

## General Consent for Growth Hormone Therapy

**Introduction:** Your child is to start treatment with growth hormone. We want you to be aware of the possible side effects of growth hormone treatment. Although these side effects are rare, we feel you should be aware of them.

The growth hormone currently used is a biosynthetic (made in a laboratory) form of growth hormone produced by recombinant DNA technology (the current method for making growth hormone in a laboratory). Growth hormone has been shown to be safe and effective in the treatment of patients who lack adequate growth hormone of their own. This synthetic growth hormone was approved for marketing in 1985 for the treatment of growth hormone deficiency. Growth hormone is approved by the Food and Drug Administration (FDA) for certain other uses as well.

Your child will receive growth hormone by daily injection. Your child will be observed at 3 to 6 month intervals. These visits will include a physical examination, height and weight measurements. At intervals, we may obtain x-rays, urine and blood tests. These tests will be obtained when clinically indicated.

The following discomforts and potential risks of growth hormone treatment include:

- Pain, bruising and potential infection at the site of blood sampling and subcutaneous (under the skin) injection.
- Your child may develop a small depression in the skin at the site of the injections.
- The chance your child may develop a disorder of the growth plate of the hip. This is not necessarily related to growth hormone treatment; however, any complaints of hip or knee pain should be promptly reported to your child's physician.
- An event known as "benign idiopathic intracranial hypertension" has been reported rarely in patients using growth hormone. This condition results from an increased pressure in the brain and can produce symptoms such as headaches, visual changes, nausea, and vomiting. Stopping growth hormone treatment has resulted in reversal of these symptoms.
- Development of antibodies (natural parts of a person's immune system) to growth hormone in approximately 30 percent of all treated patients. In general, these antibodies do not interfere with growth response to growth hormone treatment. Very rarely children may develop sufficient immunity to the growth hormone to make it ineffective. It is also possible to develop allergies to metacresol, a part of the liquid used in some growth hormone injections.
- The remote chance that your child could develop temporary diabetes mellitus which would require stopping growth hormone therapy.
- The chance that your child would develop an allergic reaction to the drug.
- Some reports suggest that scoliosis (a curving of the spine) may worsen with growth hormone therapy. This worsening is also often seen during the normal pubertal growth spurt.
- One report suggests that testes in some boys treated with growth hormone may be smaller and function less well than expected. This report has not been confirmed.
- Some reports suggest that breast development in males may increase with growth hormone therapy. This increased breast development is also often seen during the normal male

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puberty.

- Leukemia has been diagnosed in a small number of growth hormone-treated, growth hormone deficient patients. Experts cannot conclude on the basis of current evidence that growth hormone therapy is responsible for these occurrences. If there is any increased risk of leukemia to an individual patient, it is very small.
- There are recent reports that some children with a rare syndrome, known as Prader-Willi Syndrome or PWS, treated with growth hormone have died. It is not clear at this time if there is any relationship between these deaths and their growth hormone treatment.
- In a follow-up study of children treated with older growth hormone (derived from human pituitaries), investigators found a higher than expected numbers of colo-rectal cancers and non-Hodgkins lymphomas (a tumor of the lymph nodes) when they were followed into adulthood. It is not clear at this time if there is any relationship between these cancers and their growth hormone treatment.
- If a patient receiving growth hormone becomes very sick and is hospitalized, the patient's doctor should be told immediately and the growth hormone stopped.
- Growth hormone should not be used in patients with evidence of an active malignancy (cancer).
- Growth hormone has been associated with a small increase in second malignancies in patients who have been treated for cancer in the past.
- Growth hormone may increase the risk of developing a low thyroid state.
- Reports from France report that there might be an increased risk of strokes later in life.
- Growth hormone has been used in over about 80,000 patients. It is possible, however, that other side effects, which are unknown and unanticipated at this time, may occur.

Although the potential risks listed above are rarely of clinical significance, your child's condition will be monitored and every precaution consistent with the best medical care will be taken with regard to the growth hormone treatment. Although approved for some uses, growth hormone has not been approved by the FDA for all of the conditions we use it in.

The expected response to growth hormone therapy varies with the clinical condition we are treating. We will try to give you an estimate of expected response in your child. Not all children have a significant response to growth hormone. We may stop growth hormone therapy if we do not detect sufficient benefit or if significant side effects of the treatment are discovered.

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Signature of Parent or Legally Authorized Representative

Date

### CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this treatment, risks and benefits, or alternative courses of treatment, you should ask your doctors at 650-723-5791.

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