



Queensland Cancer Registry (QCR)

Research and Study Application Package - Contacting Patients -

**Queensland Cancer Registry
Cancer Council Queensland
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Version 6.0

TABLE OF CONTENTS

Section	Page
1. Introduction	3
2. Procedure for access to Queensland Cancer Registry Information	4
2.1. Flow chart of Access to Queensland Health Confidential Information Process	5
2.2. Flow chart for contacting patients study.....	6
3. Information and Instructions for Researchers	7
4. PHA Application Template	10
5. After the study had been approved	15
5.1. Visiting staff of the Queensland Cancer Registry	15
5.1.1. Eligibility and conditions for appointment	15
5.1.2. Appointment process	15
5.1.3. Policies and Procedures.....	16
6. Contacting Doctors and Patients	17
6.1. Documents to be included in the DOCTOR package	17
6.2. Documents to be included in the PATIENT package	17
6.3. Follow-up of doctors and patients	17
7. Other Information	18
8. APPENDIX.....	19
8.1. Application Checklist	20
8.2. QCR Data Items	21
8.3. Confidentiality Form.....	22
8.4. Templates to Doctor and Patient	24
8.4.1. Letter to doctor - on QCR letterhead.....	25
8.4.2. Doctor's consent form (may be adapted according to individual ethics committee requirements)	26
8.4.3. Letter to patient - on QCR letterhead.....	27
8.4.4. Patient's consent form (may be adapted according to individual ethics committee requirements)	28
8.4.5. Follow-up letter to doctor - on QCR letterhead.....	29
8.4.6. Follow-up letter to patient - on QCR letterhead.....	30
8.5. Visiting Staff Member Letter Templates to Dr Jeff Dunn	31
8.6. CSV format for matching external cases to the QCR database	32

1. Introduction

This document is for researchers who wish to undertake a study using information collected by the Queensland Cancer Registry. It lists the procedures to follow plus any letters and consent form templates for the researcher to use.

Contact Details for further information:

Person: Carly Scott
Registrar

Address: Queensland Cancer Registry
Locked Bag No. 1450
Spring Hill Post Office
QLD 4004

Phone: 07 3634 5333

Fax: 07 3258 2345

Email: carly_scott@health.qld.gov.au

2. Procedure for access to Queensland Cancer Registry Information

Any researcher applying for access to identifiable data held by the Queensland Cancer Registry must make application under the Public Health Act 2005 and receive approval from the Director General of Queensland Health. Queensland Health are the data custodians for information held by the Queensland Cancer Registry.

The researcher needs to obtain HREC approval for their research proposal from a recognised HREC institution before sending their application to the Queensland Cancer Registry. The researcher should then liaise with the Registrar, Queensland Cancer Registry regarding their application to ensure the requested data can be provided.

The following needs to be sent to the Registrar, Queensland Cancer Registry in electronic form and 1 hard copy (including original confidentiality forms) –

- Covering letter addressed to the QH Data Custodian c/- Registrar, Queensland Cancer Registry
- Queensland Health PHA Application Template
- Research Application Checklist
- Research Proposal (sent to & approved by HREC)
- HREC approval/s
- Signed confidentiality forms for all research participants

When contacting patients, the following documents are also needed –

- Doctor letter
- Doctor consent form
- Patient letter
- Patient consent form
- Study information sheets

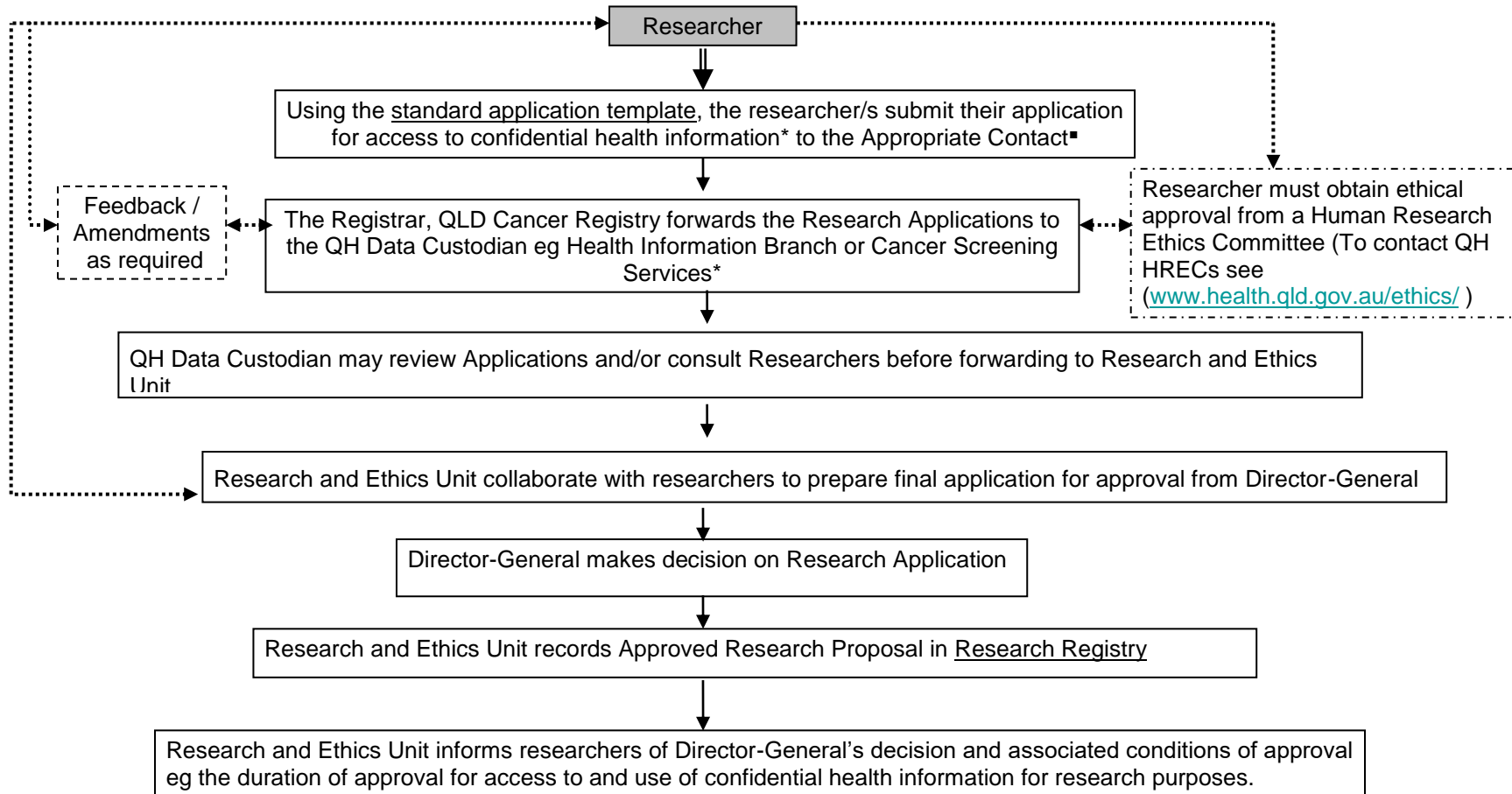
The Registrar will liaise with the researcher regarding the above documentation to ensure completeness, accuracy and availability of data. The Registrar will then forward the documentation to the Data Custodian within Queensland Health who will review the documentation and forward to the Research and Ethics Unit. The Research and Ethics Unit will prepare a brief of the research proposal and forward to the Director General of Queensland Health for approval.

Once approval is granted the Research and Ethics Unit will send a letter to the researcher advising of approval. The researcher then needs to provide a copy of this approval to the appropriate department who will be providing the information – ie. the Queensland Cancer Registry, or the Australian Institute of Health and Welfare depending on the research project requirements.

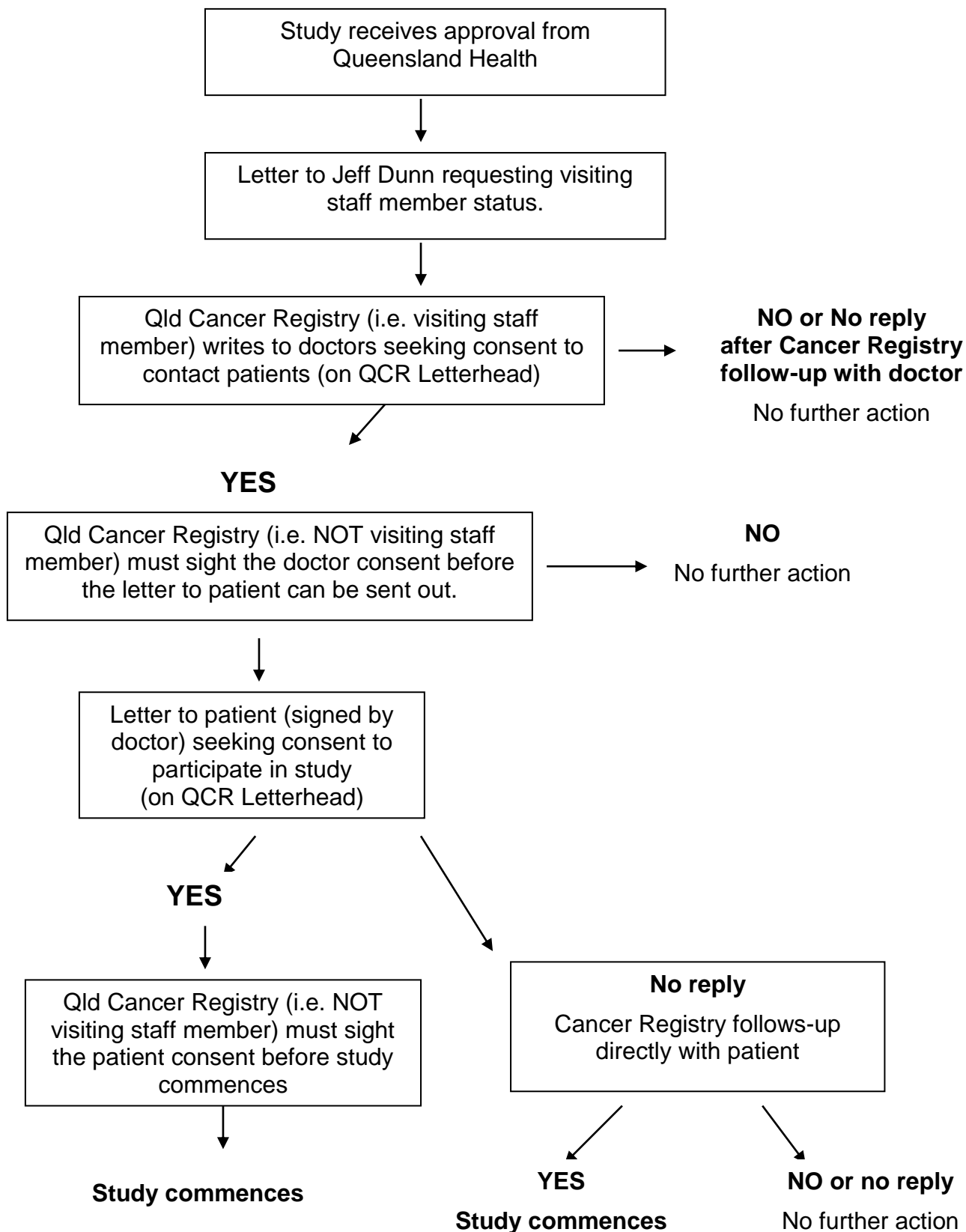
2.1. Flow chart of Access to Queensland Health Confidential Information Process

10/03/06

Overview of Application Process for Access to Confidential Health Information* held by QH for Research Purposes



2.2. Flow chart for contacting patients study



3. Information and Instructions for Researchers

Applying for release of health information held by the department for the purposes of research under the provisions of the *Public Health Act 2005*

Relevant Section/s of the Public Health Act 2005

- Chapter 6: Health Information Management, Part 4: Research Division 1, S280-292.

Intended Application of this Process

- The following information and application processes apply when individuals wish to access **health information held by the department for the purposes of research**.
- Health information under the provisions are inclusive of identifiable, de-identifiable and re-identifiable data and is therefore not restricted simply to names and personal data but may also include other combinations of data which together may enable individuals to be identified.
- An application to access data is only required when access to health information is required for formal research. If an area in QH needs access to confidential health information for evaluating, managing, monitoring or planning health services, then the applicants should contact the relevant data custodian for advice.

Health information does include tissues, tissue blocks etc. Researchers interested in using tissues or blood should contact the Coordination Planning and Research Unit, Clinical and Statewide Services Block 7, Level 13 Royal Brisbane and Women's Hospital Queensland 4029, Ph 07 3636 9865, Fax 07 3636 9854, CaSS_Research@health.qld.gov.au or visit the Web address for more information:

http://qhps.health.qld.gov.au/qhcss/research/research_home.htm

Background

- The *Public Health Act 2005* establishes mechanisms for providing health information held by the department to approved research projects.
- This applies to all researchers seeking health information for which they are unable to obtain the participants' consent to use their personal or identifying information for clearly specified research purposes. This may also apply in circumstances in which it may be inappropriate to contact the participants / patients for consent to access their health information.
- Chapter 6 '*Health Information Management*' enables researchers to apply to the Chief Executive (Director-General) or delegate for access to the health information held by the department, providing certain criteria, processes and confidentiality requirements are adhered to by successful applicants.
- Access to and use of this information will only be approved for a specified time period, which must be clearly stated in the application.
- Researchers granted access under 63(2)(j) of the *Health Services Act 1991* and S154M of the *Health Act 1937* will only have access to the requested data for 2 years post-commencement of the *Public Health Act 2005*. (ie. until 16 January 2008) (Section 489) (Note: S63 is now S62F in amended *Health Services Act 1991*)
- Details of approved applications and their studies will be kept in a register, known as "*The Research Register*" (the register) held by Queensland Health.
- Access to the register must, by law, be made available to anyone who requests it (S283 (3)).

- Researchers must have approval from a Human Research Ethics Committee (HREC) of their research proposal before applying for access to health information. Evidence of this approval must be provided in the application.
- For administrative reasons researchers must consult the data custodians to determine:
 - whether the data fields being requested are available; and
 - whether the data being requested can be provided in the timeframe being requested.
- Evidence of this consultation should be included in the application. This may be in the form of a memo or copy of an email.

Associated Costs

Extraction of health information or data may incur a fee. The data custodian will indicate whether this will occur with your request.

Instructions

Before you proceeding with your application for release of health information the following must be completed:

1. HREC approval of the research proposal
2. Evidence of support from the data custodians that the data required is available and can be provided in the timeframe requested.

Post Approval

Once approved the research project will be entered into the Research Registry by staff of the Research Ethics and Governance Unit.

Researchers must subsequently provide the data custodians with evidence of this approval, a copy of the confidentiality agreement and their application whenever they are requesting access to the specifically approved health information from Queensland Health.

You are required under the provisions of the Act to provide the Chief Executive feedback on the progress and results of the research that has arisen from accessing the approved health information. Progress and final report templates may be access from the Research Ethics and Governance Unit Web page.

Final Checklist:

- Completed PHA application for the Release of Health Information for the Purposes of Research under provision of Section 281 of the Public Health Act 2005;
- Evidence of approval from a HREC
- Evidence of signed authorisation from QH Data Custodian
- Evidence of signed authorisation from Clinical & Statewide Services for access to Pathology samples
- One signed copy of Confidentiality Agreement with names and signatures of all Applicants

Documentation may be provided in hard copy or scanned pdf.

Basis of Approval Process

To approve the application, the Chief Executive or delegate must be satisfied that the giving of the health information held by the department is in the public interest, having regard to:

- the opportunities the research will provide for increased knowledge and improved health outcomes; and
- the privacy of individuals to whom the health information relates.

If the application requests information identifying a person, the Chief Executive must also be satisfied that the identification of the person is necessary for the relevant research.

Possible Application Outcomes (S283 and S284)

- Granted: Approval.
- Granted approval subject to conditions: The chief executive may grant approval subject to conditions:
 - that the researcher must pay QH the costs of extracting the information;
 - that the information provided must be kept confidential and secure (see Confidentiality Agreement);
 - that researchers are aware of and comply with ethical requirements relevant to the conduct of the research;
 - that feedback on the progress and results of the research be provided to the chief executive.
- Further information requested: The chief executive may request further relevant information or documents from the researcher within a specified time frame, in order to finalise his/her decision.
- Denied: Approval is denied. If this occurs the Chief Executive is required to provide reasons supporting this decision.

4. PHA Application Template

PUBLIC HEALTH ACT – APPLICATION

Instructions: The information required from the researcher is provided in italics. This information should be inserted into the corresponding boxes, which may be expanded as required. The data custodian/s must sign your application form before submission, or provide a letter/email of support. Completed applications are to be submitted to the Queensland Health Research Ethics & Governance Unit at email: regu@health.qld.gov.au with the relevant attachments.

1 Title of Research Project:

2 Research Category:

Tick the research category to which the research proposal most closely aligns

- | | | |
|--|--|--|
| <input type="checkbox"/> Biomedical Study | <input type="checkbox"/> Evaluation and Planning Study; | <input type="checkbox"/> Epidemiological Study |
| <input type="checkbox"/> Clinical and applied Study; | <input type="checkbox"/> Monitoring & Surveillance Study | |

3 Principal Investigator / Co-Investigator / Additional Applicants:

This section should list:

- The name/names of the person/s proposing to conduct the research and who will be given or have access to the identifiable information for this research.*

4 Address of the Principal Investigator / Co-Investigator

Street:

Postal:

Telephone:

Email:

5 Name of Supporting Institution

6 Location/s where project will be conducted

7 Description of the proposed research study

In this section please provide:

7.1 – Describe the research study including the research objectives, benefits and outcomes.

7.2 - Describe the methodology used in the research project.

7.3 – Describe the rationale for using identifiable confidential health information.

7.4 - Describe the benefits of this research study for the community.

7.5 - How do the benefits to the public outweigh the risks for the individuals' whose identifiable information will use?

7.6 - What is the estimated duration of the research project?

8 Name/Description of Database and Data Items required:

8.1. - What is the scope of the data that the applicant/s is requesting access to for the purposes of research?

- Applicant/s **must list specific data items** required to undertake the research study. This may include but is not limited to – demographics (eg. date of birth, sex), hospital episode information, details of diagnostic data and/or details relating to health services accessed by individuals.
- It is important that all items of data are listed to ensure that data custodians can determine the availability of data requested and/or time and resources required in providing the data.

8.2. - What specific time period/s will this requested covers (e.g Jan 2000 – 2004)?

8.3 - What are the requested data intervals (e.g once only, every 3 months etc)?

9 Privacy and Confidentiality

9.1 - Who is providing the confidential information and how will the disclosure take place?

9.2 - In what form will data be disclosed (electronic or paper)?

9.3 - How will the security associated with the transfer of data be maintained?

9.4 - How will data security be maintained?

10 Authorisation from Data Custodian:

I have considered this proposal and consulted the appropriate personnel and I confirm that I have seen all relevant documents that are required. The Department is: *(tick whichever applies):*

able to confirm that the data services indicated will be provided, within the present resources;

unable to provide data services indicated, on the following grounds:

The custodian has supplied these data for an approved research request, but makes no warranty as to the fitness of the data, nor of the proposed methods, for the purpose for which the data has been provided and do not necessarily represent those of Queensland Health.

Name

Date

Position

Signature

Department

(Repeat "Authorisation from Data Custodian" if more than one required).

(A letter of support or email may be used, instead)

11 Human Research Ethics Committee (HREC) Approval

11.1 - State the name of the Human Research Ethics Committee that approved this research proposal

Evidence should be provided as an attachment that the research proposal has been reviewed by a human research ethics committee, including the contact details for each committee this applies to.

12 Undertaking of Confidentiality

- 12.1 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, such as discrete non urban indigenous communities.
- 12.2 I will not disclose confidential information in any released output (eg in reports, publications).
- 12.3 I will not use this confidential information for purposes other than for performing the specific activities detailed in my application as approved by the Chief Executive under the Act.
- 12.4 I will not use the confidential information except during the defined time period for which access to and use of this information was approved.
- 12.5 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.
- 12.6 **I agree to re-apply for approval from the Chief-Executive if:**
 - 12.6.1 - I require additional confidential information, or if
 - 12.6.2 - I want to extend the approved time period for access to or use of the confidential information,
- 12.7 The declaration of my interests in Research Proposals and associated documents shall be held in strict confidence by the relevant QH Human Research Ethics Committee and Queensland Health 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.

In signing this declaration, I declare that all researchers accessing identifiable data described in this application will adhere to the obligations specified above.

Signed by Principal Investigator

Principal Investigators Name

Date: / /

Attachments:

Please complete all the details required and attach the relevant documents.

1. Evidence of Approval from HREC , Dated: / /
2. Approval from the Data Custodian (see section 10)
3. Evidence of Approval from Clinical and State-wide Services (if Pathology samples is required)

5. After the study had been approved

All aspects of the study must be performed in the Queensland Cancer Registry (QCR) (usually by the visiting staff member) until the patient has given their consent for their details to be released.

All follow-up of doctors and patients must also be performed within the QCR. This includes all replies to doctor and patient enquires asking questions about the study.

Once the doctor and the patient has giving consent, then reports (both identifiable and non-identifiable), pathology reports etc can be taken out of the QCR.

The QCR will be reimbursed by the researcher for all costs associated with contacting doctors and patients.

5.1. Visiting staff of the Queensland Cancer Registry

5.1.1. Eligibility and conditions for appointment

Individuals must satisfy the following conditions in order to be appointed as Visiting Staff of the Queensland Cancer Registry.

- The Principal Investigator will not be eligible to be appointed as Visiting Staff of the QCR and can only see patient identifiable data once patient consent has been received.
- The Principal Investigator must write letter to Dr Jeff Dunn requesting appointment of Visiting Staff to the QCR (*refer appendix 7.4 and 7.5 for Letter Template*)

Visiting Staff of the QCR:

- Must be employed by a recognised organisation or institution (e.g. QIMR, University of Queensland, QUT, hospital staff) which requires access to Registry data for the purpose of conducting a research project.
- Must agree to be responsible to and under the supervision of the Registrar – Queensland Cancer Registry.
- Must undergo an induction and training process as appropriate for staff of the QCR.
- Must adhere to policies and procedures of the Queensland Cancer Registry and of The Cancer Council Queensland (TCCQ).
- Must sign a confidentiality agreement relating to information held within the Queensland Cancer Registry.
- Will be appointed as Visiting Staff of the Queensland Cancer Registry by TCCQ after considering a formal letter of request from Principal Investigator.

