

PATIENT INFORMATION

**Rady Children’s Hospital – San Diego**

**and University of California, San Diego**

**Informed Consent for Treatment with an Unapproved Drug**

Your child has been diagnosed with [complete this sentence].

Your doctor believes that:

* No Food & Drug Administration (FDA)-approved drug is acceptable because:
  + No such drug exists; or
  + Approved drugs have been tried but not worked; or
  + Approved drugs cause side-effects that you cannot tolerate.
* You cannot find or get your child into a clinical trial of an experimental drug that might help.
* There are no other acceptable medical options.

Your child’s doctor has told you that an unapproved drug, [insert name(s)], might help your child. This drug has not been proven to be safe or effective for your child’s condition. The FDA, however, has given your doctor permission to treat your child with this unapproved drug under its “expanded access” program (see <https://www.fda.gov/news-events/expanded-access/expanded-access-information-patients> or ask your child’s doctor to print it out for you).

Use of this unapproved drug is voluntary. [You may receive supportive care to ease your symptoms in addition to or instead of this unapproved drug.] You may want to discuss your options with others (such as your doctors or family and friends) before you decide. You may refuse this option for your child or you may say yes but change your mind later. Your decision will not affect your relationship with RCHSD or UCSD or any benefits you might be entitled to.

Information about your treatment and response will be protected according to our Notice of Privacy Practices, but may be given to the drug’s manufacturer and/or FDA as required by law.

**The treatment plan for this unapproved drug involves:**

[Describe possible duration of treatment, drug dosing/schedule, overview of monitoring/followup procedures and schedule.]

**The known risks of the unapproved drug include:**

[Categorize the risks by severity and probability. A bulleted list should be used. Be sure to consider all types of risks- psychological, social, economic, legal and physical. If further guidance is needed, see normal UCSD research consent templates.]

[If a member of the treating team has a financial interest in the drug or the manufacturer, describe here.]

**Your child’s doctor has told you that treatment with this unapproved drug is not the same as regular drug treatment:**

* **While the drug may help your child, it may not. There is no guarantee.**
* **Treatment may cause unknown side effects, including serious injury or pain, disability, or death. No compensation is available.**
* **You or your insurance are responsible for the costs of your child’s care, including [the cost of the drug and] treatment for side effects. [The drug itself is being provided at no cost.]**
* **Your insurance might not cover costs related to unapproved drugs. These are costs you may need to pay. To find out more about possible costs, contact your health plan.**

Contact Dr. [insert name] at [insert phone] if you have questions about this treatment or if your child experiences side effects. If you have questions about your rights, you may also contact the UCSD Human Research Protection Program at (858) 246-4777.

If you choose to allow your child to receive the unapproved drug, please sign below.

*I understand my child’s diagnosis, my child’s options and the above information. My questions have been answered. I would like my child to receive the unapproved drug.*

Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature : Date:

If the patient is unable to consent (a minor, incompetent, or incapacitated), please add the following information and signature:

Name of Legally Authorized Representative (“LAR”):

LAR’s Authority to Sign:  Parent (of Minor)  Legal Guardian  Other:

Signature of LAR: Date:

*I have explained the proposed treatment to the above patient/LAR, including risks, potential benefits, and alternatives, as well as any financial interest I may have in the treatment.*

Physician Name: Tel.:

Signature: Date: