**INSERT SITE LOGO/HEADER**

# Participant Information Sheet/Consent Form

***[Insert site name]***

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|---|---|
| **Title** | *The West Australian Barrett's Oesophagus Registry* |
| **Short Title** | *WABOR* |
| **Protocol Number** | *Version 3.0 dated 27-Feb-2020* |
| **Coordinating Principal Investigator** | *Professor Krish Ragunath* |
| **Site** | ***[Insert site name]*** |
| **Principal Investigator for site** | ***[insert site PI name]*** |
| **Associate Investigator(s) at site** | ***[insert site AI names]*** |

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**Introduction**

You are invited to take part in the Western Australian Barrett's Oesophagus Registry (WABOR). This is because you have recently been diagnosed with or are undergoing surveillance for Barrett's Oesophagus. The research project aims to understand the current extent of Barrett's Oesophagus in Western Australia, to reveal gaps in our understanding of the condition and develop efficient pathways for diagnosis, monitoring and early intervention.

This Participant Information Sheet/Consent Form contains five pages and tells you about the research project. It explains what will happen to your data and the research involved. Knowing what is involved will help you decide if you want to take part in the Registry.

Please read this information carefully and ask questions about anything that you don't understand or want to know more about. You are free to take this form away and discuss participation with others such as your GP, family or friends before signing the form.

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 your data is entered in the Registry or not. If you decide you want to take part in the research project, you will be asked to sign the consent form which is page five of this document. By signing the consent form, you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- 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.

**What is the purpose of this research?**
Barrett's Oesophagus is a condition in which the lining of cells in the lower oesophagus change in response to repeated exposure to stomach acids, such as occurs with acid reflux. There is some evidence that the number of people with Barrett's Oesophagus is increasing in Australia and elsewhere. However, the lack of complete and accessible data makes it difficult to undertake research and there is no standardised approach to monitoring and treating the condition. In conjunction with [SITE SPECIFIC], Curtin University is conducting a clinical registry for patients with Barrett's oesophagus.

Clinical registries are large databanks of health information used to assess and report on the effectiveness of treatments within specific areas of the health service. Information collected by clinical registries can help to assess whether approaches to disease management are safe and effective and delivered in a timely and appropriate manner. In order assess the effectiveness of current management strategies for Barrett's oesophagus, we need to collect information on the care current patients are receiving and track their condition over time. To achieve this, the Western Australia Barrett's Oesophagus Registry (WABOR) has been set up to collect information about Barrett's Oesophagus treatments and interventions.

Establishing a WA Barrett's Oesophagus clinical registry will help researchers to understand how many people have this condition and the risk factors associated with it. It will allow us to evaluate current methods for managing the condition and observe the outcomes of such approaches on patient health.

Knowing this information may help us to formulate improved strategies for screening, diagnosis and treatment of the condition which may result in improvements for Barrett's oesophagus sufferers in the future.

This research has been initiated by Professor Krish Ragunath and initial funding has been provided by Curtin University.

**What does participation in this research involve?**
If you agree to participate in this registry you will be required to complete a short questionnaire on symptoms you may be suffering. After completing this, your remaining consultation will be as per your normal standard of care. Some of the information obtained at your specialist appointment may be included in the registry database, including endoscopy findings and pathology results, however these will be collected from your medical records.

Contributing to this registry will cost you nothing, nor will you be paid.

**What information is collected?**
The types of information collected will include;

- General demographic information including gender, date and country of birth and race
- Lifestyle information including smoking and alcohol consumption
- Physical information including weight, height and waist and hip circumference
- Details of personal and family medical history
- Details of medication use
- Frequency and severity of your symptoms related to Barrett's Oesophagus
- Information related to your endoscopy including findings, treatments and complications
- Information related to pathology of collected biopsy tissues

This information does not exceed that which is already stored in your medical records.

No identifiable information about you will be stored in the Registry database where you will be identified by an ID number. However, identifiable information will be kept in a secure, restricted access folder on a Department of Health server. This is because we need to be able to link data from future consultations back to your registry file in order to track your future health outcomes.