5.1.2. Appointment process

- A letter of agreement for each appointment will be required as to terms and conditions existing for the appointment between TCCQ and the other institution.
- A letter of appointment will be issued by TCCQ to the visiting staff member setting out conditions of appointment as visiting staff of QCR.
- Visiting staff will be required to complete:
 - TCCQ employment form providing personal details
 - Tax File Number declaration (for record purposes only and will not be submitted to ATO)
 - Time sheets for hours worked as visiting staff of the QCR.
- Visiting staff will be entered into a TCCQ Payroll system recording their personal details and the hours worked as visiting staff of the QCR with the remuneration rate set as zero.
- The institution who normally pays the visiting staff member will remain responsible for payment of remuneration and benefits. Additionally the institution will be responsible for workcover claims.
- Whilst at the TCCQ, visiting staff will not be covered by the QCF's insurance other than that which pertains to TCCQ's cover of public liability.

- Appointment as visiting staff of QCR will not attract remuneration for the time spent as visiting staff of QCR.

5.1.3. Policies and Procedures

As a QCR staff member you must be aware of The Cancer Council Queensland and Queensland Health policies and abide by them, especially in terms of privacy and confidentiality and code of conduct. Such documents are:

- Public Health Act 2005: Part 2 , Division 1 Cancer Notifications. This is the legislation that QCR abides by.
- Information Standard 42A: applies the National Privacy Principles to the collection and handling of all personal information within QH, including the Registry.
- QH Code of Conduct
- QH Usage of Internet and Email Usage
- TCCQ Sunsmart policy
- TCCQ Smoke-free policy
- TCCQ Health and Safety policy
- TCCQ Internet and E-Messaging policy
- TCCQ Workplace without harassment – Essential working conditions
- TCCQ Fire Procedure and Assembly Area

For the full list of policies and procedures for the Queensland Cancer Registry, please view the document: Policies and Procedures for the Queensland Cancer Registry (Includes Confidentiality and Privacy, Release of Information and Ethical Guidelines).

6. Contacting Doctors and Patients

6.1. Documents to be included in the DOCTOR package

- Letter to doctor - on QCR letterhead and signed by Registrar (may use electronic signature)
- Consent form for doctor's signature - on plain paper or <Research Institute> letterhead with study title at the top.
- Information sheet. This may be the same information sheet that is sent to the patient.
- Letter to patient to be signed by doctor - on QCR letterhead.

This package of material will be sent to the doctor in QCR envelopes. Postage will be paid by the researcher. A reply-paid envelope with a study return label will be enclosed, addressed to the Cancer Registry Locked Bag for the doctor to return the signed consent form and the letter for the patient.

When consent from the doctor is received, the package of material listed below will be sent to the patient. A reply-paid envelope with a study return label will be enclosed, addressed to the Cancer Registry Locked Bag for the patient to return the consent form.

6.2. Documents to be included in the PATIENT package

- Letter to patient signed by the doctor (when returned by Doctor from Doctors package).
- Consent form for patient's signature - on plain paper or <Research Institute> letterhead with study title at the top.
- Information sheet.

Note: the reply-paid envelopes to the doctor and the patient will have a label on the front such as:

< Registrar, Queensland Cancer Registry >
< Locked Bag No. 1450 >
< Spring Hill Post Office >
< QLD 4004 >

< Attn: < You can write or stamp the *Study Title here* > >

These are distributed to the visiting staff member to open.

6.3. Follow-up of doctors and patients

All follow-up will be conducted in the Queensland Cancer Registry.

Follow-up letters to doctors and patients will be on QCR letterhead and signed by the Registrar (may use electronic signature)

Follow-up telephone calls to doctors and patients must be made from the Queensland Cancer Registry. Record these calls on the Telephone Log for invoicing.

7. Other Information

- Monthly meetings with the Registrar at the beginning of each month as to the progress of the study and any difficulties or questions arising during that time.
- Assistant Registrar / QCR delegate checks all pathology reports to confirm the diagnosis before a letter is sent to the Doctor.
- All letters, follow-up and telephone calls to the Doctor and Patient must be performed and stored inside the Registry walls. No written information, copies of any notifications or pathology reports or lists of patients must leave the Registry.
- Any paper which has any patient/doctor details on that you do not need must be shredded.
- Keep a copy of the letter to the patient (signed by the doctor) before sending to the patient.
- Do not keep any original pathology reports in your possession unless agreed by the Registrar. Photocopy them and give them back to QCR.
- A confidentiality agreement must be signed and an access card signed for. The access card will give you access only to the QCR door in daylight hours; you must come through the front reception and walk through to the Registry. The front door is open from 8:15am during working days.
- For access to the computer network in the Registry you will need to fill out an Access form for a login name to the system. You will also need to enable a screen saver password to the computer at which you are using, which must be set at 10 mins. The network password is changed regularly and you will be prompted when this will happen.
- PC's and desk space are limited; you need to let the registrar know when you will be visiting the Registry. Noise is a concern for Registry staff; please keep noise to a minimum. If you will be making follow-up telephone calls, please discuss with the Registrar.
- A timesheet must be filled out on a monthly basis and given at the monthly meeting.
- A costing sheet for stationery, phone calls etc. to be reimbursed must be given on a monthly basis, at the meetings.

