



AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS POLICY

Version: 1
Date: 26 August 2018

Monash University

School of Public and Preventive Medicine
Faculty of Medicine, Nursing and Health Sciences

CONFIDENTIAL

This document is confidential and the property of Monash University. No part of it may be transmitted, reproduced, published, or used without prior written authorization from the institution.

Statement of Compliance

This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007), Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95), ASCSQH Operating Principles and technical standards for Australian Clinical Quality Registries, University research policies and procedures and federal laws governing privacy and confidentiality.



ANZTCR COORDINATING CENTRE CONTACT DETAILS

Address: Australian & New Zealand Thyroid Cancer Registry
Public Health & Preventive Medicine
Monash University, Alfred Hospital Campus
533 St Kilda Road
Melbourne, Vic, 3004

Email: SPHPM.ANZTCR@monash.edu

Website: ANZTCR.org.au

IMPORTANT CONTACT INFORMATION

Registry Coordinator

Dr Liane Ioannou

Phone: (03) 9903 0046

Email: liane.ioannou@monash.edu

Clinical Lead

Professor Jonathan Serpell

Phone: (03) 9076 3290

Email: serpellj@bigpond.com

Academic Lead & Data Custodian

A/Professor Susannah Ahern

Phone: (03) 9903 0139

Email: susannah.ahern@monash.edu

DOCUMENT VERSION CONTROL

Version	Date	Reason/Comments/Approvals
1.0	21.08.2017	Initial Version Release. Proposed to ANZTCR SC on 25.07.17



CONTENTS

ANZTCR Coordinating Centre Contact Details	2
Document Version Control	2
Contents	3
1. Preface.....	4
2. Project Information.....	4
2.1 PURPOSE OF ANZTCR.....	4
2.2 PROJECT OVERVIEW	4
3. Definitions	5
4. Access To Data Held By ANZTCR	6
4.1 ELIGIBLE APPLICANTS	6
4.2 ACCESS TO ANZTCR DATA.....	6
5. Requesting Data.....	8
5.1 DATA ACCESS REQUEST PROCESS	8
5.2 REQUEST FOR NON-IDENTIFIABLE DATA.....	9
5.3 REQUEST FOR PATIENT RE-IDENTIFIABLE OR DE-IDENTIFIABLE DATA	9
5.4 PATIENT REQUEST FOR DATA ACCESS.....	9
6. Data Security For Patient Identifiable Information	9
7. Publication.....	10
8. Data Items	11
9. Forms.....	11
9.1 DATA REQUEST FORMS	11
10. Fees	11
Appendix A: Data Access Request – Researcher Form.....	12
Appendix B: Data Access Request – Non-Researcher Form	18
Appendix C: Data Access Request – Patient Form	23
Appendix D: Research Agreement	26
Appendix E: Confidentiality Agreement.....	30



This document describes the Australian & New Zealand Thyroid Cancer Registry (ANZTCR) guidelines and policies for governing the release of information for research purposes.

1. PREFACE

The Australian & New Zealand Thyroid Cancer Registry (ANZTCR) encourages the use of its data for a variety of purposes such as quality improvement, research, clinical planning and other activities that may lead to an improvement in care to patients with thyroid cancer. The ANZTCR will only facilitate access to its data for projects that meet appropriate standards of scientific merit and public health importance as determined by the Management and/or Steering Committee. This data access policy defines how data from the ANZTCR may be accessed. The policy includes the criteria and conditions for provision of de-identified individual level data, aggregate data, reports or analyses; and procedures for data request applications. It also outlines the cases in which fees for such access might be applicable, and any associated acknowledgement and publishing responsibilities.

Data collected and collated by ANZTCR is guided by strict protocols and procedures to ensure the security, privacy and confidentiality of all information collected and stored in the registry. All patient and stakeholder information will be handled in accordance with the Commonwealth Privacy Act (1988), the Privacy and Data Protection Act 2014 (Vic) and the Health Records Act 2001 (Vic), similar relevant interstate legislation, and any code of practice or guidelines made under these Acts.

All registry activities have been approved by a National Health Medical Research Council (NHMRC) approved Human Research Ethics Committee (HREC) and other participating site and Monash University Human Research Ethics Committees.

The University Privacy Compliance Framework is available at www.privacy.monash.edu.au.

2. PROJECT INFORMATION

2.1 PURPOSE OF ANZTCR

The Australian & New Zealand Thyroid Cancer Registry (ANZTCR) was developed by the Monash University Breast Endocrine Surgery (BES) Unit in collaboration with the Registry Sciences Unit (RSU). The ANZTCR is a clinical quality registry collecting data on patients diagnosed with thyroid cancer at participating health service sites in Australia to inform best-practice guidelines as well as benchmark performance in Australia with data from comparable international registries.

2.2 PROJECT OVERVIEW

The registry collects data relating to the patient's first presentation, preoperative investigations, cancer diagnosis and surgery, as well as adjuvant treatment and follow-up care up to 90 days post-diagnosis. Data is collected from patient medical records at diagnosis (1-2 weeks post-surgery) and 90 days post-diagnosis (follow-up data).

The registry allows comparison of high quality information, which can be used to develop criteria and procedures to evaluate and improve patient quality of care. Data is analysed to identify which treatments are more successful than others and compare thyroid cancer services across Australia. This will lead to improvement in patient quality of care and thyroid cancer services in the future.



Information held by the registry is used by the ANZTCR in two different ways. The data will be used to monitor:

- Performance of quality of thyroid cancer patient care in Australia;
- Performance of the Australian & New Zealand Thyroid Cancer Registry in collecting data about quality of thyroid cancer outcomes.

3. DEFINITIONS

Management Committee - The ANZTCR Management Committee is responsible for overseeing the daily operations of the registry. The Committee ensures data collection and data quality processes function effectively and complies with ethics committee regulations, legislation and registry policies.

Steering Committee - The ANZTCR Steering Committee is an independent entity which maintains governance and overall management of the ANZTCR. The Steering Committee develops and reviews policies and publications arising from the registry data.

Human Research Ethics Committee (HREC) - HRECs protect the welfare and rights of participants involved in research and they review proposals for research that involves humans. They monitor the conduct of research and deal with complaints that arise from research. Research projects requesting identifiable data and/or intending to contact patients must obtain approval from a National Health and Research Council (NHMRC) registered HREC.

Confidential Data - ANZTCR is responsible for protecting the data from unauthorised access and release by maintaining strict standards of confidentiality. Data that identifies or potentially identifies an individual patient, health care provider, institution or a caseload of a provider or reporting institution is considered propriety and confidential.

Identifiable Data – Data that contains individual identifiers making it possible to identify a specific individual.

Non-identifiable Data - Data that has never been labeled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data may be linked with other data so it can be known they are about the same data subject, although the individual's identity remains unknown.

Re-identifiable Data - Data from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.

Disclose or Disclosure - The communication of any ANZTCR information to any individual or organisation other than to the researcher or the ANZTCR.

Research Project - A scientific investigation that has been reviewed by ANZTCR Management Committee.

Researcher - The principal investigator of a research project (as defined above) or the individual requesting data from the ANZTCR.



4. ACCESS TO DATA HELD BY ANZTCR

ANZTCR data is hosted on a REDCap server that is managed by Monash University. Access to data is subject to applicable privacy laws and principles, and ethics approvals. Specific measures have been put in place to maintain the confidentiality of personal identifying information at the patient and hospital level.

Data access is generally subject to the approval of the ANZTCR Steering Committee. When considering the approval of access to ANZTCR data, the ANZTCR Steering Committee will consider whether the project satisfies the principles of research merit and integrity.

Access to the data is subject to the Data Access Request Process outlined in section 5.

4.1 ELIGIBLE APPLICANTS

Researchers, medical professionals and pharmaceutical professionals working at research institutions, hospitals, private entities, government or other health services within Australia and industry are eligible to request access to data held within the registry. All requests for data are noted in the ANZTCR Steering Committee minutes and logged.

4.2 ACCESS TO ANZTCR DATA

1. Staff who report directly to the ANZTCR Data Custodian will have direct access to the database and for operational purposes Monash University IT staff, directly involved in supporting registry systems have access for upgrades and break fixes, and are bound by Monash University confidentiality agreements.
2. All uses of ANZTCR data, in whatever context, must receive prior approval from the ANZTCR Steering Committee unless a pre-existing funding agreement is in place and has been previously approved by the ANZTCR Steering Committee. Research related requests may require specific ethics committee approval. Use of data for any other purpose will require an additional request.
3. Data access may be subject to conditions in agreements and/or research ethics approvals.
4. Under no circumstances will individually identifiable data in respect to patients, contributing clinicians, or hospitals be made available to parties other than the ANZTCR Steering Committee, authorised ANZTCR personnel, and members of any working group directed by and reporting to the Steering Committee during the course of incident, complaint or outlier management. Requests for ANZTCR data which may potentially identify a cancer patient, their physicians, or institutions involved in the patient's diagnosis and/or treatment, and all research projects which require contact with cancer patients require ethics approval and full review from ANZTCR Management Committee.
5. The ANZTCR will not release participant contact details or identifiable data that can be linked with other data. All contact with registered patients must be conducted by the ANZTCR through the Coordinating Centre. The cost of making such contact is to be borne by the researcher/s requesting the contact.
6. If a third party research or student project requires individually identifiable data for linkage or further research, this cannot be provided by ANZTCR directly. Following ethics approval, sign off by involved Centre Directors or site Principal Investigators and ANZTCR Steering Committee approval, ANZTCR



will provide the required data to the site/s involved to forward the data and patient identifying keys to the third party or student.

7. The ANZTCR will only release data of a sufficiently high level of quality and will release the least sensitive level of data that is practicable in order to fulfil the uses identified in the research proposal submitted with the data request. Tabulated aggregate data with a cell count less than 5 will be suppressed to prevent re-identification of an individual patient, physician or organisation.
8. Where only basic summary data available through public reports is requested, this can be provided by the ANZTCR Coordinating Centre without Steering Committee approval.
9. ANZTCR encourages the independent access of clinician data available through the ANZTCR REDCap Database, however should a contributing clinician request access to their own patient data ANZTCR will provide this. All requests for this category of data should be made in writing to the ANZTCR Management Committee (**Appendix B**).
10. If a hospital executive makes a specific request for its own performance data, ANZTCR will provide this information. Identification of a clinician will not be provided without the written permission of the Centre Director/Principal Investigator. All requests for this category of data should be made in writing to the ANZTCR Data Custodian (**Appendix B**). Such data requests will require Steering Committee approval.
11. For requests from industry, comparative information i.e. market share will not be provided.
12. All requests for access to the ANZTCR data are undertaken in addition to routine ANZTCR workload. As a general rule, following submission of the request form, review by the ANZTCR steering committee will occur within 4 weeks. Requests involving reports or analysis will be provided with a quote and expected time frame for completion. Most data access requests will generally be provided within 2-6 weeks following Steering Committee approval.
13. Requests must be first made to the ANZTCR Management Committee at Monash University who will either table the request at the next ANZTCR Steering Committee meeting or, in some circumstances where the data is required earlier the ANZTCR Management Committee, may circulate the request for out of session approval. Data cannot be extracted until approval is given and relevant ethics approval from participating institutions are in place.
14. All data must only be used for the purposes outlined in the written request, and approved by the Steering Committee. The researcher may only use registry information for the specified research project. If the researcher wants to use registry information for another research project, he/she must first obtain the appropriate approval for the research project. The researcher, and any individual working on the research project, may not disclose registry information to others without the prior written consent of ANZTCR. Moreover, the cancer case information may not be reproduced in any form except for internal use or with prior written consent from the ANZTCR.
15. No data may be passed onto other researchers, clinicians or any other person/entity not explicitly mentioned in the written data request.
16. ANZTCR coordinating centre will perform record-linking tasks at the ANZTCR whenever feasibly possible. Researchers may provide identified data to the registry, and the ANZTCR will return medical



information on records that were found to link. If the research project has the patient's informed consent, then linkage projects will be reviewed by the Management and/or Steering Committee.

17. Requests for access to data must comply with the National Statement on Ethical Conduct in Human Research (2007). Following ethics approval and data access sign off by the ANZTCR Steering Committee, de-identified data will be provided by secure file transfer. Following transfer, security and storage of the data provided will be the responsibility of the requester in accordance with good research practice guidelines.
18. Requests must be made in accordance with the data access policy and provide full disclosure in the request form for proposed access and usage of the data. Data access and usage must comply with all conditions in the approval given for data access.
19. Patient requests for data access to their information will be managed by the Registry Coordinator. Patients will need to provide identifying information prior to data release. (**Appendix C**)
20. If a research project continues beyond the original termination date stated in the proposal, the researcher must notify the ANZTCR in writing of the new termination date, submit corresponding approvals from an ethics committee, and obtain approval in accordance with Section 4.2 (Request for Patient Identifiable Data).

5. REQUESTING DATA

5.1 DATA ACCESS REQUEST PROCESS

1. All data requests must be formally lodged using the relevant Data Request Application Form (**Appendix A** or **Appendix B**) via email, post or fax to:

Email: SPHPM.ANZTCR@monash.edu

Post: Dr Liane Ioannou
Australian & New Zealand Thyroid Cancer Registry
553 St Kilda Road
Melbourne, 3004

Upon receipt of the completed and signed form, the ANZTCR Management Committee will present the data request to the Steering Committee at the next scheduled meeting if required under Section 3.2. Meetings are held four times per year.

2. There are three possible outcomes of the data access request. The data access request may be approved; approved subject to amendment; or declined. If the application is declined, a major revision and subsequent resubmission will be required. Approval subject to minor revision will not require a full resubmission. An out of session review of the changes will be organised.
3. Upon approval, the ANZTCR Management Committee will provide a statement of the conditions of its use with a cost estimate if applicable.
 - a. The researcher signs the Research Agreement (**Appendix D**).
 - b. All project personnel who have access to the confidential data sign the Confidentiality Agreement (**Appendix E**).



- c. The Data Custodian releases the data to the researcher.

5.2 REQUEST FOR NON-IDENTIFIABLE DATA

Aggregate data such as incidence, mortality rates and frequencies may be released provided that such disclosure does not include sufficient information that would allow the researcher to identify an individual or organisation. This may include masking cell sizes less than 5 for tabulated data.

The ANZTCR may release non-identifiable tumour-level data, which can include details about the tumour and treatment information. Patient demographic information will not be released and the tumour data will not be identifiable.

The ANZTCR will not release patient contact details.

The researcher must indicate their request for *Non-Identifiable Data* on the Data Request Application Form (**Appendix A**) and submit the application to the ANZTCR Management Committee.

5.3 REQUEST FOR PATIENT RE-IDENTIFIABLE OR DE-IDENTIFIABLE DATA

The ANZTCR will generally not release patient identifiable data.

