

PARTICIPANT INFORMATION AND CONSENT FORM (PICF)



Participant Information and Consent Form

Full Project Title: A trial of annual anal examinations (AAE) to detect early anal cancer in HIV positive men who have sex with men

Principal Researcher:

Professor Christopher Fairley, Melbourne Sexual Health Centre, University of Melbourne

Associate Researchers in Victoria:

Dr Tim Read, Melbourne Sexual Health Centre

Associate Professor Jane Hocking, University of Melbourne

Professor Jennifer Hoy, Alfred Hospital

Dr Sandra Walker, Melbourne Sexual Health Centre

Associate Professor Marcus Chen, Melbourne Sexual Health Centre, University of Melbourne

Associate Professor Catriona Bradshaw, Melbourne Sexual Health Centre, University of Melbourne

Dr Beng Eu, Prahran Market Clinic

Dr Richard Moore, Northside Clinic

Dr BK Tee, Centre Clinic

1. Introduction

You are invited to take part in this research project because you are 35 years or older, have had sex with men and have HIV infection, and are therefore at higher risk of anal cancer than the general population. This study is trying to work out if we can diagnose anal cancer when they are smaller and easier to treat.

This Participant Information and Consent Form tells you about the research project. It explains what is involved to help you decide if you want to take part.

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 your local health worker. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether you choose to take part or not.

If you decide you want to take part in the research project, you may 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 procedures 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 project?

The purpose of the research project is to determine if the introduction of yearly anal examinations will detect anal cancer at an earlier stage than it has been diagnosed previously. When anal cancer is detected earlier when it is smaller and easier to treat, the chance of cure is higher. The project will also look at the role that Human Papillomavirus type (HPV) 16 might play in detecting anal cancer early.

We are seeking between 200-600 men who have had sex with men and have HIV from each of the following clinics: Melbourne Sexual Health Centre, Alfred Infectious Diseases Clinic, Prahran Market Clinic, Centre Clinic and Northside Clinic.

The results of some of this research will be used by the researcher Dr Jason Ong to obtain a PhD degree.

This research has been initiated by Professor Christopher Fairley and is funded by National Health and Medical Research Council.

3. What does participation in this research project involve?

Participating in this research project will involve a number of different things over a five year period.

Firstly it will involve your doctor performing an anal examination once a year. This involves them having a careful look at the area around your anus and then putting a gloved finger into your anus to detect small lumps that may be early anal cancer. We'll remind your doctor when this examination is due and we will also contact you through your preferred method to let you know it is time for your next examination.

At your first visit we'll ask you to complete a questionnaire about your general health, any anal symptoms you may have and some questions about the potential risk factors for anal cancer, including sensitive questions about sexual activities over your life time and the last 6 months. Two weeks after your first examination, you will be asked to fill out a brief questionnaire about your experience of the anal examination.

At the start of the study and at the end of the study 5 years later, we will ask you to collect an anal swab (or by the doctor if you prefer). These swabs will be analysed for human papillomavirus (also known as wart virus) to see if the small number of individuals who develop anal cancer have this virus more commonly than those who do not and to better understand how HPV is transmitted. We don't propose to provide participants with the results because the presence of this virus will not change your health care in any way.

You will also be asked to complete a brief yearly questionnaire in order to find out if you

had an anal examination that year and whether this resulted in any further investigations or referrals to other health care providers. The survey can be completed via post, email or online.

We are also seeking your permission to have a nurse review your medical file to work out what tests you had or doctors you saw as a result of the examination. The reason for this is to work out if these examinations have resulted in any other medical services. If you are referred to another doctor for any procedures or treatment, we'd like your permission to obtain this information from those doctors as well.

To help us determine if there are any costs associated with anal cancer screening we would like your permission to obtain your Medicare records for referrals to other medical practitioners and medical procedures performed to investigate abnormalities found at your anal examinations. It does not involve any extra study visits, doctor visits or questionnaires. To take part you need to sign a separate consent form and provide personal details including your Medicare number for the Department of Human Services to release information about your use of healthcare services, to the ACES investigators. Information published from this part of the study would never identify any individual or reveal any Medicare number. This information will only be accessed from the date you signed the consent form.

