will be available where:

1. A diagnosis of PWS has been confirmed by genetic testing; and
2. growth velocity is < 25th percentile for bone age over 12 months; and
3. growth velocity in patients under two years of age has been assessed over a minimum six month period from the age of 12 months, with at least three supine length measurements over this period demonstrating clear and consistent evidence of linear growth failure (growth velocity < 25th percentile); and
4. the bone age is <12 (girls) or <14 (boys); and
5. sleep studies have been performed and there is no obstructive sleep disorder requiring treatment, or if an obstructive sleep disorder is found, it has been adequately treated under the care of a sleep physician and/or ENT surgeon; and
6. there is no evidence of type II diabetes.

EXIT CRITERIA

Only one of the following criteria needs to be fulfilled to stop growth hormone therapy:

1. Growth velocity fails to increase by at least 2cm/yr following at least a six month trial of growth hormone in those who do not have complete growth hormone deficiency.
2. A growth velocity in the second and subsequent years of treatment in non growth hormone deficient patients that consistently falls below the 50th percentile for age for children with Prader-Willi Syndrome.
3. Bone age of >14years (female) or >16 years (male) and the growth velocity <2cm/yr as calculated over six months.
4. An increase in bone age that exceeds the increase in height age in non-growth hormone deficient patients with very delayed bone ages.
5. BMI increases by 0.5 Standard Deviation Scores (SDS) or more in one year.
6. A malignancy that develops after growth hormone therapy was commenced.
7. A serious adverse reaction or complication that either the patient's specialist or New Zealand Growth Hormone Committee considers is likely to be attributable to growth hormone treatment.

Initial Application for Funding of Growth Hormone Therapy

Please send applications to:

NZGHC Coordinator
PHARMAC
P O Box 10-254
WELLINGTON

Phone: 0800 808 476
Facsimile: 09 929 3221 (redirects to Wellington)
Email: growthhormone@pharmac.govt.nz

Applications **must** be **complete** and accompanied by supporting data.

Have you attached:

- Patient growth charts?
- MRI scan reports?
- Signed patient's consent form?
- CNS tumour treatment form?

Patient Details – patient sticker is acceptable			
Surname:			
First Name/s:			
NHI No:			
Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female		
D.O.B:			
Address:			
Phone No:	Home:	Work:	Mobile:

Patient's Physician	
Surname:	
First Name:	
NZMC Registration Number:	
Practice Address:	
Phone No:	
Fax No:	
Email Address:	

Patient's General Practitioner	
Surname:	
First Name:	
Address:	
Phone No:	
Fax No:	

Background Data – Patient					
Birth Weight:	_____ . _____ grams				
Gestational Age:	_____ weeks	<input type="checkbox"/> Certain		<input type="checkbox"/> Uncertain	
Delivery:	<input type="checkbox"/> Normal	<input type="checkbox"/> Breech	<input type="checkbox"/> Caesarean	<input type="checkbox"/> Other	
Instrument:	<input type="checkbox"/> None	<input type="checkbox"/> Vacuum Extractor		<input type="checkbox"/> Forceps	
Apgar Score:	1min		5min		10min
Adopted:	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
Multiple Birth:	<input type="checkbox"/> Yes	<input type="checkbox"/> No			
Ethnic Origin:	<input type="checkbox"/> Caucasian		<input type="checkbox"/> Black		<input type="checkbox"/> Asian
	<input type="checkbox"/> Maori		<input type="checkbox"/> Polynesian		<input type="checkbox"/> Indian
	<input type="checkbox"/> Other (please specify)				

Background Data – Family				
Father Height:	_____ cm	<input type="checkbox"/> Reported	<input type="checkbox"/> Measured	<input type="checkbox"/> Unknown
Father Puberty: (growth spurt)	<input type="checkbox"/> Early	<input type="checkbox"/> Normal	<input type="checkbox"/> Late	<input type="checkbox"/> Unknown
Mother Height:	_____ cm	<input type="checkbox"/> Reported	<input type="checkbox"/> Measured	<input type="checkbox"/> Unknown
Mother Puberty: (menarche)	<input type="checkbox"/> Before 12	<input type="checkbox"/> 12 to 14	<input type="checkbox"/> After 14	<input type="checkbox"/> Unknown
History of GHD in the Family:	<input type="checkbox"/> Yes	<input type="checkbox"/> No		