Hospitals and clinicians may request re-identifiable data for cases reported by their own institution or practice. All patient identifiers are removed and replaced with a code.

The researcher must discuss the approval process with a representative from the Management Committee, including the terms and conditions of the Research Agreement (**Appendix D**) to be signed by the researcher, provisions regarding maintenance of confidentiality, patient contact, and sanctions for violating these provisions.

The researcher must indicate their request for *Re-Identifiable or De-Identified Data* on the Data Request Application Form (**Appendix A**) and submit the application, in addition to their ethics application and letter of ethics approval, to the ANZTCR Management Committee.

It is a requirement of the ANZTCR Management Committee that applications for the release of data for research purposes are submitted and reviewed by a HREC. Section 95A of the Privacy Act 1988 allows the Management Committee to request researchers to submit a proposal to a HREC even if it has received written notification of ethics committee approval from the investigator's institution.

5.4 PATIENT REQUEST FOR DATA ACCESS

Patient requesting access to their data held on the ANZTCR will be required to complete a Data Request Application Form (**Appendix C**) which will be available from the ANZTCR Management Committee. Upon receipt of the completed form the, the ANZTCR coordinator will:

1. Telephone the patient to confirm that they have requested their details
2. Advise the patient that their information will be sent by registered post to the address recorded on their proof of identify documents.

6. DATA SECURITY FOR PATIENT IDENTIFIABLE INFORMATION

The following restrictions apply to the use of confidential information:



Maintenance and Storage of Data by Researcher

Patient identifiable data must be encrypted or kept separate from medical data stored by the researcher. This separation applies for data kept in paper format or on a computer. The medical data will not be identified except by an identifying number with no meaning in any data set other than the researcher's or ANZTCR. The patient identifiable cancer case information will not be attributed to a source that identifies the nature of the records. Identifiable data stored on a computer network must be secured from unauthorised network access by the most effective means that are technically available. If confidential information is lost, it will be reported to the ANZTCR Office and the approving Human Research Ethics Committee.

Penalties for Violations

In addition to terminating the agreement for a violation of this policy, the ANZTCR may impose sanctions on the researcher. Individuals who have witnessed inappropriate use of ANZTCR data or a breach in confidentiality may report violations to the ANZTCR. The ANZTCR recognises that violations may occur to various degrees, however, in all cases the Management Committee will be notified immediately and the research project will be suspended for a minimum of 30 days. During that time, the Management Committee will meet to discuss the magnitude of the violation and the steps needed to rectify the infraction(s). The Management Committee will also determine if the violation(s) should be reported to the proper authorities, including the HREC.

7. PUBLICATION

Any material or manuscript to be published using ANZTCR data must be submitted for review by the ANZTCR Steering Committee prior to release for publication. ANZTCR will have thirty (30) days after receipt of the draft publication to request in writing the removal of any portions of the publication deemed by ANZTCR to inappropriately disclose patient identifiable cancer case information. Upon receipt of such request from ANZTCR, the researcher and ANZTCR will attempt, in good faith, to agree upon the modifications or revisions to the draft publication, which are reasonably necessary to protect the privacy of the subjects of the cancer case information. In no event, however, will the researcher publish identifiable cancer case information.

It must contain appropriate acknowledgement of ANZTCR. Preferred wording for the acknowledgement will be provided with the data. If the data is the primary source for a report or publication, the source of the data must be acknowledged, along with a statement that the analysis and interpretation are those of the author, not the registry. Where a research collaborator has analysed data, ANZTCR, Monash University should be acknowledged as a secondary institution. Where the author is a registry staff member, then the primary attribution should be ANZTCR, Monash University. ANZTCR reserves the right to dissociate itself from conclusions drawn if it deems necessary.

Authorship may be required when ANZTCR makes substantial contribution to the data. Copies of all published abstracts, presentations, and papers that result from the study should be sent to the ANZTCR Management Committee.



8. DATA ITEMS

The ANZTCR Management Committee will provide a list of available data items upon request. It is the policy of ANZTCR that certain data elements are not released under any circumstances.

9. FORMS

The form(s) that must be completed for each data request will vary depending on whether the applicant is a researcher, non-researcher or patient. The forms may be obtained from the ANZTCR Management Committee.

The forms are as follows:

9.1 DATA REQUEST FORMS

1. Request Access to Data - Researcher Form (**Appendix A**). This form should be used for all research-related requests.
2. Request Access to Data – Non-Researcher Form (**Appendix B**). This form should be used for non-research purposes.
3. Request Access to Data – Patient Form (**Appendix C**). This form should be used for patients who would like access to information.
4. Research Agreement (**Appendix D**). This agreement must be signed by the researcher who has been approved to have identifiable information.
5. Confidentiality Agreement (**Appendix E**). Although the Principle Investigator is responsible for assuring that the data are kept confidential, all study staff with access to identifiable ANZTCR data are required to sign a confidentiality agreement. These signed agreements will be kept on file at the ANZTCR.

