

SUBJECT CONSENT FORM

Protocol Number: MS305

Study Title: Increlex™ (mecasermin [rDNA origin] injection) Growth Forum Database – IGFD Registry: A Patient Registry for Monitoring Long-term Safety and Efficacy of Increlex™

Sponsor: Tercica, Inc.

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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 facts 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.

Project Description:

You (You equals you/your child) are being asked to take part in a research study designed to gather facts about treatment with a medicine used to replace low levels of a hormone called insulin-like growth factor-1 (Primary IGF-1). This hormone is marketed as Increlex™. It was approved by the FDA for the long-term treatment of children with severe primary insulin-like growth factor deficiency (IGFD) in 2005. It is made by Tercica, Inc., the sponsor for this study. The purpose of this study is to find out if giving Increlex™ to children with Primary IGFD is safe and helps them grow over time.

The purpose of this Informed Consent form is to tell you about what will happen in this study. Then you can talk to your doctor/study nurse and ask questions. It is important for you to understand so you can decide if you want to be part of the study. This form also explains how your child's private health facts may be used. It explains who may see these facts or give it to others during and after the study. If you agree and sign this form, it shows you agree to be part of this study and also shows that you are willing to allow your private health facts to be used.

This study hopes to enroll all children being treated with Increlex™. It is not yet known how many children will participate in the study. This is an open-ended study; your treatment and how long you take medicine will be as suggested to you by your doctor. The Sponsor reserves the right to cancel the study at any time.

Procedures:

If you agree to take part in this study, facts about you will be collected and sent to the Sponsor. These health facts will be collected for as long as you take Increlex™. If you took part in another study before and received Increlex™, this consent allows for the facts from that study to be used for this study also.

You will continue your routine medical care as decided by you and your doctor. This includes visits you have at regular time periods while you are being treated with Increlex™ and for at least one visit after you stop taking the medicine. When you begin the study, you will be asked questions about medical history, growth history, height of you/your parents, any previous medicine for slow growth, and other medicines you are now taking. Also, you will have a physical exam as you normally do, including height and weight measurements, a bone age (x-ray) and pubertal status (maturing of various sex organs). You will need to take your medicine as prescribed by your doctor.

Discomforts and Risks:

Because the reason for this study is to observe your care and keep records of health facts, there should be no physical risks or discomforts to you as a direct result of taking part in this study. Facts for this study will be obtained from you and/or your chart. If you feel that you have any side effect during treatment with Increlex™, it is important to tell this to your doctor or nurse. Ask your doctor or nurse if you have any questions about Increlex™ treatment or possible side effects.

Your child's health will be watched throughout the study.

Potential Benefits:

There is no direct benefit to you for being in this study, but the results of this study could provide valuable facts about Primary IGFD and its treatment.

Study Sponsor:

The sponsor for this study is Tercica, Inc.

Cost to Subject:

There is no added cost to you for taking part in this study. The cost for staff to collect and send facts to the Sponsor will be paid for by Tercica.

Subject Payment:

You will not be paid to be in this study.

Alternative Treatment and Procedures:

Being in this study is not meant to change your routine medical treatment as prescribed by your doctor. This study does not involve any medical care or procedures other than tracking you during treatment with Increlex™. You are free not to take part in this study. If you chose to take part, you can stop being in the study at any time. No matter what you decide, your decision to take part or not take part in this study will not affect your regular care or Increlex™ therapy.

Invitation for Questions:

You may ask the study doctor any questions you have now. If you have questions later, you may call the study doctor's office at the phone number listed on page 1 of this informed consent form. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, please call Harrison IRB, LLC, and Independent Review Board at (740) 845-0814, Monday – Friday, 8:00 a.m. – 8:00 p.m. Eastern Standard Time. Collect calls will be accepted.

Confidentiality:

All facts will be kept in a password protected electronic web-based database with the Sponsor. We will try to keep your research records private, but this cannot be guaranteed. Your records (including your medical records) and the consent form signed by you, may be looked at by the following people:

- Federal agencies that oversee human subject research (i.e. The Food and Drug Administration [FDA])
- Harrison IRB, LLC, an Independent Review Board
- The investigator and research team for this study
- The sponsor or an agent for the sponsor
- Regulatory officials from the institution where the research is being conducted, to ensure compliance with policies or monitor the safety of the study

The results of this research may be presented at meetings or in published articles. However, your name or identity will be kept private. You will also be asked to sign a separate HIPAA form. This form will explain who will have access to your protected health facts.

Study Withdrawal:

Taking part in this study is up to you; you have the right to choose to take part in this study or not. If you do not take part in the study, your doctor will still take care of you. There will be no change to the medical care your child will receive. You will not lose any benefits or medical care to which you are entitled.

Your part in this research study may be stopped at any time for medical reasons. It may also end if you do not take the medicine or do not come to scheduled visits. It may end because the sponsor decides to limit or to end this study.

New and important facts about the safety of Increlex™ may be learned during the study. Your doctor will update you. This will help you decide whether you are still willing to continue to be part of the study.

Authorization to Use and Disclose My Personal Health Facts:

I/my child authorize (give permission for) the study staff to use and share my/my child's personal health facts for the purposes of this study and research directly related to Increlex™ only. My/my child's personal health facts, that I am authorizing to be used

and shared for this study and research, includes all personal health facts that have been or will be collected or received by the study site and/or that is in my medical records at the study site.

You are free at any time to limit the use and sharing of your personal health facts for the study and research described above, without penalty or other effect. If you decide to limit use and sharing of your personal health facts, you can do so as described in the section called “Study Withdrawal”. But, you also understand that you may not be able to take part in this study or continue to take part in this study, if you choose to limit use of sharing your personal health facts.

AUTHORIZATION:

I have read this form about the study or it was read to me. I understand the possible risk and benefits of this study. I know that being in this study is my choice. I choose to be in this study. I know I can stop being in this study and I will still get the usual medical care. I will get a copy of this consent form. (Initial all the previous pages of the consent form). I give my permission to participate in this study.

Subject Signature: _____

Print Name _____ Date _____

Parent/Legal Guardian Signature: _____

Print Name _____ Date _____

Signature of person obtaining consent: _____

Print Name _____ Date _____

*Template Only – Not for use with study subjects