

**RESEARCH SUBJECT INFORMATION AND CONSENT FORM**  
**Core Program**

**TITLE:** The Genetics and Neuroendocrinology of Short Stature International Study (GeNeSIS)

**PROTOCOL NO.:** B9R-EW-GDFC(a)(10)  
WIRB® Protocol #20010790

**SPONSOR:** Eli Lilly and Company  
Indianapolis, Indiana  
United States

**INVESTIGATOR:** Robert M. Schultz, M.D.  
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United States

**SITE(S):** Pediatric Endocrine Associates, P.C.  
Suite 350  
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Atlanta, Georgia 30342  
United States

**STUDY-RELATED**

**PHONE NUMBER(S):** Robert M. Schultz, M.D.  
404-255-0015

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

In this consent form, “you” always refers to the subject. If you are a legally authorized representative, please remember that “you” refers to the study subject.

**Introduction**

Your doctor has determined that you have a growth problem or hormone problem and may benefit from treatment with (Humatrope®) - a synthetic form of human growth hormone. Currently, Humatrope® is approved for treatment of children or adults who do not make enough of their own growth hormone, and for treatment of short stature associated with Turner syndrome.

You are being asked to allow collection of information related to your growth and development, laboratory test results, and treatment with Humatrope® (if you will receive this treatment). This research study is called an “Observational Study”. This means that there are no specific instructions or procedures that must be followed. It simply collects information related to the standard treatment of your condition, to better understand growth, growth problems, and their treatment. The study, which is sponsored by Eli Lilly and Company, is being conducted in about 30 countries worldwide. It is anticipated that approximately 3000 children will participate.

### **Your Involvement**

We are interested in collecting information regarding your medical history, physical examinations, and growth, and routine laboratory studies if:

1. You are being treated with Humatrope® or are starting treatment with Humatrope®.
2. You have a growth or hormone problem related to previous treatment for cancer, leukemia or a tumor, whether or not you will be receiving Humatrope®.
3. You have a growth problem related to a condition known as SHOX deficiency (a genetic cause of short stature), whether or not you will be receiving Humatrope®.

If you agree, your information will be collected for as long as you continue to visit the study doctor for the condition related to growth or growth hormone therapy. In addition, to help us better understand how a child grows over the long term (either with or without treatment), we would like to continue to collect your information, even after you have stopped growing or have stopped treatment.

Participation in this study will not require any extra office visits. The information will be collected without your name from your medical records or during your routine visits.

### **Risks**

Because this is an observational study, there are no medical risks associated with this study as the study doctor is only collecting information from your routine clinic visit.

### **New Findings**

You will be told about any new information that might change your decision to be in this study.

### **Benefits**

This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. Information from this study may help develop a better treatment for others with growth or hormone problems in the future.

### **Costs**

There will be no cost to you for participation in this study; however, the actual routine medical care you receive will be charged as usual.

### **Payment for Participation**

You will not be paid for your participation in this study.

### **Alternatives**

This is not a treatment study. Your alternative is not to participate in this study.

### **Voluntary Participation/Withdrawal**

Your participation in this study is entirely voluntary. This means that nobody can force you to participate. You may refuse to take part or you may stop your participation at any time, without a penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent.

### **Questions**

If you have any questions about this study or your rights, contact Dr. Robert M. Schultz at 404-255-0015.

If you have questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)  
3535 Seventh Avenue, SW  
Olympia, Washington 98502  
Telephone: 1-800-562-4789.

WIRB is a group of people who perform independent review of research.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

### **Authorization To Use And Disclose Information For Research Purposes**

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

### **What information may be used and given to others?**

If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health including:

- Medical and research records
- Records about phone calls
- Records about your study visits
- Study data (information)

- Records of physical exams
- Laboratory, x-ray, and other test results
- Records about study medications
- Records about any study drug you received

**Who may use and give out information about you?**

Information about your health that tells your identity may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

**Who might get this information?**

The study sponsor also may see your health information and know your identity. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.

Information about you and your health which might identify you may be given to:

- Doctors and healthcare professionals taking part in the study
- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- The Western Institutional Review Board® (WIRB®)

The study information sent by the study doctor to the sponsor does not include your name, address, social security number, or other information that *directly* identifies you. Instead, the study doctor assigns a code number to the study data and may use your initials. Some study information sent to the sponsor could indirectly identify you. If you have questions about the specific health information that will be sent to the sponsor, you should ask the study doctor.

**Why will this information be used and/or given to others?**

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. The sponsor will use the study information for research purposes as described in the consent form. The sponsor may also use the study information to get approval for its drugs. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The sponsor may add your study information to research databases to learn more about diseases and improve the design of future studies. This may be done to learn more about whether the study drug is safe and whether it works, and to learn other ways to treat patients.

Your study information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The sponsor works with business partners in drug development. The sponsor may share your study data with these business partners. This would only happen if the business partners need the information as a part of this work with the sponsor. The business partners would also have to sign a contract that requires it to protect your study data in the same way as the sponsor.

The information may be reviewed by WIRB®. WIRB is a group of people who perform independent review of research as required by regulations.

Your medical records and study data may be held and processed on computers.

**What if I decide not to give permission to use and give out my health information?**

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

**May I review or copy the information obtained from me or created about me?**

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

**May I withdraw or revoke (cancel) my permission?**

Yes, but this permission does not have an expiration date.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

**Is my health information protected after it has been given to others?**

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

**Source of Funding**

Funding for this research study will be provided by Eli Lilly & Company.

**Consent**

I have read all of the information in this consent form, and I have had time to think about it.

All of my questions have been answered to my satisfaction.

I voluntarily agree to allow my (my child's) information to be collected as part of this observational study.

I authorize the use and disclosure of my (my child's) health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not waived any of the legal rights which I or my child otherwise would have as a subject in a research study.

***Consent and Assent Instructions:***

*Consent: Subjects 18 years and older must sign on the subject line below*

*For subjects under 18, consent is provided by the Legally Authorized Representative*

*Assent: Is not required for subjects 6 years and younger*

*Is required for subjects ages 7 through 12 years using the separate Assent Form*

*Is required for subjects ages 13 through 17 years using the Assent Section below*

\_\_\_\_\_  
Subject's Name (Print or Type)

\_\_\_\_\_  
Subject's Initials

\_\_\_\_\_  
Site and Subject  
Number

**CONSENT SIGNATURE:**

**Please write in the date at the time you sign your name.**

\_\_\_\_\_  
Signature of Subject (18 years and older)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Parent or Legally Authorized Representative  
(when applicable)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Authority of Subject's Legally Authorized Representative or Relationship to Subject

\_\_\_\_\_  
Signature of Person Conducting Informed Consent Discussion

\_\_\_\_\_  
Date