

Adult Medical Information Release Agreement

Version: 03/16/06

American Norditropin[®] Studies: Web-Enabled Research

(The ANSWER Program[®])

Program: The Norditropin[®] National Registry

Sponsor: Novo Nordisk Inc.
100 College Road West
Princeton, NJ 08540

Program ID: HGH-2149

Your Doctor:

Name: Dr. Robert Schultz

Address: Pediatric Endocrine Associates
1100 Lake Hearn Drive Suite 350

Atlanta, GA 30342

Phone Number: 404-255-0015

Nature and Purpose of the Registry

Novo Nordisk Inc. (Sponsor), the company that produces Norditropin[®], has established the Norditropin National Registry. The Registry will provide information to those doctors who prescribe Norditropin. This information will help doctors use Norditropin more efficiently and safely. Norditropin is human growth hormone. It is made by recombinant DNA technology. Recombinant DNA technology uses human genetic material placed in bacteria to make exact copies of human growth hormone. Norditropin is approved by the Food and Drug Administration (FDA) for long-term use in children with growth failure due to deficiency of growth hormone and adults with either adult or childhood onset of growth hormone deficiency. Specifically, the Registry is a computer database, which can be accessed through the Internet only by the participating doctors.

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Adult Version

The Registry will collect medical information from patients using Norditropin. This information will come from hundreds, and eventually thousands, of patients (both children and adults) using Norditropin.

Over 100 endocrinologists like your doctor will participate. The information will be used to determine the most effective dosing patterns of Norditropin.

The Registry also collects information about another hormone called insulin-like growth factor 1, or IGF-1 and its binding proteins. IGF-1 and its binding proteins are produced in the body when a person receives growth hormone. Periodic blood tests for IGF-1 will help your doctor determine your proper dose of Norditropin.

Procedures

Your doctor has determined that you have growth hormone deficiency and has planned a course of treatment with Norditropin. Your doctor will determine the dose, timing, and duration of Norditropin therapy.

By signing this release form you agree to authorize a member of your doctor's team to periodically enter the growth hormone parts of your medical information on a secure, confidential website throughout the duration of the Registry. This information includes the birth history, heights and ages of family members, the medical reason to use growth hormone, the history of other medical problems, the results of growth hormone therapy, history of any occurrence(s) of tumors you may have experienced and the results of tests taken in connection with therapy.

Duration

Your doctor will disclose data to the Registry for the duration of your Norditropin therapy and for one year after therapy has stopped. Any data entered into the Registry will remain in the Registry in perpetuity. This release expires two years after therapy has stopped to allow your doctor time to enter the data into the Registry.

Questions

If you have any questions about this study or a research-related injury, please contact your doctor.

If you have questions about your rights as a research subject, please call the QA & Compliance Administrator at Aspire Independent Review Board at (619) 469-0108 (collect calls are accepted).

Confidentiality

A unique Registry Identification Number will be assigned to your medical history. Your doctor will keep a record of your Registry Identification Number. Your name or initials and the name and address of your doctor will not be kept in the Registry Database. In this way, your medical information is kept confidential.

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Only the participating doctors and the Sponsor will see the information in (e.g. height, weight, growth hormone dose, tumor history, IGF-1 level) identified by the unique Registry Identification Number. The Sponsor will not see your name, initials or where you receive treatment.

Covance, a Clinical Research Organization, will monitor the clinic and patient ID numbers and types of visit entered into the database from each site, but will not see any clinical information. The information will be discussed, presented at medical meetings and published in the medical literature. Your doctor can view only her or his patients' information but will receive summary reports regarding all patients in the Registry.

In some circumstances, the medical information may be released to the Food and Drug Administration, other state and federal agencies and Independent Review Boards. Legal actions may require disclosure of this medical information. The confidentiality of the data will be protected to the extent permitted by law. However, once the data is released to the Registry it will no longer be protected by federal health care privacy regulations.

Participation

Your decision to release some of your medical information is entirely voluntary. You can stop the release of the information at any time. Simply tell your doctor you wish to stop. The information already entered into the database will remain in the Registry Database.

Your doctor will treat you and you can receive Norditropin therapy even if you choose not to release, or if you stop the release, of your medical information.

You will not receive money or any form of compensation for participation in this Registry.

Laboratory Costs

You will not be responsible for the costs associated with the IGF-1 and its binding proteins blood testing performed by your doctor.

Agreement

I have read and understood to the best of my knowledge the contents of this information release agreement.

I have had enough time to consider releasing information to this Registry.

I was given an opportunity to ask questions about this information release agreement, the procedures for releasing information and any other areas of concern. My questions have been answered to my satisfaction.

I have been told about the obligations of agreeing to release of this information.

I agree to share my medical information as described in this document.

I will receive a signed and dated copy of this medical information release agreement.

NOTE TO PATIENT: DO NOT SIGN THIS MEDICAL INFORMATION RELEASE AGREEMENT UNLESS YOUR DOCTOR'S CONTACT INFORMATION HAS BEEN COMPLETED ON PAGE ONE.