Basis of request for growth hormone – please provide details where possible		
Diagnosis	Tick	Details
1. Growth Hormone Deficiency (If partial, explain basis for diagnosis)	<input type="checkbox"/>	
2. Turner's Syndrome Please include karotype	<input type="checkbox"/>	
3. Chronic Renal Insufficiency Please specify	<input type="checkbox"/>	
4. Prader-Willi Syndrome	<input type="checkbox"/>	
5. Idiopathic Short Stature	<input type="checkbox"/>	
6. Other – Please specify	<input type="checkbox"/>	

Medical History			
Leukaemia/Tumour	<input type="checkbox"/> Yes	<input type="checkbox"/> No	If yes, please specify treatment regimen below:
Cytotoxic Drugs	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Surgery	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Cranial Irradiation	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Radiation Dose (greys)
Spinal Irradiation	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Radiation Dose (greys)
Gonadal Irradiation	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Radiation Dose (greys)
Total Body Irradiation	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Radiation Dose (greys)
Note: If the patient has had a CNS tumor then detailed information on the radiation sites and dose, surgery and/or chemotherapy must be supplied before growth hormone therapy will be considered. Please attach to the back of the form.			
Diabetes Mellitus	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Psychosocial Disorder	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Specify _____ _____
Nutritional Disorder	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Specify _____ _____
Impaired Cognitive Function	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Specify _____ _____
Syndrome/Dysmorphic Features	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Specify _____ _____
Allergy/Eczema	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Hypoglycaemia	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Microphallus	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Other Chronic Illness(es) Symptoms	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Specify _____ _____

Growth Hormone Secretion – IMPORTANT: Circle the correct units for GH assay

Type of Test	Date	Basal GH (please circle units)		Peak GH (please circle units)		Sex Steroid Primed
*Arginine			$\mu\text{g/L}$ mU/L		$\mu\text{g/L}$ mU/L	<input type="checkbox"/> Yes <input type="checkbox"/> No
*Insulin Blood Glucose Nadir.....			$\mu\text{g/L}$ mU/L		$\mu\text{g/L}$ mU/L	<input type="checkbox"/> Yes <input type="checkbox"/> No
*Clonidine			$\mu\text{g/L}$ mU/L		$\mu\text{g/L}$ mU/L	<input type="checkbox"/> Yes <input type="checkbox"/> No
*L-Dopa			$\mu\text{g/L}$ mU/L		$\mu\text{g/L}$ mU/L	<input type="checkbox"/> Yes <input type="checkbox"/> No
*Glucagon			$\mu\text{g/L}$ mU/L		$\mu\text{g/L}$ mU/L	<input type="checkbox"/> Yes <input type="checkbox"/> No

2 of the above asterisked tests must be performed

	Date	Result	Units (please circle or indicate)	
IGF1			$\mu\text{g/L}$	Other
IGFBP - 3			$\mu\text{g/L}$	Other

Other Hormone Secretion

Test	Date	Result	Details
TSH		____.____mIU/L	
Free T4		____ pmol/L	
Adrenal Function		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Don't know	If abnormal please provide details: _____ _____ _____
Gonadal Function		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Don't know	If abnormal please provide details: _____ _____ _____
ADH Secretion		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Don't know	If abnormal please provide details: _____ _____ _____

Prolactin secretion		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Don't know	If abnormal please provide details: _____ _____ _____
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Diagnostic tests	Date	Result	Details
Haematology profile (including WBC differential)		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	If abnormal please provide details: _____ _____
ESR		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	If abnormal please provide details: _____ _____
Biochemistry - Renal function - Liver function		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal <input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	If abnormal please provide details: _____ _____ _____ _____
Small bowel biopsy result (if taken)		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	If abnormal please provide details: _____ _____
Karotype			

Radiology	Date	Result	Details
CT Head (if done)		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	
MRI Head (if done)		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	
Skeletal x-rays (if done)		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal	

Concurrent drug therapy			
Drug	Dose	Frequency	Date started (mm/yyyy)
		<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly	
		<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly	
		<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly	
		<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly	
		<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly	
		<input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly	

