APTCQR

Australian Proton Therapy
Clinical Quality Registry

SAHMRI
South Australian Health & Medical Research Institute

AUSTRALIAN BRAGG CENTRE
FOR PROTON THERAPY
AND RESEARCH

TROG CANCER RESEARCH

About the APTCQR Registry

This patient information sheet explains why this research study is being done, what is involved in participating in the APTCQR Registry, the possible risks and benefits of your participation, and your rights as a research participant. The decision to participate is yours and you can ask for more information if you are not sure.

Because information about you and your health is personal and private, it generally cannot be obtained without your written permission. However due the nature of this registry your written consent is not being obtained, instead your private personal information will be included in the registry unless you indicate you do not wish to participate in this study. This means that members of the research team may obtain information regarding your past medical history from previous health care providers such as hospitals and other treatment centres.

We encourage you to take some time to read this information sheet think this over, to discuss it with other people and your treatment team, and to ask questions now and at any time in the future.

The aim of the APTCQR registry is to enroll patients who have been treated with radiation in order to better understand and compare the short and long-term benefits of the different types of radiotherapy. The information collected from this study will help us and other researchers learn more about radiation treatment.

The purpose of the registry is to collect demographic information (like age, ethnicity, gender, post code) and clinical data (such as diagnosis, treatments and side effects) about patients who receive radiation therapy.

You will still receive treatment and follow up care for your diagnosis as determined by your treating Radiation Oncologist. All treatments that you receive will be recorded by the study, including treatment outcomes, side effects, and progression of your disease, this will be collected as the information becomes available.

A Data Manager will review this annually to update your treatment information in the database. Participation in this study and registry will in no way change the medical treatment given to you.

What information is collected?

The following data will be collected and stored in the registry:

- Patient demographics, date of birth, gender, ethnicity, post code, date of diagnosis
- Type of tumour or clinical diagnosis and disease staging information
- Imaging studies, treatment planning studies, and tumour measurements
- Routine bloods tests, hormone levels, and any relevant laboratory results needed to assess you at baseline and any follow-up visits
- Referring physician contact information
- Information regarding ongoing care for your condition.

Treatment Data Collection: The following data regarding treatment will be collected:

- Treatments you received before radiation therapy, including previous radiation therapy, surgery, and chemotherapy, dates and number of cycles, and results of chemotherapy if available
- Dates and doses of radiation treatment
- Medical imaging or scans
- Any side effects observed
- Any treatments you received at the same time as radiation therapy

Follow-up Data Collection: The following data will be collected annually following completion of your radiation therapy treatment:

- Disease and survival status
- Hospitalisations, surgeries or other procedures
- Any new medical conditions diagnosed
- Any laboratory results, including x-rays
- Medications you are taking
- Late side effects such as hearing loss, hormonal issues or cardiac issues
- Development of any new types of cancers
- Any treatment after your radiation treatment.

Privacy and confidentiality

In addition to research personnel at your treatment centre, there are others that may have access to the identifiable data collected. This includes:

- Other research doctors and medical centers participating in this research, if applicable.
- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research.

Some of your identifiable data will be accessed and shared with organisations we intend to request a range of your health datasets from; these include and are not limited to:

- Medicare Benefits Schedule (MBS)
- Pharmaceutical Benefits Scheme (PBS)
- Births, Deaths and Marriages
- National and state cancer registries.

All identifiable data will be shared via a secure platform and only made available in order to match your records and improve data collection.

The research team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do additional research. There may be a legal requirement to pass on personal information to authorised third parties. This requirement is standard and applies to information collected both in research and non-research situations. Such requests to access information are rare; however, we have an obligation to inform you of this possibility.

What are the risks and benefits?

There are minimal risks involved compared to the overall benefits of this registry. Your involvement in this registry and data collected will help to inform future policies and radiation treatment practices in Australia. The follow up toxicity data will provide evidence for any future Medicare Services Advisory Committee (MSAC) applications ensuring both access and equity of care for all Australians with a cancer diagnosis who receive radiation treatment.

What are my rights?

You have the right to choose not to participate in this study. By completing the optout section on this information sheet or telling your treating team you do not wish to participate within 14 days of receiving this information sheet. If we do not receive a response from you in this time your information will be recorded onto the registry.

You can stop being in the research study at any time. By either contacting our coordinating centre via email on APTCQR@sahmri.com or informing your Radiation Oncologist. Leaving the research study will not affect your medical care outside of the research study.

You will not be paid to participate in this research study, taking part in this research study will not lead to any added costs for you.

Statement of privacy rights:
You have the right to withdraw your consent to the study at any time now and in the future. We will not be able to withdraw all the information that already has been used or shared on the registry. To withdraw your consent, you must do so in writing by contacting the coordinating centre via email: APTCQR@sahmri.com

You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment, but you may access this information only after the study is completed. To request this information, please contact the coordinating centre.

Reporting

The registry will provide yearly statistics relating to case accrual and outcomes to SA Health and the Federal Department of Health. A more detailed written report will be provided on an annual basis to clinicians, participating hospitals and their ethics committees. Organisations, including commercial ventures, providing funding to the registry will also receive a formal written report on an annual basis including aggregate data reports and analysis of patients included in the registry.

Coordinating Centre

The South Australian Health & Medical Research Institute is the coordinating centre (SAHMRI) for this study. Information collected as part of this study will be stored on a web-based electronic collection system as part of a password secured and firewall protected system.

Contacts
Chief Principal Investigator:
Associate Professor Hien Le
Project Manager: Kelly Skelton

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

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chair, on 7117 2229 or 8222 6841.

Should you wish to participate in this study you do not need to do anything.

Should you **NOT WISH** to participate in this registry please complete the section below and give to your treating team or email the coordinating centre on APTCQR@sahmri.com to withdraw your consent.

I **DO NOT** wish for my information to be collected on the APTCQR Registry

Full name: _____

Signature: _____

Date: _____

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