

INITIAL CONTACT TO EXPLAIN CONSENT  
AND SUBJECT ELIGIBILITY SCREEN  
(Devised for non-hospitalized subjects recruited outside the CPCS)

**INTRO:** Hello, <NAME OF POTENTIAL RESPONDENT>. My name is \_\_\_\_\_ and I'm calling on behalf of the University of California for a study supported by the National Institutes of Health.

Recently you left a message inquiring about possible participation in an important telephone interview regarding health and GHB. Thank you for your call.

Do you have about 10 minutes now to discuss the study?

**YES** continue

**NO** is there a better time for us to call you back? \_\_\_\_\_

In order to participate in the interview, the first step is for you to understand and agree or consent to participate. I will read the consent form to you. You may ask any questions you have.

The consent form is a formal document broken down into sections, I will begin with:

**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. The goal of this study is to obtain insight into the risk factors surrounding GHB use and adverse events.

**B. PROCEDURES**

If you choose to participate, a trained telephone interviewer will contact you within 4-10 weeks to ask you a variety of questions surrounding GHB use. The interview will take approximately 45 minutes.

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.

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**

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. 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. You may also choose a code-name to use for the study.

#### **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. You can also withdraw from the study at any time, or refuse to answer particular questions if you 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. An 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 cost to 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/forged](http://calpoison.org/forged) 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 may print a copy of the Experimental Subject's Bill of Rights and a study information sheet, or I can mail one to you. You have the right to decline to participate or to withdraw at any point in the study without jeopardy.

**Would you like to participate in this study?**

**NO** thank you for your time, you will not be contacted again regarding this study. Good-bye.

**YES** Date/interviewer \_\_\_\_\_

**Received consent to participate in the GHB telephone interview from:**



For all of the following questions, please understand that whenever I refer to GHB I will be referring to GHB as well as any GHB-like substance such as gamma butyrolactone (that is, GBL), butanediol or BD and gamma valerolactone (sometimes called GVL).

5. Have you ever used GHB?
6. How many times have you used it?  
(Prompt if necessary): More or less....
7. When was the last time you used it?  
(Prompt if necessary) How many weeks or months ago?
8. What did the GHB look like in appearance?  
(Prompt if needed) What form was it in?
9. How did you give it to yourself or use it?
10. Did you ever need to go to the emergency room because of GHB?
11. Do you think you may have been dependant on GHB?
12. Would you prefer to be interviewed in Spanish?

Thank you for your answers.

**IF ELIGIBLE:** You will be contacted within 10 weeks to participate in the telephone interview. It takes approximately 45 minutes and you will be reimbursed \$50 for your time.

What is the telephone or cell number where you preferred to be called?

Is there a particular time of day or evening that you prefer in general?

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”.

Thank you again for your time and willingness to participate. Goodbye.

**IF NOT ELIGIBLE:** Thank you again for your time and willingness to participate. If you meet the eligibility requirements, you will be contacted in the next week. Goodbye.