Items to be invoiced are:

- QCR Letterhead paper
- QCR Envelopes (Plain with QC Logo)
 - Sizes DL (small), DLX (slightly bigger than the DL), A5 (medium) and A4 (large)
 - QCR Reply – Paid Envelopes
 - Sizes DL, A5 and A4
 1. Number used of each
 2. Cost of postage for the amount of each size returned (ie. actually sent back via Aust. Post)
- Photocopying – number of photocopies done
- Telephone calls (Date and Time):
 1. Number of local calls
 2. Number of STD calls, locality and time spent
- Fax calls (Date and number of pages)

Items to be supplied by the visiting staff member are:

- A4 or A3 plain paper
- Postage stamps to put on every letter / package going to Dr and Patient
 - Stationery items eg pens, stapler etc...
 - Labels

8. APPENDIX

(Refer to following pages for appendix)

8.1. Application Checklist

RESEARCH APPLICATION CHECK LIST

Study Name	
Principal Investigator	

No	Requirement	Comment	Attached (Yes / No)
1.	Application Template		<input type="checkbox"/> Y <input type="checkbox"/> N
2.	Ethics approval		<input type="checkbox"/> Y <input type="checkbox"/> N
3.	Application proposal		<input type="checkbox"/> Y <input type="checkbox"/> N
	• Aims of study described		<input type="checkbox"/> Y <input type="checkbox"/> N
	• Method of data collection set out		<input type="checkbox"/> Y <input type="checkbox"/> N
	• QCR data requirements specified		<input type="checkbox"/> Y <input type="checkbox"/> N
	• An undertaking to comply with NHMRC guidelines		<input type="checkbox"/> Y <input type="checkbox"/> N
	• Measures to ensure security and confidentiality of data sent out in study		<input type="checkbox"/> Y <input type="checkbox"/> N
	• Date for de-identifying data or destruction of data supplied		<input type="checkbox"/> Y <input type="checkbox"/> N
	• Method of how data will be destroyed		<input type="checkbox"/> Y <input type="checkbox"/> N
			<input type="checkbox"/> Y <input type="checkbox"/> N
	COTACTING PATIENTS		<input type="checkbox"/> Y <input type="checkbox"/> N
4.	Copy of letter to doctor for permission to contact patient		<input type="checkbox"/> Y <input type="checkbox"/> N
5.	Copy of doctor's consent form		<input type="checkbox"/> Y <input type="checkbox"/> N
6.	Copy of information sheet for doctor		<input type="checkbox"/> Y <input type="checkbox"/> N
7.	Information sheet for patient		<input type="checkbox"/> Y <input type="checkbox"/> N
8.	Copy of letter to patient		<input type="checkbox"/> Y <input type="checkbox"/> N
9.	Copy of consent form by patient		<input type="checkbox"/> Y <input type="checkbox"/> N
10.	Copy of medical records release form		<input type="checkbox"/> Y <input type="checkbox"/> N
11.	Method of follow up for treating doctor if no reply		<input type="checkbox"/> Y <input type="checkbox"/> N
12.	Method of follow up of next of kin if patient dead.		<input type="checkbox"/> Y <input type="checkbox"/> N
13.	Method of following up patient if no reply		<input type="checkbox"/> Y <input type="checkbox"/> N
14.	Method to document verbal consent		<input type="checkbox"/> Y <input type="checkbox"/> N

8.2. QCR Data Items

Demographic Information

- Surname
- Given Name/s
- Date of Birth
- Medicare Number

- Address
- Suburb
- Postcode
- Statistical Locality Area (SLA)

→ This is the address the patient was at last notification received by QCR

- Occupation
- Sex
- Country of Birth
- Indigenous Status
- Marital Status
- Date of Death
- Cause of Death

For each Cancer the Person has:

- Site Code in ICDOv3
- Morphology in ICDOv3
- Differentiation
- Behaviour code (status)
- Date of Diagnosis
- Basis of Diagnosis
- Laterality

- Suburb (where patient was living at when diagnosed)
- SLA (where patient was when diagnosed)

→ This is the suburb the patient was at when initially diagnoses e.g. usual residence at diagnosis

If Breast Tumour:

- Tumour Size
- Number of Nodes
- Number of Positive Nodes

If Melanoma Tumour:

- Clark's Level
- Thickness
- Ulceration

For each hospital or pathology lab who has notified to QCR

- Institution
- Treating Doctor
- UR Number (pathology laboratory notifications won't have this completed)
- Admission Date
- Separation Date

8.3. Confidentiality Form



Queensland Government
Queensland Health

Undertaking of Confidentiality

BY THIS DECLARATION dated the _____ day of _____ 201_

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 under the provision of the *Public Health Act 2005*.

1. Definitions and Abbreviations

1.1. 'Act'

The *Public Health Act 2005*

1.2. 'Confidential information'

Information accessed under the Act 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.

1.3. 'NHMRC'

National Health and Medical Research Council

2. Ethical Obligations

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

2.1.1. *Public Health Act 2005*

2.1.2. NHMRC's *National Statement on Ethical Conduct in Research Involving Humans (1999)* and

2.1.3. NHMRC's *Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003)*

2.1.4. *Queensland Health Code of Conduct*

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, such as discrete non urban indigenous 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 Chief Executive under the Act.

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 Chief-Executive if:
 - 3.6.1. I require additional confidential information, or if
 - 3.6.2. I want to extend the approved time period for access to or use of the confidential information, or if
 - 3.6.3. 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 Queensland Government.
- 3.8. The declaration of my interests in Research Proposals and associated documents shall be held in strict confidence by the relevant QH Human Research Ethics Committee and Queensland Health 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.