Chronic Renal Insufficiency (if applicable)					
Test	Date	Value	Test	Date	Value
GFR*			Phosphate		
Sodium			ALP		
Potassium			Albumin		
Creatinine			Bicarbonate		
Urea			PTH		
Calcium			BP		
Hand x-ray (For evidence of renal osteodystrophy)	Details:				

* GFR should be calculated by Schwartz method: $Ht (cm) / Plasma\ Creatinine (\mu mol/L) \times 40$ and expressed as mL/min/1.73m²

Growth history prior to growth hormone treatment – please start with most recent

Date	Height (cm)	Sitting height (cm)	Weight (kg)	Bone age (G&P) yy/mm	Testicular volume		Breast stage
					R	L	

- A plotted height and weight chart must be attached to this form.
- A bone age measurement should be performed within 6 weeks of the application.

Would you like to make any other comments to support this application?

Please specify preferred brand of growth hormone should this application be approved: Genotropin
 Norditropin SimpleXx

Name of applying physician:		NZMC Number:	
Signature of applying physician:		Date:	

Consent form for clinical data transfer to KIGS international growth database (to be provided with initial applications for subsidy for growth hormone).

Introduction

Your child has been invited to participate in a survey called KIGS. Children have been treated with growth hormone for many years but we would like to learn more about the response to this treatment. A group of doctors from all over the world and a company called Pfizer maintain and support a large database called KIGS that includes data from children treated with growth hormone. The KIGS database contains medical history, diseases and treatment information (data) obtained during the children's participation in KIGS. More than 2000 hospitals in nearly 50 countries are currently participating in KIGS. The KIGS survey will increase the understanding about the nature of growth hormone deficiency, improve its clinical management and help to simplify the continuous follow-up of your child's condition. The purpose of this survey is to provide your doctor with the information from a large number of patients in a similar situation to your child.

We believe that it is important that our patients are aware that we are trying to do our best for them. Growth data comparison enables us to use the most effective growth hormone regimen and thus maximise their growth. Although the database is funded by one drug company, the study is independent of the brand of growth hormone used and the results will be widely transmitted for the benefit of all growth hormone patients. The results of this database will be sent to all doctors in New Zealand who send patient data to the database. The New Zealand Growth Hormone Committee will also use the data to form the basis of recommendations as to ongoing therapy.

What will it involve?

We would simply like to enter the data, anonymously, which would be collected as part of your child's normal clinical care, and store it on a computer database, subject to you freely giving your consent for us to do so. Anonymously means that each child participating in KIGS has a unique number assigned to them that is used to identify the child rather than using their name. In this way, your child's name is not connected to his/her data that is entered into the international database. The NZGHC Coordinator assigns the number and he/she is the only person who can identify the individual behind a number.

What if I decline to give consent?

Your child's data will not be entered in the KIGS database. This will not affect your child's medical care in any way. Even if you do give your consent to participate in KIGS, you are free to withdraw at any time. Again, should you decide to do this your medical care will not be affected in any way.

What if my child stops taking growth hormone?

If your doctor determines that it is in your child's best interests to continue to attend the clinic, you would then be asked to allow your child to also continue in the survey to monitor development and growth after stopping growth hormone.

What will happen to the information obtained from KIGS?

The data from the survey database may be used by the group of doctors, or Pfizer, for the submission to health authorities or publication in scientific journals. Personal data, including your child's sensitive health information, will be collected and processed for research purposes in connection with this survey. Your child's records obtained while they are taking part in this survey, as well as related health records, will remain strictly confidential at all times. However, these will need to be made available to authorised representatives working on behalf of Pfizer and its affiliated companies, doctors, nurses and other

personnel involved in the conduct of the survey, the independent ethics committee members who approved this research, and regulatory authorities which evaluate and audit this survey to ensure that it complies with applicable laws.

Data obtained from this survey may be analysed as part of current studies and in future research to assess health outcomes of children treated with growth hormone. The results of this survey may be published in academic journals or discussed at academic meetings. The survey data will also be transferred within and outside New Zealand. However, your child will not be referred to by name and your child's personal identity will not be revealed in any report, meeting or publication. Pfizer (which will control the use of the data) will take steps to ensure your child's personal information is protected.

