

Children's Hospital Institutional Review Board Information Sheet Emergency Use of an Investigational New Drug or Medical Device

Emergency use is defined as the use of an investigational drug (IND) or biological product or investigational medical device (IDE) with a human subject in a life-threatening situation for which no standard acceptable treatment is available, and there is not sufficient time to obtain IRB review and approval. This is sometimes referred to as "compassionate use." The U.S. Food and Drug Administration (FDA) allows one emergency use of an investigational drug or biological product or medical device without prospective IRB approval. Any subsequent use requires IRB review and approval. If you have an emergency situation, you must contact the FDA to obtain an IND and the manufacturer to arrange for shipment of the drug, biological product, or device.

In addition to contacting the FDA and the manufacturer, the Children's investigator needs to:

- Contact the IRB Chair. Describe the emergency situation and obtain verbal approval for the emergency. If the IRB chairman is not available, contact the medical director. If the medical director is not available, contact the coordinator of the Investigational Drug Service (Pharmacy).
- Obtain written consent from the parents for use of the investigational drug or biological product in the child. This will require preparation of a consent form. The [sample consent form](#) developed by the IRB staff can be adapted, or you may be able to modify a sample consent form provided by the manufacturer of the IND or IDE.
- **Within five working days**, provide a written report to the IRB that includes a description of the emergency situation, a description of the treatment outcome and a copy of the signed consent form. The FDA requires this report, which will be read into the minutes at the next regularly scheduled IRB meeting.

The FDA allows one-time use of an IND or IDE in an emergency situation. Further use requires IRB review and approval. If there is the possibility of a similar emergency occurring in the future, the IRB will request that the investigator complete an IRB application. IRB approval is necessary for subsequent uses.

If an emergency situation occurs during regular working hours, contact the IRB Office. Go to the Contact Us section of the IRB website for current IRB contact information. <http://irb.seattlechildrens.org/contact.asp>. The IRB staff can provide telephone numbers for the IRB Chair, prepare a letter to the manufacturer acknowledging the IRB Chair has given emergency approval and provide guidance for writing the consent form. During evening and weekend hours, call the hospital operator at 206-987-2131 and ask for the IRB Chair.

CHILDREN'S HOSPITAL AND REGIONAL MEDICAL CENTER

Consent Form

"Emergency Use of (specify)"

List the investigators' names, titles, divisions and/or departments and telephone numbers. Include the area code with all phone numbers.

24-hour telephone number: 206 987-2131. Ask for (specify).

Investigator's Statement

Purpose

Name of drug is an investigational medication. This means that the drug is still being tested for safety and effectiveness. The U.S. Food and Drug Administration (FDA) has not approved the drug for marketing. It is available only in research. The doctors taking care of your child are allowed to use this medication only with your written permission.

This medication will be used to treat your child for **describe**. **Provide relevant background information if available, e.g., use of drug in children and adults for treating such an emergency.**

Alternatives

If appropriate, describe any other alternatives available to use as emergency treatments.

Benefits

This drug is being given to your child to treat **describe**. It is hoped that this drug will benefit your child. This drug is under investigation and we cannot guarantee that your child will benefit from its use.

Procedures

The drug is given **describe how the drug is given, e.g., intravenously or by mouth**. **Provide an estimate of how long the drug may be given and name the dose to be used**. **If any additional monitoring is required during administration of this drug (beyond standard clinical care), describe, e.g., extra blood tests.**

Risks, Stress and Discomfort

The side effects of this medication are **describe in lay language**. As with any investigational medication there may be unanticipated side effects.

Costs

Explain if the family will be charged for the investigational medication and if there are any other costs related to receiving this investigational drug, e.g., extra laboratory tests.

Other Information

Participation in this study is voluntary. You may choose not to allow your child to take this medication. You may ask for this medication to be stopped at anytime without penalty or loss of benefits to which your child is otherwise entitled. Data regarding the use of this drug in your child will be submitted to **name the manufacturer**. The FDA and **name the manufacturer** reserve the right to review those parts of your child's medical records that are relevant to the use of the drug. These representatives are required to keep your child's identity and medical record information confidential.

In the event of a physical injury as a direct result of receiving the investigational drug, medical care at routine cost will remain available to your child at Children's. The cost of such treatment will be the responsibility of you or your insurance company.

For questions about your/your child's rights as a research participant, contact Children's Institutional Review Board (IRB) at 206 987-7804. The IRB is responsible for protecting the rights of children and families taking part in research.

Signature of Investigator

Date

Parent's Statement

The emergency use of **name of IND** as described above has been explained to me, and I voluntarily consent to have my child receive this drug. I have had the opportunity to ask questions and understand that the investigators listed above will answer future questions I have about the emergency use of this drug.

Signature of Parent or Legal Guardian

Date

Copies to: Parent/Legal Guardian
Investigators' file
Medical Records