ADULT CONSENT TO ACT AS A RESEARCH SUBJECT - UCSD FLUOROQUINOLONE EFFECTS STUDY

This form is for adults to provide consent to participate in the UCSD Fluoroquinolone Effects Study. It is also used in part for adult relatives of a deceased fluoroquinolone user to provide consent.

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. Roughly up to 10,000 people will be asked to complete questionnaires.

You are invited to participate in this study if you have taken fluoroquinolones (FQs) or are completing the study for someone whose adverse reaction contributed to their death.

If you agree 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 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 who tolerated FQs may choose to directly take a questionnaire without registering. 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 about your 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 your 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. There is currently 1 questionnaire for those who have tolerated FQs, requiring 20-30 minutes. 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 your medical history, including possible risk factors that might relate to development of FQ problems, history of FQ use, symptoms (if any), impacts on your 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 may choose to skip it. However, the more complete the information, the better our results may be.

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

1. Receive a phone call verifying the information that you provided.

2. Be contacted by our staff if further clarification of information from your 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 medications 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 records set 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 generalized 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 may refuse to participate or withdraw at any time. If you 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 you are injured as a direct result of being in this study:
If you are 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 you are injured. You 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 who had a fatal outcome:
If you are interested in completing the questionnaires on behalf of someone whose adverse reaction contributed to their death, then a spouse, parent, adult sibling, adult child, or other adult relative must sign and submit a paper copy of this form. Please see the "Special Situations" page on our website at www.fqstudy.info or ask the subject's spouse, parent, or adult relative to 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 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 fqstudy@ucsd.edu or telephone (858) 558-4950 x201). Please print and retain a copy of this agreement for your records.

_____ _____
Subject's Signature Date

_____
Print Name

For those having fatal outcomes or deceased:

If the subject is deceased, then a spouse, parent, or adult relative must complete the form below, including the name and birthdate of the deceased. Be sure to include the signature of the person completing the form, a method of contact, and indicate relationship to the deceased. We will contact you when we receive the form.

(*Please print*:)

_____ _____
Name of Deceased Birthdate (MM/DD/YYYY)

The remainder of this form regards to the person participating on behalf of the deceased:

_____ _____
Spouse/Parent/Adult Relative Signature Date

_____ _____
Print Name Relationship to deceased

(_____)_____ - _____ _____
Contact Phone Number Email Address (if available)

Mailing address:

_____

_____

_____

_____

Preferred method(s) of contact (mark at least one):

☐ Email ☐ Telephone ☐ Postal Mail

You may mail this signed form to:
UCSD Fluoroquinolone Study
9500 Gilman Drive, Dept. 0955
La Jolla, CA 92093-0995