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

.....
[Name of Applicant]

.....
[Signature of Applicant]

...../...../.....
[Date]

8.4. Templates to Doctor and Patient

(Refer to following page for templates)

8.4.1. Letter to doctor - on QCR letterhead

< Doctors Name >
< Doctors Address >
< >

< Date >

Dear Dr < > ,

As you know, the Queensland Cancer Registry collects information on all cases of cancer diagnosed in Queensland, as required under the *Public Health Act 2005*. One of the most important roles of the Cancer Registry is to facilitate research into cancer.

A study titled <study name> is being conducted by the <Research Institution> to investigate < aim/s and other information here as necessary>.

I am writing to seek your permission to approach your patient(s) who is/are registered with the Queensland Cancer Registry as having been diagnosed with <cancer site>.

This study has received ethics approval from <ethics committee>. The study has been considered and has been approved under Part 4 'Research' of the *Public Health Act 2005* to use the information in the Registry.

Following your written approval, the Queensland Cancer Registry would propose to send your patient(s) a personal letter signed by you (*letter is enclosed for your signature*) inviting their participation in this study. Only with your patient's consent will the researchers contact your patient(s) to <arrange a suitable time (for a telephone interview/ to complete the questionnaire/ other information as appropriate)>.

If you agree to your patient(s) being invited to participate in this study I would be grateful if you would:

- Complete the enclosed consent form
- Sign the letter to your patient(s) (the Queensland Cancer Registry requires that this letter to your patient(s) come under your signature).
- Return to us in the reply paid envelope
 - the consent form and
 - the signed letter.

If you do not wish your patient(s) to be approached, please indicate on the enclosed consent form and return to us in the reply paid envelope.

It is important for the scientific validity of the research to achieve as high a response rate from patients as possible. I greatly appreciate your assistance in this regard. I would be pleased to discuss any queries you may have about this request on (07) 3634 5333.

With thanks,
Yours sincerely

Ms C Scott
Registrar, Queensland Cancer Registry

8.4.2. Doctor's consent form (may be adapted according to individual ethics committee requirements)

< STUDY TITLE HERE >

Patient's name: «Given_Names» «Surname»
Date of birth: «Date_of_Birth»

Our ref number: «Pt_ID»
Date of diagnosis: «Dx_Date»

Address: «Current_Address1»
«Current_Address2»
«CURRENT_LOCALITY»

Phone: < Pt phone number >

[] **Patient contact details are correct according to my records**
If not, would you kindly supply correct patient contact details below

Address: _____

Phone: _____

[] **YES, I am happy for my patient to be approached to participate in the above study.**



Please sign the attached letter to your patient

[] **NO, I do not wish my patient to be approached**
Reasons: (optional)

Dr: «Dr_Given_Names» «Dr_Surname»

Address: «Dr_PO_Address1»
«Dr_PO_Address2»
«Dr_PO_Locality»

Telephone: «Dr_Phone1»

Doctor's signature

Date

If your patient is now being cared for by another doctor, we would be grateful if you could supply their name.

New doctor: _____

Address: _____

Please return this form and your signed letter if appropriate in the enclosed reply paid envelope to the Queensland Cancer Registry.

THANK YOU

8.4.3. Letter to patient - on QCR letterhead

< Patient Name >
< Patient Address >
< >

< Date >

Dear < Patient Title and Name >,

The Queensland Cancer Registry has contacted me about a research project titled <study name> being undertaken to < to investigate/examine etc. ...(outline the nature of the study)>.

The Queensland Cancer Registry collects, by law, information on all cases of cancer diagnosed or treated in Queensland. All information in the Registry is kept strictly confidential and is held under tight security.

One of the most important roles of the Registry is to assist cancer research. This study has been approved under the *Public Health Act 2005* to use the information in the Registry. With your consent, the researchers undertaking the study would like to < interview you by telephone/ ask you to complete a questionnaire/ other information as necessary outlining what is required of the patient.) If you agree, relevant information held by the Registry will be released to the researcher so that they can contact you directly about this. Would you be willing to take part in this research project?

Please find enclosed an information sheet that explains a little more about the study. If you are willing to take part would you please complete the enclosed consent form and return it to the Queensland Cancer Registry in the reply paid envelope, together with your contact telephone numbers. With your consent, the researcher will then < contact you to arrange a convenient time for the telephone interview/ send you the questionnaire to complete/ other information as appropriate >.

Participation in this research is entirely voluntary and any information you provide will be treated as strictly confidential. If you do not wish to participate, please indicate this on the form and return it to us.

If the Queensland Cancer Registry has not heard from you within < time period >, they will contact you to clarify whether you are willing to be involved. In the meantime, if you have any questions about the study please call <name of visiting staff member> on (07) 3634 5333.

Thank you for your assistance.

Yours sincerely

< Doctors Name >

8.4.4. Patient's consent form (may be adapted according to individual ethics committee requirements)

CONSENT FORM
< STUDY TITLE HERE >

YES, I agree to participate in the above research study.



Please complete and sign below.

I,
Full Name

of
Address

Home phone number:

Work phone number:

Mobile phone number:

have read the Information Sheet outlining the nature and purpose of the study and the extent of my involvement.

I have had the opportunity to ask questions, and I understand that I may request further information about the study as it proceeds.

I understand that participation in the study is voluntary, and that I may withdraw at any time. My decision whether or not to take part in no way effects my future medical treatment.

I give permission for the Queensland Cancer Registry to release my records held in the Queensland Cancer Registry to the researchers undertaking the study. I understand that all information will be treated in the strictest confidence. I understand that I will not be personally identified in any reports or publications resulting from this study.