10. FEES

The ANZTCR does not receive any funding to perform non-routine adhoc data analysis. Therefore, provision of data may be subject to a fee-for-service on a cost recovery basis unless in line with existing funding agreements or MOUs between registry funders/supporters. Fees will be at the discretion of the ANZTCR Steering Committee in consultation with the ANZTCR Management Committee and will be based on the complexity and estimated time taken to complete the request as well as current ANZTCR routine workload. Please see the Data Access Fee Schedule for an explanation of these.



APPENDIX A: DATA ACCESS REQUEST – RESEARCHER FORM



AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

DATA ACCESS REQUEST - RESEARCHER

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
 533 St Kilda Rd
 Melbourne, VIC 3004
 Email: SPHPM.ANZTCR@monash.edu
 Phone: (03) 9903 0046

PART A: RESEARCHER'S DETAILS

Date of Request: _____

Date required by: _____

Organisation	<input type="checkbox"/> Research/Academic Institution <input type="checkbox"/> Government Department or Agency <input type="checkbox"/> Hospital Industry: <input type="checkbox"/> Pharmaceutical <input type="checkbox"/> Private Health Insurance <input type="checkbox"/> Device <input type="checkbox"/> Other, <i>specify</i> <input type="checkbox"/> Professional Medical Organisation <input type="checkbox"/> Other (<i>please specify</i>).....		
Short title of data request:			
Principal Investigator :		Title:	
Position:			
Affiliation/Organisation:			
Address:			



Telephone:			
Email:			
Other Investigators: (add additional lines for each investigator)		Title:	
Are you a student?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If YES, what degree are you working towards?			
Name and contact details of your supervisor			
Is this a funded research project?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If YES, who has funded the project?			
Was the ANZTCR formally involved in the grant application?			
Does your project require Human Research Ethics committee (HREC) approval?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If NO, proceed to PART B	
If YES have you applied for HREC approval?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If YES which organisation's HREC did you apply to?	_____		
Have you received HREC approval?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If YES, please attach a copy of your approval certificate/s, a full copy of your application and any other relevant documents	



PART B: PROJECT DETAILS

Reason for data request. Please note that approval will only be given for the project described in this application. Use of data for any other purpose will require an **additional** request.

Type of data request	<input type="checkbox"/> De-identified patient level data <input type="checkbox"/> Aggregated/summary data <input type="checkbox"/> Report/Analysis <input type="checkbox"/> Data linkage <input type="checkbox"/> Other, specify
Title of project	
Background and rationale for the project (500 word maximum plus key references)	
Hypothesis and specific research questions	
Possible outcomes and clinical significance of this research (250 word maximum)	
Methodology of project (500 word maximum)	
Inclusion and Exclusion criteria	



PART C: DATA FIELDS REQUIRED

An ANZTCR minimum dataset containing available data fields can be requested. ANZTCR is required to maintain patient privacy. No data will be released that could potentially identify patients, clinicians or hospitals.

Data item required	Justification

PART D: RESERACHER’S SIGNATURE

I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE ANZTCR DATA ACCESS POLICY. I AGREE TO COMPLY WITH THAT POLICY.

I AGREE TO UNDERTAKE ALL ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE RESEARCH PROPOSAL, RESEARCH APPROVAL OF THE REVIEWING HUMAN RESEARCH ETHICS COMMITTEE (HREC) AND ALL RELEVANT STATE AND COMMONWEALTH PRIVACY LEGISLATION RELATING TO PATIENT INFORMATION AND HEALTH RECORDS.

I AGREE TO ADHERE TO ALL OF THE CONDITIONS PLACED ON USE AND STORAGE OF THE DATA AS OUTLINED IN ANY ANZTCR DATA ACCESS APPROVAL THAT WILL BE PROVIDED TO ME PRIOR TO COMMENCEMENT OF ANY RESEARCH ACTIVITY, DATA ANALYSIS OR REPORT.

I AGREE THAT THE INFORMATION PROVIDED BY ME TO ANZTCR IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION.

I AGREE THAT INFORMATION PROVIDED WILL NOT BE USED FOR ANY PURPOSE OTHER THAN DESCRIBED IN THE REQUEST FORM.

I AGREE THAT INFORMATION WILL NOT BE DISCLOSED TO ENTITIES OTHER THAN THOSE DESCRIBED IN THE REQUEST FORM.

I AGREE TO PROVIDE MONASH UNIVERSITY WITH A COPY OF ANY FINAL REPORT FOR REVIEW PRIOR TO PUBLISHING AND WILL ANZTCR AS THE DATA SOURCE AND WHERE APPLICABLE, MONASH UNIVERSITY AS HAVING UNDERGONE THE ANALYSIS OR COLLATED THE REPORT.

I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY ANZTCR, WHETHER IN THE FORM OF DATA, REPORTS, MODELS, SAMPLES AND REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.

