

Participant Information Sheet

Gender Diversity and Forensic Science Testing



Formal Study title: (optional)

Sponsor (if applicable): name and address: Dr Philip Carter, PHF Science, Kenepuru

Lead [Researcher / Study Doctor]: Dr Rachel Fleming and
Dr Courtney Lynch

Study Site: PHF Science – MASC, KSC and CSC

Contact phone number: 098451736

Ethics committee ref.: 2026 EXP 24711

***NOTE: The topic of this research relates to sexual assault. Please take care of your own wellbeing when reading this document and seek support if it creates discomfort for you in any way. Please see below for a list of organisations you can talk to.**

Lifeline: Call 0800 LIFELINE (0800 543 354) or send a text to HELP (4357)

Safe to talk Kōrero mai ka ora: Sexual harm helpline – 0800 044 334 or Text 4334

<https://www.safetotalk.nz/>

TOAH-NNEST Getting help lists of services: <https://toah-nnest.org.nz/getting-help/>

Women's Refuges: Crisisline: 0800 REFUGE or 0800 733 843 <https://womensrefuge.org.nz/get-help/>

Hohou Te Rongo Kahukura Outing Violence: <https://kahukura.co.nz/need-help/>

Victim support: Contact Service – 0800 842 846

<https://www.victimsupport.org.nz/crimes-and-traumatic-events/sexual-violence>

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THIS STUDY

Whether or not you take part in this study is your choice. It is important you understand what this study involves and why we are doing this. Please carefully read the following information. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. If anything is unclear, please contact any of the researchers listed at the bottom of this document.

If you do not want to take part, you do not have to give a reason, and it will not affect any care you receive. If you do want to take part now, but change your mind later, you can withdraw your samples and information from the study up to 4 weeks after donating samples by contacting the intermediary team members (listed at the bottom of this document). After this time, we may have already begun testing the samples. Please read 'What Happens After The Study or If I Change My Mind' for further information.

WHAT IS THE PURPOSE OF THE STUDY?

Our goal is to strengthen the interpretation of forensic findings in cases involving gender diverse people, so that results are robust, meaningful, and fair. We are conducting a world-leading study, addressing an important inequity: the lack of data concerning gender diverse populations has long been recognised as missing.

You are invited to take part in a study being conducted by the New Zealand Institute of Public Health and Forensic Science (PHF Science, formerly ESR) in collaboration with members of the Professional Association for Transgender Health Aotearoa, with providers of transgender healthcare, sexual health clinicians, and transgender people.

The 2018 and 2022 Counting Ourselves New Zealand Trans and Non-binary Health Surveys found that gender diverse people experience higher rates of sexual violence in comparison with cisgender people.

At PHF Science, we do forensic work for the New Zealand Police, but we are not part of the Police. Our job is to objectively figure out what may have happened, not to prove someone is innocent or guilty. In sexual assault cases, our forensic scientists often test items to determine what body fluids are present (e.g. semen) to help determine what happened (e.g. sexual contact). This information can be used as evidence in court to show what events have occurred.

Current body fluid forensic tests, however, have largely been developed and validated without considering gender diverse people. We do not know how applicable these tests are for sexual assaults involving gender diverse people. For example, how our tests for sperm may be impacted by feminising hormone therapy. We know there are cases which involve transgender women accused of sexual assault where semen was found ¹. These cases are often used to promote the harmful and false stereotype that transgender women are dangerous. However, we know that transgender women are more likely to be a victim of sexual violence, and a common effect of hormone therapy is reduction in sperm count and loss of ejaculation. Collecting specific information about this could enable us to provide statements to the police and lawyers, such as *“sperm was detected but is highly unlikely to be produced if on hormones for xyz amount of time - therefore this stain is unlikely to be deposited by this person”*. This might also help to add to what we know about fertility in people going through hormone therapy, which is a growing, but a largely unknown area of research.

