

## PARTICIPANT INFORMATION SHEET

<b>Title</b>	Pancreatic Cancer Pathways to Diagnosis Study
<b>Short title</b>	Pathways Study
<b>Protocol Number</b>	P3758 (RBWH - HREC/2021/QRBW/79630)
<b>Coordinating principal investigator</b>	Professor Rachel Neale

### 1. Would you like to take part in the Pathways Study?

We are inviting you to take part because you have been diagnosed with pancreatic cancer and we want to understand more about the ways in which people come to be diagnosed with pancreatic cancer. This information sheet tells you about the study.

Please read this information carefully and ask questions about anything that you don't understand or want to know more about (see section 10 for who to contact). Before you decide whether or not to take part, you might like to talk about it with a relative, friend, or your doctor.

**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 or not you participate.

### 2. What is the purpose of this research?

Pancreatic cancer is difficult to diagnose. The symptoms are often non-specific and there are no screening tests. Many people describe delays in diagnosis. The purpose of this research is to understand more about the signs and symptoms people experience, the journey people took from first experiencing symptoms to receiving their diagnosis, and the factors that might influence how quickly people are diagnosed.

We will use this information to develop ways to help patients in the future to be diagnosed as quickly as possible, and with fewer tests and treatments along the way.

### 3. Who is conducting this research?

This research is being led by the QIMR Berghofer Medical Research Institute, in collaboration with scientists and doctors from Australia, New Zealand, and the United States. A full list of collaborators is on our website. Please let us know if you would like us to send you a list.

### 4. What will I be asked to do if I take part?

If you take part you will:

- **Complete a survey.** You can complete a paper survey, or you can complete the survey online, by going to <https://qimrberghofer.edu.au/PathwaysStudy>. We estimate that the survey will take about 15 minutes to complete.
- **Take part in an interview** with one of our research staff. You can choose whether you would like the interview to be by telephone or using zoom videoconferencing. If you give permission, we will record your interview. We estimate that the interview will take about 30 minutes.

## 5. Can somebody else answer the questions on my behalf?

You can nominate somebody who is familiar with your health history to answer questions on your behalf. We will still need you to sign the consent form.

## 6. Will you access my health information?

We will ask for your permission to access information related to your diagnosis of pancreatic cancer, and other medical conditions that may have influenced your pathway to diagnosis. This information will help us understand your pathway to diagnosis. It will also inform a much larger national study where we will not be talking to patients directly. Allowing access to your medical records is optional.

We may seek information from:

- Your general practitioner: we may ask your general practitioner to complete a short survey about your health and how you came to be diagnosed with pancreatic cancer;
- Hospitals where you have received treatment: when you go to hospital, information is recorded in a database held by the health department. With your consent, we can access information from this database.
- Medicare Benefits Schedule and the Pharmaceutical Benefits Scheme. For more information about this, see the blue box below.
- Other government databases. We may obtain information from databases such as the register of deaths or state cancer registries.

### Medicare Benefits Schedule and Pharmaceutical Benefits Scheme Data

When you see a doctor, or have a test or procedure outside a public hospital, the information is recorded in a database called the **Medicare Benefits Schedule** (MBS). However, the database does not hold information about what you talked to the doctor about, or the results of your tests.

When you are dispensed a medication that is subsidised by the government, information such as the type of medication and the date it was dispensed are recorded in a database called the **Pharmaceutical Benefits Scheme** (PBS).

The MBS and PBS databases are held confidentially by Services Australia. We will ask you to sign a separate consent form if you are willing for us to obtain your complete MBS and/or PBS information from these databases; we will send the form securely to Services Australia. Information about the data we will obtain is on the back of the Services Australia consent form.

*Services Australia is not involved in the conduct of this study other than to release your Medicare Benefits Schedule (MBS) and/or Pharmaceutical Benefits Scheme (PBS) claims information.*

## 7. What are the possible benefits of taking part?

There are no direct benefits to you, although you might appreciate the opportunity to tell your story. We hope that this study will help future patients and their families who are faced with a diagnosis of pancreatic cancer. *We will offer you a \$20 Coles/Myer e-voucher to compensate you for your time.*

## 8. What are the possible risks of taking part?

There are minimal risks associated with taking part in this project. You may find it distressing to talk about how you came to be diagnosed with pancreatic cancer. If you do, you should let your interviewer or our project manager know; they will give you information about where you can seek support. With your permission, which we will seek at the time of your interview, we will write to your general practitioner to let them know of your need for support.

## 9. What if I decide to take part and then change my mind?

You can change your mind about taking part at any time and you do not have to give us a reason. For example, if you complete the questionnaire, you can decide not to take part in the interview. You can also stop the interview at any stage. You can ask us not to access your health data in future, or to destroy any data we have already collected.\*

If you have signed the Services Australia consent form (allowing us to access your MBS and/or PBS records) you

can withdraw this consent, and ask us to destroy any MBS/PBS information we have already obtained.\* This will not affect your access to health services or government benefits.

You can let us know if you would like to withdraw from any aspects of the study by telephone, email, or by writing to us.

\* Please note: if information about you has already been analysed or included in a publication it may not be able to be destroyed.

#### **10. What will happen when the research project ends?**

We will not contact you again after you have completed the interview, unless we need to check on some information you have given us. We may continue to obtain information from your medical records and the MBS/PBS for up to 5 years after all participants have been interviewed.

#### **11. What will happen to the information collected about me?**

By signing the consent form you consent to research staff collecting and using your personal information for the Pathways Study.