Name: _____

Signature _____



AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY DATA ACCESS REQUEST - RESEARCHER

FOR OFFICE USE ONLY:

Short Title of Data Access Request: _____ _____	
ANZTCR Steering Committee decision (or delegate)	<input type="checkbox"/> Approved <input type="checkbox"/> Approved – Subject to amendment <input type="checkbox"/> Declined
If approved, subject to amendment, please list required changes	
Approved by ANZTCR Steering Committee Chairperson (or delegate):	
Signature: _____	
Date of approval: _____	



APPENDIX B: DATA ACCESS REQUEST – NON-RESEARCHER FORM



AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY DATA ACCESS REQUEST – NON-RESEARCHER

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: APPLICANT'S DETAILS

Date of Request: _____

Date required by: _____

Organisation	<input type="checkbox"/> Research/Academic Institution <input type="checkbox"/> Government Department or Agency <input type="checkbox"/> Hospital Industry: <input type="checkbox"/> Pharmaceutical <input type="checkbox"/> Private Health Insurance <input type="checkbox"/> Device <input type="checkbox"/> Other, <i>specify</i>		
Authorised requester's name		Title	
Position			
Organisation:			
Address:			
Telephone:			
Email:			



Please note that approval will only be given for the use described in this application. Use of data for any other purpose will require an **additional** request. This information will be reviewed by a committee and may incur a fee depending on the complexity of the request.

Request Title	
Type of data request	<input type="checkbox"/> Aggregated data/summary data <input type="checkbox"/> Report/Analysis
Purpose of the request	
What question/s need to be answered by the information requested	
Description of the type of information required. (Please include the subpopulation, and cross tabulation of the variables of interest required)	
Reference period for the data of interest	
Possible outcomes and potential uses of this request	
Name all entities that the information requested will be disclosed to	<input type="checkbox"/> Internal use only <input type="checkbox"/> Government department/agency, specify..... <input type="checkbox"/> Other organisation, specify.....
If this request is to be used to support an application for regulatory approval and are there potential implications for the registry? E.g. additional data items to be collected etc.	



PART C: DATA FIELDS REQUIRED

An ANZTCR minimum dataset containing available data fields can be requested to ensure the information you require is utilised when requesting a summary report. ANZTCR is required to maintain patient privacy. No data will be released that could potentially identify patients, clinicians or hospitals.

Data item required	Justification

PART D: APPLICANT’S SIGNATURE

I CERTIFY THAT I HAVE READ AND UNDERSTOOD THE ANZTCR DATA ACCESS POLICY AND I AGREE TO COMPLY WITH THAT POLICY. I AGREE TO UNDERTAKE THE ACTIVITIES DESCRIBED IN THIS REQUEST IN ACCORDANCE WITH THE AGREED USE.
I AGREE THAT ANY INFORMATION PROVIDED WILL NOT BE USED FOR ANY PURPOSE OTHER THAN DESCRIBED IN THE REQUEST FORM
I AGREE THAT INFORMATION WILL NOT BE DISCLOSED TO ENTITIES OTHER THAN THOSE DESCRIBED IN THE REQUEST FORM.
I AGREE TO PROVIDE MONASH UNIVERSITY WITH A COPY OF ANY FINAL REPORT FOR REVIEW PRIOR TO PUBLISHING IF REQUESTED AND WILL ACKNOWLEDGE ANZTCR AS THE DATA SOURCE AND WHERE APPLICABLE, MONASH UNIVERSITY AS HAVING UNDERGONE THE ANALYSIS OR COLLATED THE REPORT. I AGREE THAT THE INFORMATION PROVIDED BY ME TO ANZTCR IS TRUE, ACCURATE, COMPLETE AND WITHOUT MATERIAL OMISSION. I ALSO AGREE THAT THE INFORMATION PROVIDED TO ME BY ANZTCR, REGARDLESS OF HOW COMMUNICATED OR RECORDED, IS CONFIDENTIAL AND CONFIDENTIALITY OF ALL INFORMATION AND COMMUNICATIONS WILL BE MAINTAINED UNLESS OTHERWISE AGREED BY BOTH PARTIES.

Name: _____

Signature _____



AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY DATA ACCESS REQUEST – NON-RESEARCHER

FOR OFFICE USE ONLY:

Short Title of Data Access Request: _____ _____	
ANZTCR Steering Committee (or delegate) decision	<input type="checkbox"/> Approved <input type="checkbox"/> Approved – Subject to amendment <input type="checkbox"/> Declined
If approved, subject to amendment, list required changes	
Approved by ANZTCR Steering Committee Chairperson (or delegate): Signature: _____ Date of approval: _____	



APPENDIX C: DATA ACCESS REQUEST – PATIENT FORM



AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY DATA ACCESS REQUEST – PATIENT

Please return your application via email or post using the details below:

Australian & New Zealand Thyroid Cancer Registry
533 St Kilda Rd
Melbourne, VIC 3004
Email: SPHPM.ANZTCR@monash.edu
Phone: (03) 9903 0046

PART A: PATIENT DETAILS

Date of Request: _____

Date required by: _____

<p>A certified copy of proof of identity is supplied as follows: (please tick x boxes)</p> <p>NEEDS TO DISPLAY NAME & ADDRESS AT TIME OF SURGERY</p>	<input type="checkbox"/> Birth Certificate <input type="checkbox"/> Passport <input type="checkbox"/> Certificate of Australian Citizenship <input type="checkbox"/> Medicare Card <input type="checkbox"/> Drivers Licence <input type="checkbox"/> Signed letter from General Practitioner verifying proof <input type="checkbox"/> Other (utility bill, bank statement etc.)
First Name:	
Family Name :	
D.O.B:	
Address:	
Telephone:	
Email:	



PART B: DETAILS REQUESTED

Data details that appear on the Data Capture Form (DCF) are shown in the table below. Please tick those you wish to access.

