Title of research study:

Oxybutynin for post-surgical bladder pain and urgency

Investigator: Eric A Kurzrock, M.D.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because your child is being scheduled to have bladder surgery.

What should I know about a research study?

(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
  - Medical treatment, if any, that is available for complications.
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document**.**

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 916-734-2823

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to Urology Resident on-call. In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-admin/.You may talk to a IRB staff member at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.

Do not write below this line. For IRB stamp and version date only.

- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

Most patients have urinary urgency after bladder surgery. Our current treatment to prevent and treat this feeling is to start the patient on an "anti-spasmodic" or "anti-muscarinic" medication called Ditropan (oxybutynin). This medicine relaxes the bladder muscle. Our goal is to determine if oxybutynin is better at relieving bladder urgency in the oral form (liquid) or given through a skin patch (transdermal). Ultimately, we want to find the best form of the medicine for our patients to feel better after surgery.

How long will the research last?

We plan to enroll patients until December 31, 2025. The study duration is 6 weeks.

How many people will be studied?

We expect about 200 people here at UC Davis will be in this research study.

What happens if I say yes, I want to be in this research?

If you decide to allow your child to participate, the treatment your child receives will be chosen by chance, like flipping a coin. Your child will have an equal chance of receiving the current standard treatment of oral oxybutynin right before surgery while in the hospital or the transdermal (skin) patch one to two days prior to surgery.

During the stay in the hospital, which is usually one to two days, we will monitor your child to see if s/he has pain or a feeling of urgency to urinate. These procedures would be done whether or you're your child participates in the study. .

All participants in the study

Both groups will receive a new prescription for oral oxybutynin. This is to be given to your child if he/she is having urinary urgency or frequency.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to read, understand and sign this informed consent form. If your child is in the group that uses the patch, you will be required to apply this to his/her back or leg one to two days prior to surgery.

What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. We will also ask for your permission to destroy or retain any data or specimens collected.

Is there any way being in this study could be bad for me?

Privacy risk: There is a potential risk loss of confidentiality from participation in this study but there is little risk to your child in this area, as all data is stored on the UCDMC password protected, encrypted hard drive. Only study personnel will have access to the data at any time.

Physical risk: Both forms of oxybutynin are very well tolerated but have a well-known side effect profile. The most common side effects of both forms are dry mouth, dizziness, flushing/over-heating, drowsiness and constipation. The skin patch has the additional risk of skin irritation under the patch.

In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, one form of oxybutynin may work better in relieving your child's pain and feeling of urgency. If enough subjects are enrolled, we may determine which form of oxybutynin is better at relieving urgency after surgery.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

If we access protected health information (e.g., your medical record), you will be asked to sign a separate Permission to Use Personal Health Information for Research (HIPPA) form to give your permission.

Do not write below this line. For IRB stamp and version date only.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/legal/privacy/) and in an attached document.

You research data will be stored, indefinitely, on a password protected computer and may be used for future IRB approved research depending on the Research Team's needs. Your information will be "coded" when stored on the computer, which will link your data directly to a Study ID number, instead of your name.

Can I be removed from the research without my OK?

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

You or your health plan will be billed for the costs of routine medical care you receive during the study. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. You will be expected to pay for the usual deductibles and co-payments, and for any routine care that is not covered. Only the costs of research or experimental procedures will be paid by the study**.**

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at HS-IRBAdmin@ucdavis.edu.

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

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Permission to Take Part in a Human Research Study

Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

Printed name of child

Signature of parent or individual legally authorized to consent to the child's general medical care

Date

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Printed name of parent or individual legally authorized to consent to the child's general medical care

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of parent

Date

Printed name of parent

If signature of second parent not obtained, indicate why: (select one)

- ❑ The IRB determined that the permission of one parent is sufficient.
- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

Assent

- ❑ Obtained
- ❑ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
- ❑ Waived by the IRB because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

Signature of person obtaining consent and assent

Date

Printed name of person obtaining consent

Do not write below this line. For IRB stamp and version date only.