Irish Prostate Cancer Outcomes Research (IPCOR)

Patient Information Sheet

You are being invited to take part in Irish Prostate Cancer Outcomes Research (IPCOR) which aims to establish a cancer registry of all men newly diagnosed with prostate cancer in Ireland.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part it won't affect your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

What is a cancer registry?

When a person is diagnosed with cancer, the doctor and hospital record important details about the patient and their cancer. The **National Cancer Registry Ireland** has been collecting this data since 1994.

Cancer registries are set-up to:

- collect comprehensive information on all new cases of cancer occurring in a defined population
- collect information on cancer deaths in the same population
- store this information securely and permanently
- analyse the information and produce regular reports on the incidence and prevalence of cancer in Ireland

Why is a cancer registry necessary?

A cancer registry is the only way that we can investigate how many people are getting cancer and what types of cancer they have. Most countries in the world have a registration system including England, Wales, and Scotland. A cancer registry has been running for over 20 years in Ireland. By working with cancer researchers, cancer registries have been able to identify the causes of some cancers. It also allows us to look at how cancer patients are treated and how successful treatments have been for different types of cancer. A cancer registry helps us to ensure cancer screening programmes are working and shows whether the number of people getting cancer is going up or down, so the health service can ensure services and staffs are available in the right place.

The information registered about cancer patients is vital for research into cancer. Cancer registration is supported by all the main cancer charities.

Why is this Irish Prostate Cancer Outcomes Research registry being established?

In Ireland, the National Cancer Registry collects general information about all cancer cases in Ireland. This prostate cancer registry will provide more detailed information on your prostate cancer journey, the effects of the treatment(s) for your disease, with a particular emphasis on your experience of health care services and information provided to you and the impact of the disease on your physical and mental well-being. The prostate cancer registry will follow your progress after treatment. The results of this data will better enable doctors to gauge the quality of care you received, enable health service providers to plan better for future prostate cancer care pathways and ensure that improving patient experiences are at the heart of healthcare treatment and planning decisions.

Who is funding this research project?

This project is being funded Movember, an International Prostate Cancer charity, in partnership with the Irish Cancer Society.

Why am I being asked to take part in the registry?

You are being asked to take part in the registry as you have recently been diagnosed with prostate cancer.

What information will the registry collect?

We need to know some details about you (such as your name, address, age and sex). We need these details to make sure we are recording the right information about the right person. We also need to know about the type of cancer you have, the treatment/s you are receiving and your progress. We would like to know about the impact that prostate cancer and the treatments have had on your quality of life and everyday functions. We also need to know about other diseases or conditions you may have, for example, heart disease may affect survival so we would need to know if you have heart disease so we can accurately account for survival differences. We need this information to help us to identify possible causes of prostate cancer and to find which treatments are the best. The registry will analyse the data and produce public annual reports on the outcomes of prostate cancer treatment and care. You will be able to view these reports on the registry website. It is important to note that no patient, doctor or hospital will be identified in any of the annual reports.

Do I need to do anything?

If you consent to take part in this study, we will be asking you to:

A. Complete a number of questionnaires. You will need to complete some forms which will assess the impact that prostate cancer and the treatment/s have had on your quality of life and everyday functions. We will ask you to complete some questionnaires before your treatment starts and then annually from then on.

B. Give permission to allow your clinical and health related questionnaire data to be linked to your biological specimens and for your biological specimens to be used in future ethically approved research studies. Your biological specimens may include your biopsy and/or radical prostatectomy tissue or blood, urine, serum and saliva that are collected for diagnostic purposes or that you may have consented to be collected in a biobank. The biological specimens with the accompanying de-identified data will only be used in research studies that have received ethical approval from the relevant Research Ethics Committee and have been reviewed and approved by the IPCOR Steering Committee.