Surgeon Name	
Hospital/Site	
Date of Diagnosis	
Date of Surgery	
Preoperative Imaging & Tests	
Reason for Surgery	

Surgery Type	
Surgery Details	
Pathology & Staging	
Surgical Complications	
Postoperative Complications	
Recurrence	

I hereby apply for access to information relating to me held by the Australian & New Zealand Thyroid Cancer Registry.

Patient's signature: _____

Date: _____

Please send a copy of my information to above address:

Please send a copy of my information to: _____

PART C: THIRD PARTY RELEASE DETAILS

If your request relates to releasing this information to a third party/surgeon, please complete the following:

Name:	
Position:	
Address:	
Telephone Number:	

I hereby agree for information relating to me, held by the Australian & New Zealand Thyroid Cancer Registry, to be released to the above party.

Patient's signature: _____

Date: _____



APPENDIX D: RESEARCH AGREEMENT



AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

RESEARCH AGREEMENT

Name of Study: _____

BY THIS DECLARATION dated the _____ day of _____ 20__

I, _____ of _____

[Name of Investigator]

[Institution]

recognise and accept as my responsibility regarding the use of information provided by the Australian & New Zealand Thyroid Cancer Registry (ANZTCR) for the above named study in accordance with the terms and conditions of this Agreement.

1. DEFINITIONS & ABBREVIATIONS

1.1. “Disclose” or “disclosure” shall mean the communication of information to any individual or organisation other than to the Researcher or the ANZTCR.

1.2. “Confidential information”. Information accessed under the Public Health Act 2005 and/or information of a sensitive or confidential nature and any extract, derivation, or aggregation of this information that may enable identification of individuals, doctors, public or private facilities, or communities. This includes information derived from data linking or matching with information from other sources.

2. USE OF ANZTCR INFORMATION

The Researcher may use information provided by the ANZTCR only for the Research Project. If the Researcher wants to use such information for another research project, the Researcher must obtain the appropriate approval for the research project from an ethics committee and ANZTCR Management Committee. The Researcher, and any individual working on the Research Project, shall not disclose the ANZTCR information to others without the prior written consent of ANZTCR. Moreover, the ANZTCR information shall not be reproduced in any form except for internal use or with the prior written consent of ANZTCR.

3. PUBLICATION

In the event the Researcher wants to publish the results of the Research Project, the Researcher shall first provide to ANZTCR written notice of Researcher’s intent to publish and a draft of the publication. ANZTCR shall have thirty (30) days after receipt of the draft publication to request in writing the removal of any portions of the publication deemed by ANZTCR to inappropriately disclose confidential information. Upon receipt of such a request from ANZTCR, the Researcher and ANZTCR shall attempt in good faith to agree upon the modifications or revisions to the draft publication which are reasonably necessary to protect the privacy of the subjects. In no event, however, shall the Researcher publish confidential information without the written consent of ANZTCR.



4. CONTACTING PATIENTS

If the Researcher wants to contact patients, the Researcher shall submit a written request to ANZTCR identifying patients the Researcher wants to contact and the purpose of contacting the subjects. If ANZTCR approves such request, ANZTCR shall contact the patients (or the legal guardian of the subject if a guardian has been appointed by a court) and request the patient's written consent to be contacted by the Researcher. In no event shall Researcher contact a patient unless ANZTCR has first obtained such written consent.

5. CONFIDENTIALITY INFORMATION

All confidential data shall remain the property of ANZTCR and shall be destroyed, de-identified or promptly returned to ANZTCR at the end of the project, upon request of ANZTCR, or upon termination of this Agreement.

6. ANNUAL REPORTS

On or before the **[insert date]**, the Researcher shall submit to ANZTCR an annual report regarding the progress of the Research Project, all publications resulting from the Research Project, changes in the Research Project protocol, personnel or any incidents that may have resulted in the disclosure of confidential information, and any other information requested by the ANZTCR Management Committee.

7. REPRESENTATIONS OF THE RESEARCHER

The Researcher represents and warrants to ANZTCR, upon execution of this Agreement and throughout the term of this Agreement, that:

- (a) The Researcher has obtained appropriate approval for the Research Project from (i) an ethics committee, (ii) the ANZTCR Management Research Committee.
- (b) The Researcher, and any individual working on the Research Project, shall comply with the terms of this Agreement and the Australian & New Zealand Thyroid Cancer Registry's Policy: Requests for Data.
- (c) The Researcher, and any individual working on the Research Project, shall conduct the Research Project in accordance with all applicable federal and state laws, rules, and regulations.

