

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT (Telephone Interview)
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 suffered an adverse reaction after ingestion of GHB and were treated in a hospital. Your health care provider gave you information about our study at the time of your discharge. This form is asking for your participation in a telephone interview. The interview will take approximately 45 minutes. Your participation in the study is entirely voluntary and you are free to refuse to answer questions or stop at any time. Upon completion of the study a \$50 reimbursement for your time will be mailed to you. In order to be eligible for the telephone interview and the \$50.00 reimbursement, you also need to consent to allow your health information to be used for study purposes and provide your address for mailing the \$50.00. We have taken precautions to safeguard your privacy. Information obtained in this study will be maintained confidential to the fullest extent possible. The goal of the interview is to obtain insight into the factors surrounding GHB use and adverse events.

B. PROCEDURES

Health Information: In the course of this study, the researchers have gathered information about you either directly, through laboratory tests, confirmation of toxicology tests, or by reviewing your medical records. This information is used to determine your eligibility for our studies, and is used to characterize adverse events with GHB and find out whether they can be related to identifiable risk factors. The information from this interview will be gathered directly over the telephone. 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 participate you may decline at any time, and there will be no further contact. If you should decline your name, address, phone number is strictly confidential and will not be released to anyone.

If you choose to participate you must sign and mail this consent form to the investigators. Within 4-10 weeks, you will receive a telephone call from a trained interviewer who will ask you a variety of questions surrounding GHB use. The interview will take approximately 45 minutes. Upon completion of the interview you will be mailed a \$50.00 reimbursement within 4 weeks.

C. RISKS AND DISCOMFORTS

There is a possibility that participation in this study could result in loss of privacy. Information about you will be kept as confidential 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 you 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 from taking part in this study. The knowledge obtained in this study may increase understanding of the incident and co-factors for GHB use and as a result lead to a better understanding of the predictors of adverse effects.

F. ALTERNATIVES

If you choose, you may decline to participate in this study by not returning the consent form. You can also withdraw from the study at any time, or refuse to answer particular questions if you so wish.

G. TREATMENT AND COMPENSATION FOR INJURY

No injury is expected as a result of participating in the telephone interview.

H. REIMBURSEMENT

You will be reimbursed \$50.00 for the time you spend participating in this study. You must complete the telephone interview that is expected to take approximately 45 minutes. Your address is necessary for mailing the \$50.00. It usually takes 4 weeks to receive the payment that will be mailed to your preferred address.

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

If you have any further questions about this study you can call Dr. Jo Dyer, Dr. Ilene Anderson or Dr. Susan Kim any time toll-free at 1-800-977-7969 or 415-502-6041. In addition, you may obtain further information about this study at the calpoison.org/forge 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. You have been given a copy of the Experimental Subject's Bill of Rights and a 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 in this study, you should sign and return this form to the address at the bottom. Include your preferred phone numbers, mailing address and best times to reach you by phone.

I consent to participate in the GHB telephone interview.

Signature: _____ Date: _____

Address: _____

Telephone contact numbers: _____

Best days and times to call: _____

Do you prefer the FORGE study to Leave or Not Leave (circle one) phone messages. When attempting to reach you, "GHB" will not be mentioned, only "the FORGE study".

Mail to:
California Poison Control System, UCSF
FORGE study
UCSF box 1369
San Francisco, CA 94143-1369