We are also aiming to find out how the vaginal environment may change with hormone therapy or when surgically constructed. When forensic scientists find vaginal cells on a sample, this information can be used to support a claim that sexual contact has occurred. We want to know if our existing tests for vaginal material are still useful when hormone therapy or surgery is involved. If not, we aim to develop appropriate tests.

¹ “Takataapui TV: Transgender in Jail”, from <https://www.pridenz.com/gaynz/5934.html>

This study aims to address these gaps by examining whether gender-affirming care changes the detection of body fluids in forensic testing. We will review all available body fluid tests, so future data is more representative of everyone in Aotearoa New Zealand.

We know that a medical examination following sexual assault can be difficult and re-traumatising. Survivors place a lot of trust in the people conducting these examinations and tests, and we need to ensure that the science behind this process is robust and trusted by the community, victims, and the justice system.

HOW IS THE STUDY DESIGNED?

This study involves two parts, an Online Survey, and a one-off collection of samples (Sample Study). We are aiming for at least 100 people to participate in the Sample Study, but will proceed with less depending on number of participants.

We will carry out forensic testing for different body fluids on the provided samples. We may also use them to develop new tests for body tissues or fluids relevant in sexual assault cases.

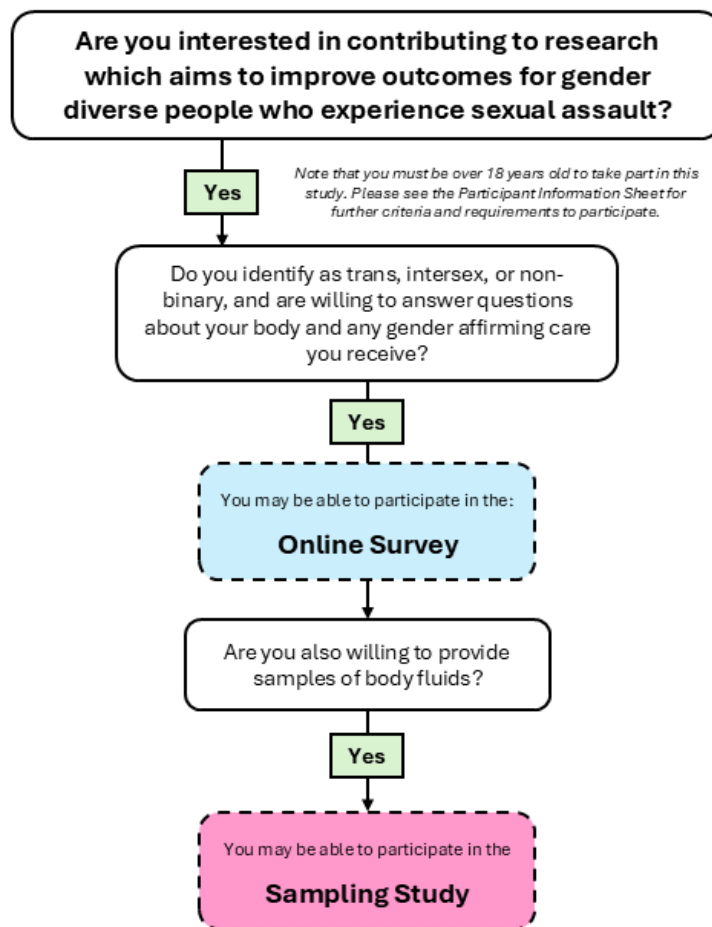
You will not be requested to change any aspect of therapy or treatment you are on. No clinic visits or inpatient stays will be required. You can take the samples in your own home. A brief questionnaire will accompany the sample pack.

WHO CAN TAKE PART IN THE STUDY?