**How is the information stored?**
Data from all participating Western Australia hospitals will be pooled together and maintained securely by the Centre of Clinical Research and Education (CCRE) at Curtin University. The CCRE have considerable experience managing registries across the health sector.

Data will be stored electronically on a secure password-protected, isolated computer environment housed at Curtin University and accessible only to Registry Data Managers. The registry will retain the information we collect for an indefinite period because we hope to track the long-term results and outcomes of participants with Barrett's Oesophagus into the future.

**Do I have to take part in this research project?**
No. We understand that not everyone is comfortable to have their personal details documented in a databank. 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 by contacting WABOR directly. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment or your relationship with those treating you.

**What are the possible benefits of taking part?**
There will be no clear benefit to you from your participation in this research. However, improvements in the diagnosis and treatment of Barrett's Oesophagus may arise from the study which could potentially benefit you or others with the condition in the future.

**What are the possible risks and disadvantages of taking part?**
Any information obtained for the purpose of this registry that can identify you will be treated as confidential and stored securely. Identifying information is protected by privacy legislation and would only be disclosed with your permission, or in compliance with the law. All data will be safeguarded by State and Commonwealth privacy laws.

To ensure that your private information is safeguarded, registry staff must comply with very strict privacy principles.

**What will happen to information about me?**
It is anticipated that the results of this research project will be published in scientific journals and presented in a variety of forums such as conferences. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

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

Researchers may use de-identified, group data for future research projects, however any further research undertaken using WABOR data will require additional approval by a Human Research Ethics Committee. Please be aware that by consenting to having your information stored in the Registry, you agree that the information collected may be used for further research relating to treatments and outcomes of patients with Barrett's oesophagus. This may include ongoing linkage to other hospital data and datasets kept by the WA Department of Health such as WA cancer and mortality registries for the purpose of attaining information about long term health outcomes. De-identified data may also be aggregated with other national and international Barrett's Oesophagus registries. Future data linkage would only be possible after gaining additional ethical approval. To protect your privacy, all linkage activities are bound by privacy legislation and must meet specific privacy and security conditions before ethical approval is granted. The data provided for further research would not contain any identifying information.

Any future access to registry data by other organisations or researchers will be approved by a Human Research Ethics Committee and will be bound to the same State and Commonwealth legislations.

**Who is organising and funding the research?**
This research project is a collaboration between gastroenterologists from public hospitals in Western Australia, and clinical researchers from PathWest and Curtin University. Funding to establish the registry has been provided by Curtin University. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**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 HREC of the Sir Charles Gairdner and Osborne Park Health Care Group (SCGOPHCG).

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

**Further information and who to contact**
If you want any further information concerning this project, you can contact

**Clinical contact person**

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|---|---|
| Name | *Professor Krish Ragunath* |
| Position | *Professor of Medicine, Curtin University* |
| Telephone | *9266 5824* |
| Email | *krish.ragunath@curtin.edu.au* |

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:

**Reviewing HREC approving this research and HREC Executive Officer details**

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|---|---|
| Reviewing HREC name | *Sir Charles Gairdner Osborne Park Health Care Group (SCGOPHCG) HREC* |
| Telephone | *6457 2999* |
| Email | *HREC.SCGH@health.wa.gov.au* |

# Consent Form

| | |
|---|---|
| **Title** | *West Australian Barrett's Oesophagus Registry* |
| **Short Title** | *WABOR* |
| **Protocol Number** | *[Protocol Number]* |
| **Project Sponsor** | *Curtin University* |
| **Coordinating Principal Investigator/ Principal Investigator** | *Professor Krish Ragunath* |
| **Associate Investigator(s)** *(if required by institution)* | *[Associate Investigator(s)]* |
| **Location** *(where CPI/PI will recruit)* | *[Location where the research will be conducted]* |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

**Declaration by Study Doctor/Senior Researcher**†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.