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Plain Language Statement Melbourne School of Population and Global Health

Project: Client experiences of intrauterine device (IUD) insertion at a sexual and reproductive health training clinic.

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Introduction

You are invited to take part in a study being conducted by researchers at the University of Melbourne and Sexual Health Victoria. You have been identified as someone who is attending a Sexual Health Victoria clinic for the insertion of an intrauterine device (IUD). The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research. Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about. Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time.

What does research involve?

This study aims to understand client experiences of IUD insertion.

As a participant, you will be asked to:

- Give your consent to participate in the study by reading and agreeing to the conditions detailed below.
- Answer a series of online survey questions relating to your experience of having an IUD inserted. Survey completion will take approximately 10 minutes.
- Consent to a member of the research team from SHV accessing information from your clinical records. Information will include: your age, whether you are a concession card and/or Medicare card holder, previous IUD insertions/removals, type of IUD inserted, any discomfort and pain relief taken, and whether your IUD was inserted by a clinician undertaking training at SHV. This information will be linked to your survey response using your clinical software number but will be entirely de-identified for privacy prior to analysis (see *Confidentiality* on page 3).

We understand that some people may be uncomfortable about the topic of sexual health, however, questions are largely based around the IUD insertion procedure itself, rather than your own personal sexual health or history. Should you experience any discomfort while completing the survey you are free to withdraw at any time.



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Why were you invited for this research?

You have been invited to participate in this study as you are having an IUD inserted at an SHV clinic. You are under no obligation to participate in the study.

Consenting to participate in the project and withdrawing from the research

Your consent to participate in the study will be indicated by you opening the survey by clicking on the link or via the QR code provided and confirming your consent. You can withdraw from the study at any stage, by closing the window without submitting your answer. This will not impact your relationship with the SHV clinical team or research team. As all survey data will be de-identified shortly after it is submitted, it is not possible to withdraw your survey data after submission. However, no data will be saved if you choose to close the survey before submitting your responses.

Possible benefits and risks to participants

There will be no direct benefit to you from taking part in the study. However, findings from this study will help us to better understand client experiences of accessing an IUD service and having an IUD inserted. This will help to improve IUD services in future and improve information about IUDs to the community.

There are limited risks involved in completing the online survey. There is a small chance that the survey questions about your pain or sexual and reproductive health may cause you discomfort. Should this occur, you can discontinue the survey with no consequence. Should you experience any distress, you can opt to talk with the attending SHV clinician while in the IUD recovery room, or you may wish to contact an external support service. A distress protocol is in place to ensure participant wellbeing. Some suggested support services are below:

- Beyond Blue Support Service is available 24/7 for brief counseling: 1300 22 4636 or <https://www.beyondblue.org.au/get-support>.
- Lifeline is available 24/7 for crisis support: 13 11 14 or <https://www.lifeline.org.au/get-help/>.
- The Centre Against Sexual Assault (CASA) is available for brief counselling Mon to Fri, 9am-5pm: 03 5441 0430, and crisis support at all other times: 1800 806 292.

Research involving diagnostic testing or possible incidental findings

Although the study involves questions relating to your IUD insertion, this is NOT a replacement for a follow-up appointment. Should you have any concerns following your IUD insertion we recommend that you contact the SHV clinic. Post-care is not within the scope of the study.

Confidentiality

All responses to the survey collected will be confidential. Once your survey data is received, a member of our research team who is based in the SHV clinics will link your survey data with your SHV clinic record by matching your clinical software record number with your survey responses (as described in *What does the research involve* on page 1) using the date and time of your appointment, which will be removed before dataset linkage is completed. Your clinical record and clinical software record number will only be viewed by the lead clinical researcher, not the student researchers. The lead clinical researcher will de-identify your information by removing any identifiable data, such as area postcode, and



date and time of appointment. The lead clinical researcher will then generate a random participation identification number, after de-identification, that will be linked to your survey responses. The date and time of your appointment and of when you completed the survey will also be removed from the dataset before analysis. All de-identified participant data will be analysed together and may be written up and presented in student research theses, academic papers and/or conference presentations. **You will not be identifiable in any way.**

Storage of data

Data will be collected through the online Qualtrics and downloaded and stored on a University of Melbourne Researcher Desktop accessible only to members of the research team (current and future). The Chief Investigator will manage the data, and access will be provided only to members of the research team with ethical approval. The de-identified data will be stored on a secure server at the University of Melbourne for analysis and then transferred to a secure archive platform. After the required period of 5 years, it will be destroyed. De-identified data/information used in this research may also be used in future projects that are closely related to this study, the same general area, or could make valuable use of this data. De-identified data may be shared with primary members of the Family Planning Alliance Australia, for the purpose of generating national datasets that can inform evidence-based best practice in IUD service provision and health promotion. You will not be identifiable in these potential datasets in any way.

Use of data for other purposes

In accordance with data sharing guidelines, de-identified data may be made available for use by the other researchers. This data will be held on secure public repositories and may be a requirement of some journals prior to publication. Any shared data will not include your identifying details.

Results

A brief report of survey findings will be available approximately July 2025. If you would like a copy of the research, please provide your email address at the end of the survey. Your email address will be stored separately from your survey responses and will be used only for the purpose of sending you the report.

Complaints or concerns

This project has human research ethics approval from The University of Melbourne (Project ID: 30981). If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 1376 or Email: research-integrity@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence, please provide the name of the research team and/or the name or ethics ID number of the research project.