Print Name

Signature

Date

Name of Patient:

Name of legally
authorized
representative:

Name of Person
obtaining this
agreement:

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Pediatric Medical Information Release Agreement

Version 06/12/02
Revised 07/25/02
Revised 02/10/03
Revised 02/03/05
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(The ANSWER Program[™])

Program: The Norditropin National Registry

Sponsor: Novo Nordisk, Inc.
100 College Road West
Princeton, NJ 08540

Program ID: HGH-2149

Your Child's Doctor:

Name: Dr. Robert Schultz

Address: Pediatric Endocrine Associates
1100 Lake Hearn Drive Suite 350

Atlanta, GA 30342

Phone Number 404-255-0015

Nature and Purpose of the Registry

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Recombinant DNA technology uses human genetic material placed in bacteria to make exact copies of human growth hormone. Norditropin is approved by the Food and Drug Administration (FDA) for long-term use in children with growth failure due to deficiency of growth hormone and adults with either adult or childhood onset of growth hormone deficiency.

Specifically, the Registry is a computer database, which can be accessed through the Internet only by the participating doctors. The Registry will collect medical information from children using Norditropin. This information will come from hundreds, and eventually thousands, of patients (both children and adults) using Norditropin. Over 100 endocrinologists like your child's doctor will participate. The information will be used to determine how well Norditropin promotes growth in children and to determine the most effective dosing patterns of Norditropin.

The Registry also collects information about another hormone called insulin-like growth factor-1, or IGF-1 and its binding proteins. IGF-1 and its binding proteins are produced in the body when a person receives growth hormone. How well a child grows may depend on how much IGF-1 and its binding proteins are produced. Depending on your child's doctor's usual practice procedures, IGF-1 and its binding proteins blood testing may be done zero to 4 times a year.

Procedures

Your child's doctor has determined that your child has growth failure and has planned a course of treatment with Norditropin. Your child's doctor will determine the dose, timing, and duration of Norditropin therapy.

By signing this release form you agree to authorize a member of your child's doctor's team to periodically enter the growth hormone parts of your child's medical information on a secure, confidential website throughout the duration of the Registry. This information includes the birth history, heights and ages of family members, the medical reason to use growth hormone, the history of other medical problems, the results of growth hormone therapy, history of any occurrence(s) of tumors your child may have experienced and the results of tests taken in connection with therapy.

Duration

Your child's doctor will disclose data to the Registry for the duration of your child's Norditropin therapy and for one year after therapy has stopped. Any data entered into the Registry will remain in the Registry in perpetuity. This release expires two years after therapy has stopped to allow your child's doctor time to enter the data into the Registry.

Confidentiality

A unique Registry Identification Number will be assigned to your child's medical history. Your child's doctor will keep a record of your child's Registry Identification Number.

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Your child's name or initials and the name and address of your child's doctor will not be kept in the Registry Database. In this way, your child's medical information is kept confidential.

Only the participating doctors and the Sponsor will see the information in (e.g. height, weight, growth hormone dose, tumor history, IGF-1 level) identified by the unique Registry Identification Number. The Sponsor will not see your child's name, initials or the where your child receives treatment.

Covance, a Clinical Research Organization, will monitor the clinic and patient ID numbers and types of visit entered into the database from each site, but will not see any clinical information. The information will be discussed, presented at medical meetings and published in the medical literature, but individual patient's identity will be kept confidential. Your child's doctor can view only her or his patients' information but will receive summary reports regarding all children in the Registry. In some circumstances, the medical information may be released to the Food and Drug Administration, other state and federal agencies and Institutional Review Boards. Legal actions may require disclosure of this medical information. The confidentiality of the data will be protected to the extent permitted by law. However, once the data is released to the Registry it will no longer be protected by federal health care privacy regulations.

Participation

Your decision to release some of your child's medical information is entirely voluntary. You can stop the release of the information at any time. Simply tell your child's doctor you wish to stop. The information already entered into the database will remain in the Registry Database.

Your child's doctor will treat your child and your child can receive Norditropin therapy even if you choose not to release, or stop the release, of your child's medical information.

You or your child will not receive money or any form of compensation for participation in this Registry.

Laboratory Costs

You will not be responsible for the costs associated with the IGF-1 and its binding proteins blood testing performed by your child's doctor.

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Agreement

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I have been informed of the obligations of agreeing to release of this information.

I agree to share my child's medical information as described in this document.

I will receive a signed and dated copy of this medical information release agreement.

NOTE TO PATIENT / LEGALLY AUTHORIZED REPRESENTATIVE: DO NOT SIGN THIS MEDICAL INFORMATION RELEASE AGREEMENT UNLESS YOUR CHILD'S DOCTOR'S CONTACT INFORMATION HAS BEEN COMPLETED ON PAGE ONE.

	<u>Print Name</u>	<u>Signature</u>	<u>Date</u>
Name of Patient:	_____	_____	_____
Name of legally authorized representative:	_____	_____	_____
Name of Person obtaining this agreement:	_____	_____	_____

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Pediatric _____

CHILD ASSENT

{To be completed by all subjects age seven or older}

I have talked about this Registry with _____
Parent/Guardian Name
and with my doctor and I agree to take part.

Signature of Child *Date*

Signature of Witness *Date*

Child Assent not obtained for the following reason(s):

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