8. INDEMNIFICATION

The Researcher shall indemnify, defend and hold harmless ANZTCR against any claims, liabilities, damages, and expenses, including, without limitation, reasonable legal fees incurred by ANZTCR arising out of or related to the acts or omissions of the Researcher in connection with this Agreement.

9. TERM

The term of this Agreement shall commence on the date hereof and shall end on **[insert date]** or on the date the Research Project ends, whichever occurs first, unless sooner terminated as provided herein. This Agreement may be renewed or extended for additional terms by mutual written agreement of the parties.



10. TERMINATION

(a) For Cause. ANZTCR may terminate this Agreement upon breach by the Researcher of any material provision of this Agreement, provided such breach continues for ten (10) working days after receipt by the Researcher of written notice of such breach from ANZTCR.

(b) Without Cause. Either party may terminate this Agreement without cause by giving the other party at least thirty (30) days' advance written notice thereof.

(c) Effect of Termination. In the event of such termination, the Researcher shall promptly return all ANZTCR information to ANZTCR, in any and all formats. The following provisions shall survive the termination of this Agreement: Paragraphs 3, 4, 5, and 9. Notices to the parties hereunder shall be deemed given if in writing when delivered in person, by registered or express post.

Notices shall be addressed as follows:

Researcher:

Australian & New Zealand Thyroid Cancer Registry
School of Public Health & Preventive Medicine
Monash University
533 St Kilda Road, Melbourne, VIC 3004

(d) Entire Agreement. This Agreement contains the entire understanding of parties with respect to the subject matter hereof and supersedes all prior agreements, written or oral, and all other communications between the parties relating to such subject matter. This Agreement may not be amended or modified except by mutual written agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed and entered into by their authorised representatives as of the date first set forth above.

Australian & New Zealand Thyroid Cancer Registry

Researcher

A/Prof Susannah Ahern
Registry Data Custodian

[Name]
[Title]
[Department]



APPENDIX E: CONFIDENTIALITY AGREEMENT



AUSTRALIAN & NEW ZEALAND THYROID CANCER REGISTRY

CONFIDENTIALITY AGREEMENT

Name of Study: _____

BY THIS DECLARATION dated the _____ day of _____ 20____

I, _____ of _____

[Name of Appointee]

[Address of Appointee]

recognise and accept as my responsibility the following obligations regarding the confidentiality of the information which has been provided to me by the Australian & New Zealand Thyroid Cancer Registry (ANZTCR).

1. DEFINITIONS & ABBREVIATIONS

1.1. "Confidential information". Information accessed under The Public Health Act 2005 and/or information of a sensitive or confidential nature and any extract, derivation, or aggregation of this information that may enable identification of individuals, doctors, public or private facilities, or communities. This includes information derived from data linking or matching with information from other sources.

1.2. "NHMRC". National Health and Medical Research Council

2. ETHICAL OBLIGATIONS

I certify that in my capacity as the holder of this information, I will comply with the guidelines and legislation detailed in the:

- 2.1. Commonwealth of Australia Privacy Act 1988, incorporating the Privacy Amendment (Private Sector) Act 2000.
- 2.2 Guidelines approved under Section 95A of the Privacy Act 1988 (National Health and Medical Research Council, December 2001).
- 2.3 Health Records and Information Privacy Act 2002 (NSW).
- 2.4 National Statement on Ethical Conduct in Research Involving Humans (National Health and Medical Research Council, 2007)
- 2.5 NHMRC's Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003).

3. CONFIDENTIALITY OBLIGATIONS

3.1. In the course of using confidential information for research purposes, I acknowledge that I will be exposed to information which if inappropriately used or disclosed may impact on individuals, public or private facilities or communities.



- 3.2. I will not disclose confidential information in any released output (eg in reports, publications).
- 3.3. I will not use this confidential information for purposes other than for performing the specific activities detailed in my application as approved by the Management Committee.
- 3.4. I will not use the confidential information except during the defined time period for which access to and use of this information was approved.
- 3.5. I agree to take all the reasonable steps necessary to ensure that the confidential information is kept confidential, including storing or disposing of all data, information, documents and associated correspondence in a secure manner.
- 3.6. I agree to re-apply for approval from the ANZTCR Management Committee if:
- I require additional confidential information;
 - I want to extend the approved time period for access to or use of the confidential information;
 - Additional individuals require access to this information as part of the approved research study.
- 3.7. I acknowledge that unauthorised use or disclosure of confidential information by me may subject me to prosecution under the laws of the relevant state or territory in Australia.
- 3.8. The declaration of my interests in Research Proposals and associated documents shall be held in strict confidence by the relevant Human Research Ethics Committee and ANZTCR Committee members or employees, and it shall not be used or disclosed to any other person without my prior consent or when it is legally required to be disclosed.
- 3.9. I agree to dispose of confidential data in a secure manner on completion of the project.

In signing this declaration, I declare that I will adhere to the obligations specified in this document.

Signature

Name (Print)

Position

Phone

Email