Signed: _____ **Date:** _____

Contact person: < *Name and Contact Number of Researcher in the Registry* >

OR *I do not wish to participate in the above research study. (please tick if appropriate)*

8.4.5. Follow-up letter to doctor - on QCR letterhead

< Doctors Name >
< Doctors Address >
< >

< Date >

Dear Dr < > ,

As you are aware, one of the most important roles of the Queensland Cancer Registry is to facilitate research into cancer. It is important for the scientific validity of the research that we achieve high response rates from patients and I seek your assistance in this regard.

A short while ago I wrote to you about a study titled <study name> being conducted by the <Research Institution> to investigate < aim/s and other information here as necessary>. We appear not to have received your response and so I am writing again to seek your permission if possible to approach your patient(s) who is/are registered as having been diagnosed with <cancer site>.

This study has received ethics approval from <ethics committee>. The study has been considered and has been approved under the *Public Health Act 2005* to use the information in the Registry.

Following your written approval, the Queensland Cancer Registry would propose to send your patient(s) a personal letter signed by you (*letter is enclosed for your signature*) inviting their participation in this study. Only with your patient's consent will the researchers contact your patient(s) to <arrange a suitable time (for a telephone interview/ to complete the questionnaire/ other information as appropriate)>.

If you agree to your patient(s) being invited to participate in this study I would be grateful if you would:

- *Complete* the enclosed consent form,
- *Sign* the letter to your patient(s),
- *Return* to us in the reply paid envelope
 - the consent form
 - the signed letter.

If you do not wish your patient(s) to be approached, please indicate on the enclosed consent form and return to us in the reply paid envelope.

I greatly appreciate your assistance and I would be pleased to discuss any queries you may have about this request on (07) 3634 5333.

With thanks,
Yours sincerely

Ms C Scott
Registrar, Queensland Cancer Registry

8.4.6. Follow-up letter to patient - on QCR letterhead

< Patient Name >
< Patient Address >
< >

< Date >

Dear < Patient Title and Name >,

The Queensland Cancer Registry collects information on all cases of cancer diagnosed in Queensland. One of the most important roles of the Registry is to assist cancer research. For this research to be worthwhile, it is essential that we hear from as many people whom we contact as possible.

A short while ago you received some information from your doctor about a research project titled <study name> being undertaken to < to investigate/examine etc. ...(*outline the nature of the study*)>. We appear not to have received your response and so I am contacting you again to clarify whether you are willing to be involved in the study. I have enclosed a copy of the original letter signed by your doctor.

With your consent, the researchers undertaking the study would like to < *interview you by telephone/ ask you to complete a questionnaire/ other information as necessary outlining what is required of the patient.* >. If you agree, relevant information held by the Queensland Cancer Registry will be released to the researcher so that they can contact you directly about this. Would you be willing to take part in this research project?

Please find enclosed an information sheet that explains a little more about the study. If you are willing to take part would you please complete the enclosed consent form and return it to the Queensland Cancer Registry in the reply paid envelope, together with your contact telephone numbers. With your consent, the researcher will then < *contact you to arrange a convenient time for the telephone interview/ send you the questionnaire to complete/ other information as appropriate* >.

Participation in this research is entirely voluntary and any information you provide will be treated as strictly confidential. If you do not wish to participate, please indicate this on the form and return it to us.

In the meantime, if you have any questions about the study please call <name of visiting staff member> on (07) 3634 5333.

Thank you for your assistance.

Yours sincerely

Ms C Scott
Registrar, Queensland Cancer Registry

8.5. Visiting Staff Member Letter Templates to Dr Jeff Dunn

<< On your Letterhead >>

Dr Jeff Dunn
Executive Director
The Cancer Council Queensland
P.O. Box 201
SPRING HILL QLD 4004

Date

Re: Appointment of Visiting Staff of the Queensland Cancer Registry (QCR)

I would like to request the appointment of research staff involved in the approved study of '*Title of Study here.....*' as Visiting Staff of the Queensland Cancer Registry, as required by Queensland Health.

The following are the staff we would like appointed as Visiting Staff of the Registry:

Ms xxxxxxxxxxxx
Ms xxxxxxxxxxxxxxxx

The duties undertaken by these staff necessitate access to patient information listed in the Queensland Cancer Registry. Their appointment as Visiting Staff of the Registry will ensure that recruitment of patients to the above study continues smoothly.

Thankyou for considering this request.

Yours sincerely

Principal Investigator Name
PI Position etc....

8.6. CSV format for matching external cases to the QCR database

The file format is below. Field positions have a comma in between – if the data has a comma in it the field must be enclosed in double quotes. The surname and given names should be in capitals. The sequence number (ie: the first field) is any unique number. If you do not have a unique number, leave blank and then the first character in each line would be a comma.

seq_no, (unique number)
surname, (IN CAPITALS)
given_name_1, (IN CAPITALS)
given_name_2, (IN CAPITALS)
sex, (in 1=male, 2=female format)
date_birth (in DDMMYYYY format)- if the day or month is eg. the 5th, make sure that it says 05 and not just 5. There are no slashes in the Date.

There must be a Surname and a Given_Name_1 in the record, not left blank.
Please also ensure that the file does not contain any header details, the first record should be the first record of the data.

the data should look like this:

```
102,MOUSE,MICKEY,PETER,1,03111962  
103,DUCK,DONALD,MIKE,1,21031982  
104,LAMB,MARY,,2,11021922
```

To get your file into a CSV format the easiest way is to save your list in EXCEL as a comma delimited file. E.g. when you select save, in the 'save as type' chose CSV (Comma delimited), this will save your list in a CSV format.

Ensure a password is applied to the data file; you may also WINZIP the file with a password.

Post the data on a floppy disk or a CD and send by Registered Post to:

Carly Scott
Registrar
Queensland Cancer Registry
Locked Bag No. 1450
Spring Hill QLD 4004

E-mail the passwords to carly_scott@health.qld.gov.au separately.