

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

CONSENT TO BE A RESEARCH SUBJECT (Medical Record Review)

GHB Use: Motivations, Medical Consequences and Risks (FORGE study)**A. PURPOSE AND BACKGROUND**

Dr. Jo Dyer and FORGE, the GHB study group, with the California Poison Control System and the University of California San Francisco are conducting research on GHB adverse events. You have been asked to participate in this study because you have used, or may have used, GHB. We are asking for your permission to review your medical records for this hospital admission and use your health information for research analysis. This information is completely confidential and your name will not be used in any publication.

B. PROCEDURES

Health Information: In the course of this study, the researchers will gather information about you either directly, through laboratory tests, confirmation of toxicology tests, or by reviewing your medical records. This information will be used to decide if you are eligible for our studies, and will be used to characterize the adverse events with GHB and find out whether they can be related to identifiable risk factors. The information to be gathered will include results of physical examinations, diagnostic tests, treatments and details about the incident that brought you to the hospital. If you are eligible and decide to participate in other components of this study you will be contacted for a telephone interview about your experiences with GHB. If you participate in the telephone interview there is a \$50.00 reimbursement for your time answering questions.

All personal health information will be stored in a research database and evaluated for research purposes. Access to the database will be limited to study researchers only. If you choose not to consent to medical record review and use of personal health information the investigator cannot use the information from your medical records and you cannot participate in this research study. If you choose to participate you must sign and mail this consent form to the investigators. Then you may also consider signing the second consent form, to participate in a telephone interview.

C. RISKS AND DISCOMFORTS

There is a possibility that participation in this study could result in loss of privacy. Information about you will be handled as confidentially as possible, but complete confidentiality cannot be guaranteed. On rare occasions, a court has subpoenaed research records, but a Certificate of Confidentiality has been obtained from the Federal Government for this study to help insure your privacy. This Certificate means that the researchers cannot be forced to tell people who are not connected with the study, including courts, about your participation, without your written consent.

Exceptions: A Certificate of Confidentiality does not prevent researchers from voluntarily disclosing information about you, without your consent. For example, we will voluntarily disclose information about incidents such as child abuse, and intent to hurt yourself or others. In addition, a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. Finally, the Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

D. CONFIDENTIALITY

Confidentiality: Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. In this study you will be asked about drug use and other possibly illegal activities. Dr. Jo Dyer, the research team members, research associates and other sites associated with this study will have access to information about you.

Representatives from the Human Research Committees may also review or receive information about you. Your name will not be used in any published reports about this study. To further protect your privacy, records are maintained on a secure database where entry is restricted to authorized passwords. During analysis the participants will be assigned numbers and the subject names removed. If information about you is disclosed to anyone outside the study your privacy may no longer be protected by federal regulation. However, we are not disclosing your personal health information to people outside of the study.

Keeping Study Records: Dr. Dyer will retain your research records, including information from your medical records, for at least 6 years or until the study is completed, whichever is longer. However personal health information cannot be used for additional research without additional approval from either you or a review committee.

E. BENEFITS

You will not benefit directly from taking part in this study. The knowledge obtained in this study may increase the understanding of GHB toxicity and lead to a better understanding of the predictors of adverse effects.

F. ALTERNATIVES

If you choose, you may decline to participate in this study.

G. TREATMENT AND COMPENSATION FOR INJURY

No injury is expected as a result of record review or releasing health information to investigators.

H. REIMBURSEMENT

You will receive no reimbursement for participation in this study, however, if you do participate, you will have the opportunity to participate in the home telephone interview for which there is a **\$50 reimbursement for your time answering questions.**

I. COSTS

There will be no additional cost to your insurance carrier, the hospital or you as a result of your participation in this study.

J. QUESTIONS OR PROBLEMS

If you have any further questions about this study, you can call Dr. Jo Dyer, Dr. Ilene Anderson or Dr. Susan Kim any time at 1-800-977-7969, or 415-502-6042. In addition, you may obtain further information about this study at the calpoison.org/forg website. If for any reason you wish further information about the protection of volunteers in research studies, you may contact the Committee on Human Research of the University of California. You may reach their office between 9:00am and 5:00pm Monday through Friday at (415) 476-1814 or by writing to the Committee on Human Research, Box 0962, University of California-San Francisco, San Francisco, CA 94143.

K. CONSENT

Participation in research is voluntary. Declining to participate in this study will not affect your treatment in any way. You were given a copy of the Experimental Subject's Bill of Rights and study information sheet. You have the right to decline to participate or to withdraw at any point in the study without jeopardy to your medical care. You may also withdraw your authorization for this study to use your personal health information by contacting Dr. Dyer to inform her of

your decision. If you withdraw your authorization, the information already collected may continue to be used, to maintain the integrity of the study.

If you wish to participate, you should sign below and return this form by mail:

Date

Subject's Signature

Mail to:

California Poison Control System, UCSF

FORGE study

UCSF box 1369,

San Francisco, CA 94143-1369