

INFORMED CONSENT

TITLE: Pfizer International Growth Study (KIGS)
SPONSOR: Pfizer Inc
PROTOCOL NO.: TRN 87-052-45
INVESTIGATOR: Robert M. Schultz, M.D.
TELEPHONE: (404) 255-0015 ext. 127 – office number
(770) 985-7790 – 24- hour number
(404) 533-4052 – pager number

Please note: If you are reading this form to decide whether your child should participate in this study, the term “you” refers to your child.

INTRODUCTION

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed procedures. This statement describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

If you are not completely truthful with your study doctor regarding your health history, you may harm yourself by participating in this study.

The study is being conducted for Pfizer Inc. Your study doctor is being paid by Pfizer Inc to conduct this study.

PURPOSE AND BACKGROUND

You are being asked to take part in a survey research study because you are being treated with Genotropin® for your growth.

The purpose of this study is to evaluate the long-term safety and effectiveness of treatment with Genotropin®. During the study your study doctor will collect information about children whose growth is not normal and what happens to these children and their growth if they are treated with the human growth hormone, Genotropin®.

Your study doctor will provide the information about your health to the sponsor. Your study participation will last until you have reached your full height.

About 60,000 children in more than 50 different countries take part in KIGS.

STUDY PROCEDURES

You will be asked to read and sign this informed consent before any study-related procedures are performed. If you agree to participate you will visit the study doctor as you usually do. Your medical and health information including your date of birth, diseases, treatments, height, weight, birth weight and treatment with Genotropin® will be collected.

The results of all your tests and procedures from each visit you make to your study doctor will be sent to the sponsor. You will not have any extra tests performed or take any extra medication as part of your participation in this study.

RISKS

There are no expected physical risks associated with your participation in this study.

Measures will be taken to protect subject privacy; however, absolute confidentiality cannot be guaranteed.

UNFORESEEN RISKS

There may be risks from participating in this study that are unknown.

BENEFITS

There is no benefit to you from taking part in this study. The results obtained during this study may, in the future, help others understand more about the condition of children with impaired growth and their response to treatment with human growth hormones.

NEW FINDINGS

Any new important information which is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

ALTERNATIVE TREATMENT

This research study is for research purposes only. The only alternative is to not participate in this study.

COMPENSATION FOR PARTICIPATION

You will not be paid for taking part in this study.

COSTS

There will be no charge to you or your insurance company as a result of your participation in this study.

CONFIDENTIALITY

Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this informed consent document (under "Confidentiality" or "Authorization to Use or Disclose Protected Health Information"). The study doctor, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

Your study-related medical information will not include your name. To keep your name a secret, the study doctor will use a number and your date of birth instead of your name. This number is called a code, and only the study doctor and the people who work with your study doctor, such as the nurse, will know your code. The study doctor will always use this code and your date of birth instead of your name when sharing your study-related medical information. Every subject who participates in this study will have their own code and any information that is shared about you will contain only the code and your date of birth. Your study doctor will use a computer to send the coded information about you to a file called a database that is controlled by the sponsor in Sweden using a secure Internet connection. The database file holds all the coded information on every subject who participates in this study.

The study doctor's computer will "encrypt" the information before sending it over the Internet. This means the computer will make the information look like nonsense. For example, the computer can make the number 123 look like *^#. This is how all the information will be kept safe and secret as it travels over the Internet. Once the information reaches the database, it will be de-encrypted by another computer in Sweden. That means it will be made to look like it did before it left the study doctor's office so that *^# will look like 123 again. But your name will never leave the study doctor's office, will never travel over the Internet and will never get into the database file in Sweden. Your identity will always be kept secret and stay at the study doctor's office.

Only your study doctor and your study doctor's staff will be given the unique codes and passwords that will allow them to enter and change the information about you on the database.

COMPENSATION FOR INJURY

Since you will not receive any additional study-related medicines or undergo any special medical procedures during the study, Pfizer Inc has made no special compensation arrangements. If routine medical treatment harms or injures you, you should contact your study doctor. You will not lose any of your legal rights as a research subject by signing this consent form.

EMERGENCY CONTACT/IRB CONTACT

If you think of any additional questions about the study or to report a research-related injury please contact your study doctor at the telephone number listed on page 1 of this form.

If you have any questions about your rights as a research subject, or complaints regarding this research study, you should call or write Schulman Associates Institutional Review Board, Inc., (SAIRB), 4290 Glendale-Milford Road, Cincinnati, Ohio 45242 toll-free number 1-888-55SAIRB (1-888-557-2472) during business hours Monday - Friday 8:00 a.m. to 4:30 p.m. EST. SAIRB is an independent committee established to help protect the rights of research subjects.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Taking part in this study is voluntary. You may choose not to participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care.

The study doctor or sponsor may remove you from the study without your consent for any of the following reasons: if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if it is discovered that you do not meet the study requirements, at the discretion of the study doctor, if the study is canceled, or for administrative reasons.

INFORMED CONSENT

I have read and understand this informed consent. I have had time to evaluate and discuss my taking part in this study. Taking part in this study is voluntary. I may decide to take part or I may withdraw my consent at any time. The decision to participate or not participate in this study will not affect the medical care I receive.