As the study's sponsor, Pfizer has obligations to retain your child's study records for at least 15 years. If you withdraw your consent for your child to be included in the survey, we will no longer collect your child's personal data, but we may need to keep using information already collected, for the ongoing purposes of the study.

By agreeing to take part in this research and signing the consent form, you agree to the collection, use and disclosure of your child's personal and sensitive information, including their medical records, for the healthcare and medical research purposes described above.

The information that is submitted to this database is simply the growth response data from each child that receives growth hormone. This data is sent anonymously with no patient identification. The only people in the world who are able to identify your child from the data that is sent in are the people named at the bottom of this form. The database has been reviewed and approved by the Auckland Ethics Committee. If you agree to your child's growth data being entered into this database, there will be no change in the usual care that your child receives. They will not be required to take any additional medication or attend their doctor any more frequently than they currently do at present. A monitor from the drug company that sponsors this database or from government agencies will need to have access to your child's growth records to check the accuracy of the data entered.

Can I have access to the data?

Yes. You have the right at all times to see the data on the computer concerning your child. You can also ask your doctor to correct any incorrect information in the database concerning your child.

What about?

Participation in KIGS is 100% voluntary. If your child develops any problems during participation in the KIGS survey please tell your doctor immediately.

If you agree to your child's growth data being entered onto this database then please complete the consent below. If you have any questions you may phone Professor Wayne Cutfield or Associate Professor Paul Hofman of the New Zealand Growth Hormone Committee at the Liggins Institute on 09 373 7599 Ext 86691 or Kyle Reid, NZGHC Coordinator, on 0800 808 476. We are happy to answer any questions you may have.

Written Consent Form: KIGS – Pfizer International Growth Database

Thank you for reading the information about the KIGS survey. If you would like to let your child take part, please read, date and sign this form.

- I have read the attached information sheets on this survey and have been given a copy to keep. I have been able to ask questions about the project and I understand why the research is being done and any risks involved.
- I give permission for someone from the research team, including the Pfizer Survey Representative, health authorities and ethics committees to look at my child's medical records to verify the information stored in the database. I understand that the information will be kept confidential.
- My child's participation in KIGS is voluntary and I understand that I will not benefit financially.
- I know how to contact the research team if I need to and how to get information about the results of the research.

Name of patient:	
Name of Parent/Guardian:	
Relationship of Parent/Guardian to patient:	
Signature of Parent/Guardian:	
Date:	

Name of person taking consent:	
Signature of person taking consent:	
Signature:	
Date:	

Renewal Application for Funding of Growth Hormone Therapy

Please send applications to:

NZGHC Coordinator
PHARMAC
P O Box 10-254
WELLINGTON

Phone: 0800 808 476
Facsimile: 09 929 3221 (redirects to Wellington)
Email: growthhormone@pharmac.govt.nz

Patient Details – patient sticker is acceptable				
Surname:				
First Name/s:				
NHI No:				
Gender:	<input type="checkbox"/> Male	<input type="checkbox"/> Female		
D.O.B:				
Address:				
Phone No:	Home:	Work:	Mobile:	
Applying physician:				Date:
Practice Address:				
Phone:				
Fax:				
Email:				
Serial data				
3-monthly visit date				
Chronological age				
Height/Length (cm)				
Weight (kg)				
Pubic Hair (Tanner)				
Breast/Genitalia (Tanner)				
Testicular volume (mls)				
Bone age (Annual)				
IGF-1 (6-monthly) (units)				
T ₄ - Units: _____ - Normal range: _____				
Compliance	<input type="checkbox"/> Excellent <input type="checkbox"/> Good <input type="checkbox"/> Poor	<input type="checkbox"/> Excellent <input type="checkbox"/> Good <input type="checkbox"/> Poor	<input type="checkbox"/> Excellent <input type="checkbox"/> Good <input type="checkbox"/> Poor	<input type="checkbox"/> Excellent <input type="checkbox"/> Good <input type="checkbox"/> Poor
Medical disorders (new or existing): _____ _____ _____	Medications (including dose, frequency & start date if new): _____ _____ _____			
Adverse event since beginning GH therapy? <input type="checkbox"/> Yes <input type="checkbox"/> No _____ _____	_____ _____ _____			