This study has the following inclusion criteria (noting that not all of these apply to everyone's body):

- The participant is 18 years or older, is trans, non-binary and/or intersex, and is willing to disclose their gender identity, and sex assigned at birth
- May be on gender affirming hormone therapy and willing to disclose type, dose, length of time on hormones, and testosterone/estrogen level at time of filling out the survey/questionnaire, if known
- May or may not have undertaken gender affirming genital surgery and are willing to disclose these surgeries if so
- For the Sampling Study (**this does not apply if you only want to do the online survey**): Willing to donate after 7 days of abstinence from penetrative (penis in vaginal or anal) sex and 24 hours after oral sex, whichever fluids apply to you. We know these may not be possible depending on the hormones you are taking:
- Semen sample (if applicable, we understand that if you are taking gender affirming hormone treatment you may not be able to ejaculate)
 - Swabs of penis (if applicable)
 - Vaginal swabs (if applicable)
- Menstrual blood (if applicable, we understand that if you are on testosterone, you are unlikely to be bleeding)

- Anal swabs



WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document and complete the Online Survey. If you choose to participate in the sampling study, you will provide your postal address and be sent a courier bag with a sample pack, information sheet, consent form, and sampling instructions in it. You will be asked to collect samples of body fluids relevant to you (self-collected in the privacy of your own home) and complete a questionnaire. Reading the Participant Information Sheet (this document), the consent form, and answering the consent form will take a maximum of 30 minutes. The Online Survey should take a maximum of 30 minutes. If you are donating samples, the accompanying questionnaire should take a maximum of 30 minutes. You can keep the Participant Information Sheet.

The collection of samples will require a maximum of 30 minutes of your time except of the collection of any vaginal and menstrual swabs if those apply to you, as these will need to be collected apart from each other over your cycle. You can donate as many or as few samples as you would like. Once you have finished donating samples, you will send them back to us (we will provide a pre-paid courier bag).

WHAT WILL HAPPEN TO MY BODY FLUID SAMPLES?

The samples you donate will be stored securely at PHF Science and will be labelled with a code rather than your name. Your name and other identifying information will only be known by two representative members of the research team (the intermediary team members) and will not be disclosed in any publications or to the rest of the research team.

As a voluntary participant you possess the right to withdraw from this project without providing a reason for up to 4 weeks after sample donation. If you choose to withdraw, you can decide whether you want us to still use your samples you have provided in the last 4 weeks. You can also ask that the donated sample is destroyed or, if you prefer, returned to you. After 4 weeks' time, we may have already begun testing the samples.

Your samples will be tested for various markers for different body fluids. No DNA profiling or analysis will be done on your samples.

If there are remaining samples, these will be stored until the completion of the research in a secure -80°C or -20°C freezer. If you indicate (at the end of this form) you are willing to be approached in the future for your samples to be used for future research, these samples will be retained for 6 years (after which the consent forms and samples will be destroyed). Any remaining samples will be destroyed unless you tell us you want your samples to be returned to you. We acknowledge that for some people, bodily tissue carries genealogy, spiritual essence and sacredness that connects you to your ancestors and future generations. Before consenting to tissue storage, we encourage you to seek guidance from those who hold knowledge about your cultural practices before making your decision.

Data obtained from the donated samples will be stored indefinitely on PHF Science's digital storage system. If you participate, you will be randomly assigned a code, so your name is not associated with your donated samples. Your identity will only be accessible by the two members of the research team in charge of this information (the intermediary team members). Consent forms (identifiable information) will be kept securely in a locked cabinet at PHF Science for 6 years, following which they will be destroyed.

The data gathered during this research could be used to advance forensic science knowledge and improve investigative practices that could assist future cases. Findings could be published in peer-reviewed scientific journals or presented at conferences to share knowledge with other forensic scientists working in this field. Your identity will remain confidential in all publications and presentations, and no information that could identify you will be included in any published material.

Following the completion of this research, the summary of the results obtained will be available for all participants and you can request a copy by ticking this on the consent form.

WHAT ARE THE POSSIBLE RISKS OF THIS STUDY?