**Confidentiality:** We are very careful to maintain the confidentiality of your information. All of your data, including your MBS, PBS, and other health data, will be coded with a participant identification number and held separately from information that could identify you, such as your name and address. It will be stored securely on QIMR Berghofer's computer network, and only approved staff will be able to access it. We will never share your information that could identify you with anybody else.

**How long data are stored:** All the information we collect will be kept for at least 5 years after the end of the study. After this, your identifying information will be permanently deleted from the computer system, and any paper copies will be destroyed. This will make it impossible for anybody to link the information back to you.

**Inspecting the data:** Your health records and any information obtained during the research project can be inspected by relevant authorities, in order to verify the data. This includes authorised staff from QIMR Berghofer, Professor Rachel Neale, or other bodies as required by law. By signing the consent form, you authorise access to this confidential information for this purpose.

**Publishing and presenting the data:** The results of this research project may be published and/or presented in journals, newsletters, conferences, public presentations etc. The results will only be presented in such a way that you cannot be identified, except with your permission. For example, we will only report results for groups of people and not for individuals

**Accessing your information:** In accordance with relevant Australian and state privacy and other relevant laws, you have the right to request access to your information collected by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

#### **12. Will my information be used for any other studies?**

Sometimes information collected for one study is valuable for other studies. We may use your information in other studies related to cancer without notifying you. These will have to be approved by relevant ethics and scientific committees, and we will never share information that could identify you.

#### **13. Who is organising and funding the research?**

The research is being conducted by Professor Rachel Neale at the QIMR Berghofer Medical Research Institute and the Pathways Study group. It is funded by a research grant from PanKind, and has received some additional funding from Viatris (a pharmaceutical company). Neither PanKind nor Viatris will have access to the data, and they will have no influence over the results or their presentation. No member of the research team will receive a personal financial benefit from your involvement in this research project.

#### **14. Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the

QIMR Berghofer Medical Research Institute HREC and the Royal Brisbane and Women's Hospital HREC.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Services Australia has confirmed that this research and any associated documents is approved by a Human Research Ethics Committee (HREC) and is registered with the National Health and Medical Research Council (NHMRC).

The study is bound by Commonwealth and State privacy laws and must protect your anonymity and the confidentiality of your information to the fullest extent possible.

## 15. Support services for people with pancreatic cancer and their family/carers

- Pankind
  - Pancreatic Cancer Support Groups are listed on the Pankind website at: <https://pankind.org.au/living-with-pancreatic-cancer/support-groups/>
- Pancare Foundation
  - Supportive information is available at: <https://www.pancare.org.au/pansupport/>
  - Telehealth consultation with a counselling therapist by calling 1300 811 698, or at <https://www.pancare.org.au/living-well/telehealth-support/book-your-call-support/>
- Cancer Council
  - Professional support service can be accessed at: 13 11 20.
  - Online community forum at: <https://onlinecommunity.cancercouncil.com.au/>

## 16. What if I have a question or want to make a complaint about the study?

If you want any further information concerning this project you can contact one of the following:

For general questions about the study:

- The Principal Investigator: Professor Rachel Neale (07) 3845 3598 or [Rachel.neale@qimrberghofer.edu.au](mailto:Rachel.neale@qimrberghofer.edu.au)
- The Principal Investigator (RBWH): (07) 3846 7892 or  
Professor Benedict Devereaux [bdevereaux@ddq.net.au](mailto:bdevereaux@ddq.net.au)
- The Project Manager: Dr Bridie Thompson (07) 3845 3296 or, Freecall 1800 344 007  
[bridie.thompson@qimrberghofer.edu.au](mailto:bridie.thompson@qimrberghofer.edu.au)

If you wish to discuss the study with someone who is not directly involved, particularly in relation to matters concerning complaints about the conduct of the study, or your rights as a participant, you can contact any of the committees listed this [link](#).

If you have a privacy complaint in relation to the use of your MBS/PBS data you should contact the Office of the Australian Information Commissioner. You will be able to lodge a complaint with them.

Website: [www.oaic.gov.au](http://www.oaic.gov.au)

Telephone: 1300 363 992

Email: [enquiries@oaic.gov.au](mailto:enquiries@oaic.gov.au)

Mail: GPO Box 5218, Sydney NSW 2001

Your personal information held by Services Australia is protected by the Privacy Act 1988 and cannot be given to a third party without your consent or where otherwise permitted by law. For more information about privacy, go to [servicesaustralia.gov.au/privacy](http://servicesaustralia.gov.au/privacy)

## Contacts for concerns or complaints

QIMR Berghofer Medical Research Institute HREC Telephone: (07) 3362 0117 Email: HREC.Secretariat@qimrberghofer.edu.au	Royal Brisbane & Women's Hospital HREC Telephone: (07) 3647 1007 Email: RBWH-Ethics@health.qld.gov.au
Name: Research Governance Manager Position: Metro North Office of Research Telephone: (07) 3647 9550 Email: MNHHS-RGO@health.qld.gov.au	
The conduct of this study at Bankstown-lidcombe Hospital, Liverpool Hospital and Campbelltown hospital, has been authorised by the South Western Sydney Local Health District, any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer on (02) 8738 8304, email: SWSLHD-ethics@health.nsw.gov.au and quote project number [2022/STE00115].	
St Vincent's Health and Aged Care Human Research Ethics Committee Telephone: (07) 3435 1615 Email: svhac.hrec@svha.org.au	