

PARENT CONSENT FOR CHILD TO ACT AS A RESEARCH SUBJECT - UCSD FLUOROQUINOLONE EFFECTS STUDY

This form is designed for parents of children who have experienced side effects of fluoroquinolone antibiotics to provide consent to participate in the UCSD Fluoroquinolone Effects Study.

Purpose of this study:

Beatrice A Golomb, MD, PhD and her colleagues at the University of California, San Diego (UCSD) are conducting a research study to find out more about the possible side effects (such as tendon, muscle and joint pain, sleep, cognitive, behavioral, mood, and sensory effects) of fluoroquinolone antibiotics (such as Cipro (ciprofloxacin), Levaquin (levofloxacin), Avelox (moxifloxacin), Tavanic, Zymar, and Ciloxan). This study is open to participation by all those who have taken fluoroquinolones and are fluent in the English language. The study includes questionnaires for both those who have experienced side effects of fluoroquinolone medications and those who have taken and tolerated them without side effects. For children, only participants who have experienced side effects are being sought. Roughly up to 10,000 people will be asked to complete questionnaires.

Your child is invited to participate in this study if he/she has taken fluoroquinolones (FQs) and experienced side effects.

If you agree for your child to participate in this study, you will be asked to:

1. Register for the study. This allows you to be given an individualized link to each survey. Using your individualized link, you or your child can take a break and restart a survey from the screen where you left off, for up to 1 month after starting the survey. Those contacting the study office by email, phone, or postal mail will likewise receive links, though the links might not allow for resuming a questionnaire.
2. Fill out one or more questionnaires either online or in writing asking you or your child about their experience taking FQs. Each questionnaire may take up to 40-90 minutes to complete, depending on the individual. They may take less or more time depending on one's experience. You should only complete questionnaires designated appropriately to your experience of tolerance / side effects with FQs. There are currently 3 questionnaires for those who may have experienced adverse effects from FQs. The total time commitment for people completing all 3 questionnaires is up to 3.5 hours. More questionnaires may become available in the future. Each questionnaire may be completed separately, so as to distribute the total time commitment. Participation in each questionnaire is voluntary. Questionnaires will inquire about one's medical history, including possible risk factors that might relate to development of FQ problems, history of FQ use, symptoms (if any), impacts on one's life, and contact information for further follow up. Your consent is necessary to participate in the survey. All questions are optional. If you do not feel comfortable answering any particular question, you or your child may choose to skip it. However, the more complete the information, the better our results may be.

If you agree for your child to participate in this study, you might be asked to:

1. Receive a phone call verifying the information that was provided.
2. Be contacted by our staff if further clarification of information from the completed questionnaire is needed.

Benefits:

There may not be any direct benefit to you from participation in this study. However, the findings may be of help to future patients on fluoroquinolone medications or for whom treatment with FQs is being considered. The study may provide valuable new information about side effects of FQs, addressing many of the questions we (the investigators) are often asked by patients. Thus, we may learn more about how serious the effects can be, how often (and how completely) the problems resolve when the medication are stopped, how long it takes for improvement to occur, whether certain fluoroquinolones or doses are more or less likely to cause problems, and whether any treatments are reported to help the problems. The research is intended to be used in publications that will help educate health care providers about the effects of fluoroquinolones, and to help both patients and doctors make the best decisions regarding use and treatment.

Risks:

Risks of participation are minimal, and are those risks associated with completing any questionnaire. Loss of confidentiality is a possible risk, but we take pains to limit this risk, as described in the confidentiality section below.

As an additional risk, it is possible in filling out these questionnaires that you may experience boredom or annoyance or possibly recall emotional experiences perceived as unpleasant. If you find yourself having unpleasant feelings and you wish to discontinue a questionnaire, you may take a break or stop at any time. The study is not tied to any particular group outside of UCSD, either online or in-person, and your relationship or status within online or in-person groups will not be affected by your participation or lack thereof.

Confidentiality:

Data collected in the study will be stored by the company Qualtrics. Qualtrics meets the privacy requirements on health care set records by the Health Insurance Portability and Accountability Act (HIPAA). Only study personnel who have signed confidentiality agreements and the UCSD Institutional Review Board will have access to any information provided and no identifying information will be published. Research records will be kept in a locked cabinet and confidentiality will be maintained to the extent provided by the law. In any written reports or presentations, only general results will be reported and no individual participant will be identified. All feedback and comments submitted through the questionnaires will be anonymous when shared in publications or presentations.

Alternatives to participation:

The alternative to participation in this study is to not participate.

Participation is voluntary/Discontinuation of participation:

Participation in this research is entirely voluntary. All questions and items in the associated questionnaires are completely voluntary, and individual questions may be skipped if desired. However, the more complete your information is, the better our survey can identify discoveries and report information. You or your child may refuse to participate or withdraw at any time. If you or your child

would like to discontinue, close your browser window. If you would like your submitted material to be withdrawn, you may contact us within 1 month to have your records destroyed.

Costs:

There are no costs associated with participation in the study.

What if your child is injured as a direct result of being in this study:

If your child is injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if your child is injured. You or your child may call the Human Research Protections Program Office at (858) 246-4777 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

For fluoroquinolone users under the age of 18:

If you or your child is under the age of 18, a parent/guardian must sign a “Parent Consent For Child To Act As A Research Subject” consent form before your child participates. Children ages 7-17 should additionally be given their own choice in participation. Children 7-12 should complete the form “Child Assent to Act as a Research Subject.” Children 13-17 should complete the form “Adolescent Assent to Act as a Research Subject.” Please see the “Special Situations” page on our website at www.fqstudy.info or have a parent/guardian contact our office for further information.

For questions or problems:

If you have any questions, or research-related problems, you may contact the UCSD Fluoroquinolone Study via email at fqstudy@ucsd.edu or telephone at (858) 558-4950 x201. You may call the University Human Research Protections Program Office at (858) 246-4777 for more information about rights as a research subject or to report research-related problems.

The electronic version of the “Experimental Subject’s Bill of Rights” will be made available before the start of each questionnaire, and it may be accessed at:

http://irb.ucsd.edu/Bill_of_RightsEnglish.pdf

By signing below, you are indicating your agreement for your child to participate in the study. You agree that you understand that your responses will be held in accordance with U.S. Federal laws regarding privacy of health information. You agree that the purpose and general nature of the study has been explained to you. You also know whom to contact for any additional information (email fgstudy@ucsd.edu or telephone (858) 558-4950 x201). Please print and retain a copy of this agreement for your records.

Parent Signature

Date

Print Parent Name

(_____) _____ - _____
Parent/Guardian Phone Number

Child Name

Additional Forms:

If the subject is 7 or older, the subject is required to indicate their willingness (“assent”) to participate by including additional forms available on our website at www.fgstudy.info on the page “Special Situations.” If a child of 7 or older does not want to participate, their wishes should be honored. If the subject is between the ages of 7 and 12, please attach a completed form “Child Assent to Act as a Research Subject.” If the subject is between the ages of 13 and 17, please attach a completed form “Adolescent Assent to Act as a Research Subject.” If the subject is 6 or younger, no additional form is needed, only this form.

You may mail this signed form along with any additional form “Adolescent Assent to Act as a Research Subject” or “Child Assent to Act as a Research Subject” to:

UCSD Fluoroquinolone Study
9500 Gilman Drive, Dept. 0955
La Jolla, CA 92093-0995

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| Human Research Protections Program | |
| UC San Diego | |
| Approved | |
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| Do not use after | 02/14/2019 |