You may find the collection of samples causes discomfort. Taking samples from genitalia may lead you to feel gender dysphoria. If this is the case, please feel free to seek support from any of the organisations listed at the beginning of this document, your family, whānau, and friends. Minimal physical discomfort may also occur. A finger prick is required to provide a blood sample, and the insertion of swabs into the vagina or rectum can be uncomfortable. If you do not wish to provide these samples, you do not have to.

If you are living in shared accommodation with people who do not know you are transgender, non-binary and/or intersex, there is a slight risk that participating in this study may 'out' your gender identity to them. To avoid this, we will make the sampling process as discreet as possible. The sample packs will be sent to you (to an address you provide) in a non-descript courier bag. Within this there will be an unlabeled large envelope containing smaller envelopes for individual sample types. These smaller envelopes will be labelled with a simple sample code, e.g. SE for semen, and your specific donor code. The details of the samples and their codes will be in the sample collection instructions. All of the samples can be stored at room temperature and can stay in your room or anywhere else you feel is secure. You will only be contacted by the named researchers above through email.

Incidental findings (unexpected information from the test) are unlikely. We will not be doing any tests which directly tell us about your health or any diseases. We will not be undertaking any DNA profiling or analysis in this study and therefore will not be able to identify any differences in chromosome count (e.g. Klinefelters or Turners). If you donate semen, there is the possibility that we may identify a low sperm count or the absence of sperm. If you are on estrogen or testosterone blocking medication, this is likely expected, but you may not be aware of it. There is a small chance that an anal sample could reveal the presence of blood. This could warrant further investigation for bowel cancer. If either event was to occur, it would be the responsibility of the representative researchers to discreetly inform you and advise you to see an appropriate healthcare professional (this will not be paid for by PHF Science). If you DO NOT want to be informed of these incidental findings, you are asked to record this on the Consent Form (at the end of this document).

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You will receive a koha of a \$10 gift card if you donate any of: blood, saliva, and cheek swab samples. If you donate any anal, semen, penis, vaginal, or menstrual swabs, you

will receive an additional \$10 voucher per type, up to a maximum of \$40. For example, if Ella donates blood, cheek swabs, vaginal swabs, and anal swabs, they get a \$30 voucher. The other benefits of this study are directly related to the research conducted. This research aims to ensure that the science behind this process is robust and trusted by the community, victims and the justice system.

WILL ANY COSTS BE REIMBURSED?

Postage costs will be covered by the research team, as you will be sent pre-paid courier bags. It is anticipated that no other costs will be incurred.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the researchers will record information about you and your study participation. This includes the results of any tests and your answers to the questionnaire. You may not take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only the two intermediary members of the research team will have access to your identifiable information. Including within this is your IP address, which will be collected as part of the survey to remove duplicate submissions.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the researchers. Instead, you will be identified by a code. The two intermediary members of the research team will keep a list linking your code with your name, so that you can be identified by your coded data if needed, for example, to communicate results to you or any incidental findings if you agree to these on the consent form. If you donate samples, your code will be used to link your survey response to data obtained from testing these samples. No other information from other sources will be linked. De-identified information may be used by supervised machine learning methods during analysis for greater accuracy.

The de-identified results of the study will be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

If you agree, your coded information may be used for future research related to improving sexual assault testing in cases involving gender diverse people. This is completely optional and you can indicate whether or not you agree to this on the consent form. Your information may be added to information from other studies, to form much larger sets of data. You can also indicate on the consent form whether you agree to be contacted to participate in future research as part of our ongoing research programme. If you agree, this would involve completing a new consent form relevant to this research, and may involve providing new samples (or allowing us to use samples collected from this current study) and filling out new questionnaires.

Security and Storage of Your Information.

Data obtained from the donated samples will be stored indefinitely on PHF Science's digital storage system. If you participate, you will be randomly assigned a code for your donated samples instead of your name. Information regarding your identity will only be accessible by the two intermediary researchers. Consent forms (identifiable information) will be kept securely in a locked cabinet at PHF Science for 6 years, following which they will be destroyed.