Participation in any aspect of this study is completely voluntary. It is up to you to decide whether you would like to take part in the entire study or whether you would like to participate in only part A or only part B of the study. You are fully entitled to refuse to complete the questionnaires (Part A) and/or link your data to your biological specimens and allow your biological specimens to be used in future ethically approved research (Part B). Your decision will not affect your care in any way.

What will it involve if I decide to take part?

If you agree to take part in the questionnaire study (A)

We will ask you to sign the Consent Form and return it to us. We will give you a copy of this Patient Information Leaflet and Consent Form to keep. Here is what will happen next:

a) A designated representative from the National Cancer Registry has sent you a number of questionnaires to complete along with this patient information leaflet and consent form. This first set of questionnaires has been sent to you to complete and return to us before your treatment starts. The National Cancer Registry will send your name and address to a designated researcher at the Clinical Research Facility in Galway who will send you follow up questionnaires annually.
b) We would ask that you fully and honestly complete the questionnaires as required and to send them back to us as per the instructions.

If you agree to link your clinical and patient health related questionnaire data to your biological specimens and for your biological specimens to be used in future research studies (B)

We will ask you to sign the Consent Form and return it to us. We will give you a copy of this Patient Information Leaflet and Consent Form to keep.

a) Your biological specimens, which are being collected as part of your regular treatment procedures or for the purposes of biobanking, will be labeled in such a way that they can be linked to your clinical data and questionnaires but you will not be named. This will be conducted by means of a unique numbering system.
b) Your biological specimens and your accompanying clinical and questionnaire data may be used in future research studies that have received ethical approval from the relevant Research Ethics Committee and have been reviewed and approved by the IPCOR Steering Committee.

What will we do with the data we have collected?

We are very careful with the data we collect and follow strict rules about how we look after it and who can use it. We store the information on computers in a safe place with secure passwords. It is all kept strictly confidential and is only available to appropriate staff. All the information we collect will be anonymised, password protected and encrypted. The information from your questionnaires will be stored on a HSE server based in Galway and on a secure database at the National Cancer Registry. Fully compliant with National Data Protection Standards, every effort will be made to keep your identity completely safe at all times. Reports that we publish will never identify any particular person, doctor or hospital.

What kind of research will my biological specimens be used for?

Your biological specimens may be included in studies which investigate different aspects of cancer risk, development and progression. Future research may be aimed at understanding the genetic influences related to cancer development and its growth as well as proteins that could be used for early detection and targeted for novel treatments. At this moment, it is not possible to give exact details about the projects in which your biological specimens may be included because the ideas for these projects have yet to be imagined. However, your biological specimens will only be included in projects which are ethical i.e. have been reviewed and approved by the relevant Research Ethics Committee and by the IPCOR Steering Committee.

What are the risks associated with taking part in this study?

There are no physical risks associated with completing questionnaires; linking your data to your biological specimens and allowing your biological specimens to be used in future ethically approved research.

What are the benefits associated with taking part in this study?

It is unlikely that you will directly benefit from the research, because many years are spent doing research and then implementing important findings. However, the results of the research will provide, we hope, new insights into better ways to treat and manage prostate cancer as well as more efficient and patient focused healthcare delivery. You will not benefit financially should research lead to a new test or treatment.

What happens if I change my mind?

You can change your mind at any time by contacting the Principal Investigator Mr David Galvin (david@ipcor.ie), or the project manager Áine Murphy (PM@ipcor.ie) or by contacting us via the website www.ipcor.ie . We will send you a form and when this form is completed and returned to the registry, data from your questionnaires will be destroyed and your clinical data and biological specimens will not be used. If you change your mind after a long period of time, clinical data, data from questionnaires and your biological specimens may have already been used. It is not possible for us to recall information and biological specimens from researchers once they have been used.

Who has approved this project?

The relevant ethics committee has reviewed and approved all aspects for this study including the patient questionnaires, the linking of your data to your biological specimens and the use of your biological specimens in future ethically approved research studies.