I voluntarily agree to participate in this study. By signing this consent form, I have not given up any of the legal rights, which I otherwise would have as a subject in a research study. I will receive a copy of this signed consent form.

Printed Name of Subject

Signature of Subject (Child Assent for
Subjects 12 to Age of Majority)

Date

Printed Name of Parent or Legal Guardian*

Signature of Parent or Legal Guardian*

Date

***By signing this assent/consent form, I verify that I have the legal authority (legal custody) to give permission for this child to participate in this study.**

I have provided copies of guardianship papers to the study doctor or designee that document that I have the above-described legal authority (please attach).

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent

Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

During your participation in this research study, the study doctor and study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the study) and record it on study forms. The study doctor will keep this personal health information in your study-related medical records (that we will refer to as "your records"). In addition, the study doctor may obtain, and include in your records, information regarding your past, present and/or future physical or mental health and/or condition, such as medical records from your primary care physician. Your records may include other personal information (such as social security number, medical record numbers, date of birth, etc.) which could be used to identify you. Health information that could identify you is called "Protected Health Information" (which we will refer to as "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization." Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the study doctor and staff to use your PHI to conduct this study; to monitor your health status; possibly, to develop new tests, procedures, commercial products and to prepare reports or publications.

By signing this authorization, you also are agreeing to allow the study doctor to disclose PHI as described below:

- Your PHI may be disclosed to the sponsor of this study and any agents, representatives, or consultants working on behalf of the sponsor to conduct this study (referred to as "the sponsor"). The sponsor will use and disclose your information only for research and regulatory purposes or to prepare research publications related to this research study. The sponsor will analyze and evaluate the PHI and may also reanalyze the PHI and study results at a later date and combine them with results of

other studies. The sponsor may disclose your PHI to the United States Food and Drug Administration (FDA) and other U.S. and foreign government health organizations as part of applications to gain approval for investigational medications or to meet other reporting requirements such as reporting side effects. The study staff will assign a code number and/or letters to your records which means that you will not ordinarily be identified in the records sent to the sponsor; however, the sponsor may look at your complete study records, which would identify you. Your name will never appear in any sponsor forms, reports, databases or publications, or in any future disclosures by the sponsor. In addition, the sponsor, regulatory authorities, or other oversight bodies may visit the study site to oversee the way the study is being conducted. They may review your PHI during these visits to make sure the information is correct, and they may review your PHI for other uses allowed by law.

- The Institutional Review Board ("IRB") may have access to your PHI in relation to its responsibilities as an Institutional Review Board.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Your identity will remain confidential and, except for the disclosures described above, will not be shared with others unless such disclosure is required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this form, not to see or copy your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization will never expire unless and until you revoke (cancel or withdraw) it. If you sign this Authorization in the states of California or Washington, however, it will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner. You have a right to

revoke it at any time. If you revoke the authorization, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must send a written notice to the study doctor's office, stating that you are revoking your Authorization to Use or Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue your participation in this study.

You will receive a copy of this form after you have signed it.

Printed Name of Subject

Signature of Subject
(For subject's the age of Majority)

Date

Printed Name of Parent/Legal Guardian

Signature of Parent/Legal Guardian

Date

Authority of Legally Authorized Representative to act on behalf of Subject

Printed Name of Person Explaining Authorization

Signature of Person Explaining Authorization

Date

SAIRB APPROVED
IRB #08-0501-0
DATE: January 30, 2008

ASSENT FORM
(Subjects 7-11 years of age)

TITLE: Pfizer International Growth Study (KIGS)
SPONSOR: Pfizer Inc
PROTOCOL NO.: TRN 87-052-45
INVESTIGATOR: Robert M. Schultz, M.D.
TELEPHONE: (404) 255-0015 ext. 127 – office number
(770) 985-7790 – 24- hour number
(404) 533-4052 – pager number

You are being asked to be in a research study. This research study is being done to collect information about your health because you are taking a medicine (Genotropin®) for your growth.

About 60,000 children may be in this study.

If you decide you want to be in this study, you will continue to visit your study doctor as you usually do. Your study doctor will send information about your health including the results of any tests you have to the study sponsor. You will not have any extra tests or visits to see your study doctor while you are in this study.

We will try not to let people know you are in this study, but we cannot promise.

This will not cost you or your parents any money.

You can ask the study nurses and study doctor questions any time.

If a report is written about the study your name will not be in the report.

Your parents (or guardian) must say it is okay for you to be in this study.

If you say no, no one (including your parents) can make you take part in the study. You do not have to be in this study. It is up to you. If you say okay now, but you want to stop later, that's okay too. All you have to do is tell us.

Informed Consent
Protocol No.: TRN 87-052-45
Assent

SAIRB APPROVED
IRB #08-0501-0
DATE: January 30, 2008

CONSENT

Being in this study is up to me. Whatever I decide, no one will be upset with me.
If I want to withdraw from the study, I just have to tell my parents or my study doctor.

I agree to be in the study.

I will be given a copy of this signed form to keep.

Printed Name of Subject

Signature of Subject
(Child Assent for Subjects 7-11 years of age)

Date

Printed Name of Person Conducting Assent Discussion

Signature of Person Conducting Assent Discussion

Date

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