Participant Information Sheet/Consent Form

Health/Social Science Research - Adult providing own consent

St Vincent's Hospital Sydney

Title	A qualitative study exploring diverse cultures, practices, and experiences of GHB use among people who identify as heterosexual and cisgender or transgender and live in Australia
Short Title	GHB Cultures, Practices & Experiences
Protocol Number	2021/ETH11824
Project Sponsor	St Vincent's Hospital Sydney
Coordinating Principal Investigator	Dr Krista Siefried (National Centre for Clinical Research on Emerging Drugs, UNSW)
Principal Investigator	Prof Nadine Ezard (St Vincent's Hospital Sydney Drug and Alcohol Service)
Location	St Vincent's Hospital Sydney (SVHS) and online

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, which is called "*A qualitative study exploring diverse cultures, practices, and experiences of GHB use among people who identify as heterosexual and cisgender or transgender and live in Australia*". You have been invited because you have expressed interest through our social media campaign, or you have expressed interest to staff who contacted you through the Psychiatric Alcohol and Non-Prescription Drugs Assessment (PANDA) Unit. Your contact details were obtained through the online form you have completed.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local health worker.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. This will not impact your relationship with any of the services or people involved in the study.

If you decide you do want to take part in this research project, you will be asked to sign the consent section. By signing it, you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to be involved in the research described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

This study will explore GHB use by people who identify as heterosexual and either cisgender or transgender and live in Australia. The study aims to understand experiences of GHB overdose, dependence, withdrawal, benefits and harms, knowledge sharing, self-regulation approaches and harm-reduction strategies.

GHB harms are increasing in Australia. There has been a significant increase in people coming to the emergency department with GHB toxicity. Unpublished data from St Vincent's Hospital Sydney has shown that, on average, 22 people per month come into the Emergency Department related to GHB use. At St Vincent's Hospital Sydney, between 2001 and 2020, there has been an 252% increase in the number of people coming into to the emergency department with GHB toxicity.

This research aims to fill a knowledge gap about what is happening when people use GHB to develop GHB harm-reduction strategies and programs.

The results of this research will be used by a UNSW Medicine student in their thesis to obtain a University of New South Wales Medicine Honours degree. This research has been initiated by a researcher who works at The National Centre for Clinical Research on Emerging Drugs (NCCRED) (UNSW) and St Vincent's Hospital Sydney Alcohol and Drug Service, Dr Krista Siefried. This study is funded by NCCRED internal funds. NCCRED is funded by the Australian Department of Health and is governed by a consortium consisting of The University of New South Wales, Flinders University, Curtin University, and St Vincent's Health Australia.

3 What does participation in this research involve?

If you decide to participate, you will complete an online expression of interest form asking about your age, location, sexuality, GHB use and contact details, which will take roughly 10 minutes. A study coordinator will contact you if you appear eligible to participate in the study. The study coordinator will provide further information about the study, confirm your eligibility and formally invite you to attend an interview for the study. While on the phone, the study coordinator will email you a weblink to the Participant Information Sheet/Consent form.

If you decide to participate, you will complete a 60-minute semi-structured interview. The interviewer will ask questions related to *(1)* the cultures, languages and contexts of GHB use; *(2)* perceived benefits and harms associated with GHB use, and *(3);* questions to understand the knowledge of and use of strategies to mitigate or reduce harm related to GHB use.

Interviews will be conducted either in person at St Vincent's Hospital Sydney or via telehealth interview for people from other parts of Australia. Interviews will be recorded and transcribed word for word.

If you participate in this study you will be reimbursed with a $50 grocery store voucher.

4 Other relevant information about the research project

Approximately 30 participants will be recruited across Australia to take part in this study. At least 10 participants who presented to the St Vincent's Hospital PANDA Unit with complications related to GHB overdoses will be recruited.

The **National Centre for Clinical Research on Emerging Drugs** is leading this research in partnership with researchers from the **University of New South Wales**, **The University of Sydney** and **La Trobe University**. This study is a sister study of the "*Qualitative study exploring diverse cultures, practices and experiences of GHB use among LGBTQ Australians*" study (UNSW HEC ref: HC200977) which recruited 30 LGBTQ people and follows the same methodology as the current proposal. For that reason, this study does not aim to recruit people who identify as LGBTQ.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given a copy of this Participant Information and Consent Form to sign and you will be given a copy to keep or provided an electronic PDF copy if you choose.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with professional staff or your relationship with UNSW, NCCRED or SVHS.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include the development of new evidence to inform crucial GHB related health promotion, harm reduction and overdose prevention programs operating at partner organisation sites and the health sector broadly. There is unlikely to be a clear benefit to you personally from your participation in this research.

7 What are the possible risks and disadvantages of taking part?

There is some chance that you will experience psychological distress during the interview. Some of the potentially sensitive interview topics are:

- discussions of drug overdose;
- emergency department admission;
- drug use and method of administration;
- sexual consent/assault.