The data obtained during this research could be utilised in the publication of scientific papers in peer-reviewed journals or presented at conferences. No results used for publication will be identifiable.

Following the completion of this research, the summary of the results obtained will be available for all participants and you can request a copy by ticking this option on the consent form.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

This research includes basic information such as age, gender, and sex assigned at birth. It is possible that this research could one day help people in the same groups as you.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected. Please ask if you would like to access this information. If you have any questions about the

collection and use of information about you, you should ask the research team members listed at the end of this document.

Rights to Withdraw Your Information.

If you do want to take part now, but change your mind later, you can withdraw your samples and information from the study up to 4 weeks after donating samples by contacting the intermediary members of the research team. After this time, we may have already begun testing the samples. Please read 'What Happens After the Study or If I Change My Mind' for further information.

Māori Data Sovereignty

Māori data sovereignty is about protecting information or knowledge that is about (or comes from) Māori people. We recognise the taonga of the data collected for this study. To help protect this taonga:

- We have consulted with Helena Rattray, Kaiputaiao Social Scientist at PHF Science about the collection, ownership, and use of study data.
- We have consulted with Grace Feltham and Georgina Dawson from the Māori Impact Team at PHF Science about the collection, ownership, use of study data and the data/tissue management plan.
- We allow Māori organisations to access de-identified study data, for uses that may benefit Māori.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

After the study, we may contact you for the following reasons (if you have said YES to these on the consent form):

- 1) To tell you if we found any unexpected results (incidental findings)
- 2) To send you a summary of the results
- 3) To ask if you want to participate in further research

You can withdraw from this study at any time without needing to provide a reason by contacting one of the intermediary researchers. We will stop collecting any **further** information or samples from you. You can tell us if you still want to be contacted for any of the reasons above or not.

If you completed the Online Survey only:

If you only took part in the online survey and did **not** donate a sample, you can request for your consent to be withdrawn at any time, up until 4 weeks after completing the

survey and we will delete your survey responses from our records. After 4 weeks, the survey information will have been analysed and be included in draft manuscripts. The participant can contact the two intermediary research team people to ask for their data to be withdrawn up until that 4 week mark.

If you donated any samples:

- **Within 4 Weeks of Sample Donation:** You may choose what happens to your sample:
 - Allow us to continue using it,
 - Request that it be destroyed, or
 - Ask for it to be returned to you.
- **After 4 Weeks of Sample Donation:**
After 4 weeks, we may have already begun testing your sample. You can still withdraw your consent, but your previously donated sample may continue to be used in research. Your survey information will also still be used, as we will need this for analysis.

CAN I FIND OUT THE RESULTS OF THE STUDY?

The data obtained during this research could be utilised in the publication of scientific papers in peer-reviewed journals or presented at conferences. No results used for publication will be identifiable.

Following the completion of this research, the summary of the results obtained will be available for all participants and you can request a copy by indicating such on the consent form and providing an email address.

WHO IS FUNDING THE STUDY?

The Ministry of Innovation, Business, and Employment (MBIE) has funded this research project through the Strategic Science Investment Fund (SSIF). The affiliations of the investigators are listed with their contact information at the end of this document.

WHO HAS APPROVED THE STUDY?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Health and Disability Ethics Committee has approved this study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Rachel Fleming, Science Leader (Intermediary team member)
+64 9 8451736
Rachel.fleming@phf.science.nz

Courtney Lynch, Senior Scientist (Intermediary team member)

+64 9 871 1827

courtney.lynch@phf.science.nz

For Māori cultural support please contact:

Georgina Dawson, Māori Impact Manager

+64272669134

georgina.dawson@phfscience.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Email: hdecs@health.govt.nz

Phone: 0800 400 569 (Ministry of Health general enquiries)