



PROSTATE
CANCER
OUTCOMES

REGISTRY
AUSTRALIA &
NEW ZEALAND



CHOMNZ | centre for health outcome
measures new zealand

Participant Explanatory Statement

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THIS IS FOR YOU TO KEEP

1. Introduction

A New Zealand Prostate Cancer Outcomes Registry has been established to improve the quality of care provided to men with prostate cancer. The registry collects data on the care and health outcomes for men who have been diagnosed with prostate cancer in New Zealand. Your voice and prostate cancer experience matter, so we are also gathering information from as many men as possible about quality of life before and after treatment.

PCOR-NZ is the New Zealand arm of the Prostate Cancer Outcomes Registry Australia and New Zealand (PCOR-ANZ), a trans-Tasman registry funded by The Movember Foundation, with the support of the Ministry of Health and all specialty medical societies managing prostate cancer disease.

This Participant Explanatory Statement has been sent to you in response to PCOR-NZ being notified of your recent diagnosis of prostate cancer. The notification has been received from either your hospital/clinic or the NZ Cancer Registry. The purpose of this statement is to tell you about the registry and to explain what it involves for you personally should you decide to participate.

Please read this information carefully. If you are unsure of or would like more information about anything you read, please feel free to ask. You may also like to discuss the registry with a relative, friend or your local health worker before deciding whether you would be happy to take part.

Participation in this registry is **voluntary**. You will receive the best possible care whether or not you decide to take part. You will automatically be included in the registry unless you “opt out”. You can opt out at any stage. **If you decide you want to opt out of participating in the registry, please contact us on 0800 008 436 or email us at pcornz@chomnz.org.nz**

2. What is the purpose of this registry?

The aim of PCOR-NZ is to improve the quality of care provided to men with prostate cancer. For the first time, doctors, researchers, and men affected by the disease are working together to improve the wellbeing of those diagnosed and living with prostate cancer. We expect to receive approximately 3000 prostate cancer notifications across NZ per year.

3. What does participation in this registry involve?

PCOR-NZ will collect information on your name, NHI number, date of birth, ethnicity, address and contact details; the date you were referred for diagnosis; the name of your diagnosing/ treating clinician and institution; clinical information related to your diagnosis such as staging and pathology results, and dates and details of procedures or treatment provided for your prostate cancer. At 12 months post-treatment, PCOR-NZ will collect your 12-month PSA level and add any additional

treatment you may have had since the initial data collection. Information will be collected by accessing your electronic or paper medical records either on site or via remote access to the hospital/private clinic patient management system, and only with approval from these institutes. Data will be collected by approved staff working in, or on behalf of, your hospital or specialists' clinic. In addition, if you have received treatment in another state/territory within Australia or in NZ, your information may be shared with other PCOR registries.

You may be asked to complete a 5-minute questionnaire to assess your quality of life, before treatment (i.e., within 90 days of diagnosis) and then again annually after treatment (treatment also includes the decision to adopt an "Active Surveillance" or "Watch and Wait" approach). Questionnaires can be completed via post, over the phone or online. To complete online, please send your email address to pcornz@chomnz.org.nz and we will send a direct link to you.

You may receive a phone call from a PCOR-NZ staff member if we have not received your questionnaire and you have not opted out of the registry. This call is an opportunity for you to ask questions about the registry or to advise us if you wish to opt out.

4. What are the possible benefits of participation?

While you will receive no direct benefit from contributing to this registry, your experience matters. Your involvement will contribute to a better understanding of the impact of different types of prostate cancer treatments and identify improvements to clinical care. A major indirect benefit from the registry will be the ability to monitor quality of care across Australia and New Zealand to ensure the delivery of the best possible health service to men with prostate cancer.

5. What are the possible risks?

Information within the registry is identifiable. Identifiable data refers to your National Health Index number (NHI), name, date of birth and address. This information is required to enable PCOR-NZ to collect data about your care from participating hospitals and clinicians. An allocated PCOR-NZ staff member will also have access to your medical record; however, they must comply with very strict privacy principles. Your data will be safeguarded by NZ policies and procedures, and laws and guidelines governing privacy and confidentiality.

The Health and Disability Ethics Committee have approved the storage of collected data on secure servers located in Sydney and Canberra, Australia. A backup copy of the data is stored in New Zealand at Centre for Health Outcome Measures NZ (CHOMNZ), 132 Peterborough St, Christchurch.

6. Do I have to take part in the registry?

Participation is voluntary. If at any stage, you decide you no longer wish to contribute to the registry, you can choose to:

A: opt-out of the registry, or

B: have clinical data collected but opt out of completing questionnaires [Data Collection only]

If you opt out, any information we may have collected will be removed from the registry except for your National Health Index number (NHI), name, date of birth and diagnosing date/clinician/institute. These details are kept to ensure we do not contact you again.

7. What will happen to information about me?

Some information collected by PCOR-NZ will also be included in the bi-national PCOR-ANZ. Data storage and security will be managed by Dacima Software and Movember who have ISO 27001-

certified Security Management Systems. As this is an ongoing registry, data will be kept indefinitely in a secure environment.

If you do not opt out, your identifiable data may be provided back to your treating clinician or hospital for quality assurance or care purposes. De-identified information collected about you may also be used for research purposes within New Zealand and overseas, but only for research that is scientifically sound and has appropriate approvals. You will not be identified in any published work.

Your NHI number may be used to link to other Ministry of Health related data collections to ensure accurate and complete data of PCOR-NZ and these collections. This will only be done with ethics approval and in accordance with relevant privacy laws and Ministry of Health protocols. Linkages may include the following:

- NZ Cancer Registry
- NZ Births, Deaths and Marriages Registry records
- NZ Radiation Oncology National Dataset
- NZ NHI Dataset (e.g., to collect ethnicity data where missing from your medical record; if no ethnicity available, it will be recorded as 'unknown' in PCOR-NZ)
- Urology Tumour Standards Dataset

8. Can I access the information kept about me?

In accordance with New Zealand privacy laws, you have the right to access the information collected and stored by the PCOR-NZ about you. Please contact us if you would like to access your information.

9. What is the oversight for this registry?

This registry has undergone an independent review and received approval from the Northern A Health and Disability Ethics Committee, which reviews national and multi-regional studies [ethics reference number 15/NTA/92]. Participating sites have approved local ethics and undertaken consultation with Maori as appropriate.

10. Who can I contact?

Further information concerning this registry can be obtained by contacting us on free-call number 0800 008 436 or emailing us at pcornz@chomnz.org.nz or through the PCOR-ANZ website www.prostatecancerregistry.org.

The attached questionnaire covers a range of subjects that are related to health and wellbeing. Some of these are sensitive or very personal. If you are concerned about your physical or emotional health and would like some help, you may like to contact:

- Your GP or treating clinician
- Cancer Society Helpline: 0800 226 237
- Prostate Cancer Foundation New Zealand: 0800 477 678
- Lifeline NZ: 0800 543 354

If you wish to contact someone, independent of the study, about ethical issues or your rights or to make a complaint, you may contact an independent health and disability advocate on:
Phone: 0800 555 050 or via email: advocacy@advocacy.org.nz