

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT (Focus Group Participation)
GHB Use: Motivations, Medical Consequences and Risks (FORGE study)

A. PURPOSE AND BACKGROUND

Dr. Jo Dyer, PharmD in the Department of Clinical Pharmacy and Dr. Judith Barker, PhD, in the Department of Anthropology, History & Social Medicine of the University of California San Francisco, are doing a study of the beliefs and meanings assigned to and desired from GHB and adverse experiences with GHB (gamma hydroxybutyrate). You are being asked to participate in this study because you may have some ideas about and/or experience with GHB.

B. PROCEDURES

In the course of this study, the following will occur:

1. You will be interviewed once as a part of a focus group composed of 6-8 other people who are similar to you in terms of background and experience with GHB. This focus group interview will take about two hours.
2. An audiotape recording will be made of the focus group conversation, and will later be transcribed (typed).
3. The information to be gathered will include your opinions and understandings about GHB and about some of your either first-hand or second-hand experiences with it.

This 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 you cannot participate in this research study.

C. RISKS AND DISCOMFORTS

Participation in this study will involve a loss of privacy. The researchers will ask you and the other people in the group to use only first names during the group session. They will also ask you not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussions private. In order to minimize loss of privacy, study records will be handled as confidentially as possible. Study information will be made anonymous as possible through the use of codes, and kept in locked files at all times. No individual identities will be used in any reports or publications resulting from the study. No one else will be told anything you say. Only study personnel will have access to the codes or the files. After being transcribed (typed), audiotapes of focus group conversations will be destroyed. 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.

D. CONFIDENTIALITY

Confidentiality: Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. Dr. Jo Dyer, Dr. Judith Barker, members of the focus group, 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

There is no benefit to you from participating in this study. An indirect benefit is that health professionals will have a better understanding of how people think about and experience GHB. This will enable them to design effective prevention strategies and interventions.

F. ALTERNATIVES

Without jeopardy, you are free to choose not to participate in this study. You can also withdraw from the study at any time, or refuse to answer particular questions if you so wish.

G. COSTS AND REIMBURSEMENTS

There will be no costs to you as a result of taking part in this study. At the completion of the focus group interview, **you will be paid the sum of \$150 to compensate you for your time and effort.** You must provide your social security number to be paid by check, and your address is necessary for mailing the check.

H. QUESTIONS

If you have questions about this study you can call Dr. Barker or **name of research assistant** at any time, collect if necessary, at (415)-476-7241.

If you have questions or comments about participating in this study, you should first talk with Dr. Barker. If for some reason you do not wish to do this, you may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. You may reach the Committee's office between 8:00am and 5:00pm, Monday to Friday, by calling (415) 476-1814, or by writing to the Committee on Human Research, Suite **315**, Laurel Heights Campus, Box 0962, University of California San Francisco, CA 94143-0962.

I. CONSENT

PARTICIPATION IN RESEARCH IS VOLUNTARY. You are free to decline to be in this study or without jeopardy to withdraw from it at any point. Declining will not affect your treatment in any way. 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.

_____ asked for my consent on ____/____/____
Printed name of researcher Date

I consent to participating in this study. I have been given a copy of this consent form to keep.

Signature of Participant Date