You will have the right to pause or cease the interview at any time should if you feel distressed. You can stop and withdraw your consent if you no longer wish to participate.

The interviewer may support you to call a crisis support line as outlined in this section of the e-PISCF. If the interviewer believes you are at risk of harming yourself or others, the interviewer may break confidentiality and provide details to emergency services.

You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling through your local ADIS or other

appropriate support (e.g. Lifeline), this support will be provided by qualified staff who are not members of the research team and will be provided free of charge.

Contact details

Lifeline	13 11 14
Alcohol Drug Information Service (ADIS)	1800 250 015

In very rare instances we may be required to disclose information provided by you to a court.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

9 Could this research project be stopped unexpectedly?

It is expected that study will be completed within 18 months. This is based on our prior study where we interviewed 30 participants in LGBTQ communities, which was able to continue via telehealth throughout the Australian Covid-19 lockdowns. In this previous study, 30 interviews provided enough data for the purpose of the research. However, the present study could be completed earlier if the data can be collected, analysed, and published ahead of schedule. It is not expected that any other reason for early termination will be necessary.

10 What happens when the research project ends?

The research team intend to publish and report the results of the research. All information will be published in a way that will not identify you or any study participant. The research team and partner organisations will also update their websites with results from the study. You will be informed where you can find this information when you are interviewed.

If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

Based on the findings of this study and our work in LGBTQ communities, the investigator team will develop and conduct a quantitative survey. It is intended that the findings of this research will also be utilised to develop harm-reduction resources.

This study will be carried out primarily by a UNSW medical student completing their Honours year at SVHS under the supervision of the Coordinator Principal Investigator.

All interview data will be de-identified. Any related publications will also be available on the NCCRED website. Results from this study will be incorporated into the medical student's honours thesis and will be presented (de-identified) in scientific publications and conferences.

There is no anticipated secondary use of this data. Any further use of the data generated in this study would be developed into study protocols and re-submitted to the HREC for review and approval.

You will be asked if the study staff can contact you for future studies. If you choose to remain contactable, your first name and email address will be kept within the study files.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using information about you for the research study.

The research team will store the data collected from you for this research project for:

- A minimum of 7 years after the publication of research results.

The information about you will be stored in a:

- non-identifiable format where your identity will be unknown;
- secured server at St Vincent's Hospital, Sydney.

You will be asked to provide your consent for the research team to share or use the information collected from you in future research that:

- will be specific to the aims of this research;
- will be an extension of, or closely related to, the original project;
- or is in the same general area of research.

At this time there are no planned secondary research projects. Any future research using your data in this way will undergo its own secondary ethics approval by the St Vincent's Hospital Sydney Human Research Ethics Committee.

Your information will only be shared in a format that will not identify you.

- Information collected from you in an electronic format will be stored on a SVHS password-protected electronic folder only accessible to the approved research investigators.
- Audio recordings will be stored on a SVHS password protected electronic folder only accessible to the Chief Principal Investigator Dr Krista Siefried and the designated research team member who conducts your interview. Audio recordings will be made available to a professional transcription service.
- Recordings will only be made available to a transcription service who have a confidentiality agreement with SVHS, and all transcriptions of the recordings will have any names or identifying characteristics removed.

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The personal information that the research team collects in the expression of interest form will also be maintained by the methods above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to amend the information provided in your interview.

12 Complaints and compensation

If you suffer any distress or psychological injury as a result of this research project, you should contact the research team as soon as possible. You may have access to support through Medicare, as well as through other available resources such as the ADIS. Study staff can assist you with identifying and arranging appropriate treatment and support.

Any complaints or feedback you have about this study or study staff can be directed to either the Coordinating Principal Investigator, the SVHS Research Office or the Human Research Ethics Committee – details are found at the end of this document.

13 Who is organising and funding the research?

Dr. Krista Siefried, who is employed by NCCRED and holds a research appointment at SVHS (unfunded), is conducting this research project. This study is funded by NCCRED internal funds. NCCRED is funded by the Australian Department of Health and is governed by a consortium consisting of The University of New South Wales, Flinders University, Curtin University, and St Vincent's Health Australia. The UNSW Medicine Honours Student and NCCRED Research Assistant have research appointments at SVHS to ensure interviewer continuity through the project.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of St Vincent's Hospital Sydney (reference: 2021/ETH11824). This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the researcher on +61 447 982 933 or any of the following people:

Research contact person

Coordinating Principal Investigator	Krista Siefried
Position	Clinical Research Lead
Telephone	+612 9065 7808
Email	krista.siefried@svha.org.au

Local Principal Investigator	Nadine Ezard
Position	Clinical Director
Telephone	+61 447 982 933
Email	Nadine.ezard@svha.org.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Research Office Manager
Position	Research Office Manager
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	St Vincent's Hospital Human Research Ethics Committee
Position	Research Officer
Telephone	+61 2 8382 4960
Email	SVHS.Research@svha.org.au

Local Research Office contact

Name	Research Governance Officer
Position	Research Governance Officer
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au