We are also seeking your permission at the end of the study to ask the cancer registry if you have been diagnosed with anal cancer. We expect this to be very uncommon, but we need to do this to be sure that the results of the study are valid.

You will not be paid for your participation in this research.

In brief, this study asks you to have:

- A yearly anal digital exam by your HIV doctor
- An anal swab (at your first visit and last visit 5 years later)
- One questionnaire 2 weeks after your digital exam
- A yearly questionnaire over the next 4 years

4. What are the possible benefits?

By having an examination every year, it may be that if you develop anal cancer it will be diagnosed earlier than it would have otherwise been diagnosed. However, we cannot guarantee or promise that you will receive any benefits from this research.

If this study does show that anal cancer is diagnosed earlier this research may lead to the widespread introduction of examinations every year both in Australia and elsewhere.

5. What are the possible risks?

You might feel some embarrassment or discomfort from the anal examination.

If your doctor finds an abnormality that needs further investigation, they may refer you to another doctor for an opinion and further investigation as part of your medical care.

This examination is not intended to check for prostate cancer. However, during the examination if your doctor notices a prostate abnormality they will discuss this with you at the time.

6. 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. Your decision whether to take part or not, or to take part and then withdraw, will not affect your relationship with your doctor.

If you decide to withdraw, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing. If you decide to leave the project, the researchers would like to keep the health information that has been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them when you withdraw from the research project.

7. How will I be informed of the final results of this research project?

We will publish grouped (non-identifying) results of the study on the Melbourne Sexual Health Centre website at www.mshc.org.au/ParticipantSummaries.

8. What will happen to information about me?

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will only be used for the purpose of this research project. It will be disclosed only with your permission, or in compliance with the law. Your questionnaires will be stored in a password-protected electronic database. Your name will not be in the database but there will be a code allowing specific members of the research team to link the data to your name. This database will be kept for a minimum of 15 years and will only be accessible to members of the research team. Information about the management of anal or rectal abnormalities may be obtained from your health records at this and other health services for the purposes of this research. Access to the database that links the coded data to your name will be restricted to only the research staff working on this project that are based at Melbourne Sexual Health Centre, and only if it is necessary to carry out this project.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified. Results of anal examinations will be recorded in your clinic medical record.

9. Can I access research information kept about me?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of The Alfred Hospital.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

* Once a young person has turned 14 years old they must consent to their own information being released.

** Please attach supporting evidence

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Date of Processing	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	03/05/09	00023	Level B consultation	\$38.30	\$34.30	\$34.30	\$4.00	Cash Bulk Bill
22/06/09	23/06/09	11700	ECG	\$29.50	\$29.50	\$29.50		
Scrambled ordering Provider number*	Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode	Ordering Provider postcode	Hospital indicator	Item category		
999999A	999999A	20/04/09	2300	2302	N	1		
			2300		N	2		

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution	Net Benefit	Scrambled Prescriber number*	Pharmacy postcode
06/03/09	01/03/09	03133X	Oxazepam Tablet 30 mg	Concessional Ordinary	\$5.30	\$25.55	9999999	2560
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	\$30.85		9999999	2530
Form Category	ATC Code	ATC Name						
Original	N05 B A 04	Oxazepam						
Repeat	N05 B A 01	Diazepam						

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.

12. Who can I contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal researcher Professor Fairley on 9341 6241 or any of the following people:

Name: Dr Jason Ong
Role: Doctor and PhD Student
Telephone: 9341 6214

Name: Prof Christopher Fairley
Role: Researcher and Doctor
Telephone: 9341 6236

For complaints:

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:

Name: Ms Rowan Frew
Position: Manager, Office of Ethics and Research Governance, The Alfred Hospital
Telephone: 90763848