Researchers applying under Chapter 6, Part 4 of the Public Health Act 2005 (Qld) (PHA) to be given health information held by Queensland Health or a Hospital and Health Service for research purposes (a ‘PHA application’) should familiarize themselves with the following processing requirements:[[1]](#footnote-1), [[2]](#footnote-2)

Guidance notes

for applying to be given health information for research under Chapter 6, Part 4 of the *Public Health Act 2005*

#### When is a PHA application required?

A PHA application is required when a researcher seeks to be given Information held by Queensland Health where **both** of the following apply:

* valid consent by, or, where relevant, on behalf of the individual about whom the Information relates has not been obtained for the disclosure and/or use of the Information for the purposes of approved research
* the disclosure is not between ‘designated persons’ as defined in s139A HHB Act for use in research ‘for evaluating, managing, monitoring or planning health services’ under s150(a) HHB Act

A data custodian may also request a PHA grant be obtained prior to disclosing the Information to provide assurance of valid authorisation to disclose.

Note that an 'opt-out' consent does not constitute a valid consent and a PHA approval may be required. Please check with your local Research Governance Officer (RGO).

Please Note:Health information that is capable of identifying an individual held in the private sector or by the Commonwealth is dealt with under the *Privacy Act 1988* (Cth). Queensland Health has no jurisdictional authority or administrative responsibility for health information held by the private health sector or the Commonwealth Government.

#### A PHA application may not be required if one or more of the following applies:

* Every individual about whom the Information relates validly consents to the disclosure and/or use of the Information for the purposes of the research.
* If the participant is an adult who has impaired capacity for consenting to participation in the research and the tribunal under the *Guardianship and Administration Ac 2000* (Qld) or, if that legislation does not apply, another person authorized under a law to make decisions for the participant consents to the participant’s participation in the research.
* If the Information is Confidential Information, every member of the research team who will be given the Information is a ‘designated person’ under s139A of the *Hospital and Health Boards Act 2011* (Qld) the Information will be used for research for ‘evaluating, managing, monitoring or planning a health service’ under s150(a) of the *Hospital and Health Boards Act 2011* (Qld) and the subject matter of the research directly relates to a current ‘health service’[[3]](#footnote-3) as defined in that Act.[[4]](#footnote-4)

#### Who can apply for PHA approval?

It is preferred that a PHA application be made by:

* the Coordinating Principal Investigator (CPI) for multi-centre research (on behalf of all sites), or
* the Principal Investigator (PI) for single-site research (i.e. the person to whom the HREC approval has been given)

Prior to submission of the application for assessment by the Director-General of Queensland Health as chief executive under the *Public Health Act 2005 -* or their delegate - it is the responsibility of the applicant to ensure that:

* the PHA application is complete, and
* all required documentation is provided, and
* all required approvals have been obtained, and
* all required signatures including the signature of the CPI/PI have been obtained.

Please note data custodians may have specific local requirements regarding access to the Information sought. You are advised to consult the relevant data custodians regarding Information disclosure requirements.

#### Information required in the application

It is the applicant’s responsibility to provide the following information in the PHA application:

a copy of the Human Research Ethics Committee (HREC) approval letter for the research [section 282(2)(i) requires that the application must state the views of an HREC about the research including contact details for the committee]

* + the title of the research project appearing on the HREC approval letter must be the same as the title of the research project for which the PHA application is made (the PHA approval letter will refer to the study as outlined in the HREC approval letter)
	+ the research project can only be reviewed by a fully constituted HREC registered with the National Health and Medical Research Council (not a sub-committee) when considering the request for a waiver of consent (see Chapter 2.3. *Qualifying for Waiving Conditions for Consent* of the *National Statement on Ethical Conduct of Research in Humans (2007*) – Updated 2018

signature of the CPI/PI and date of signing in the undertaking of confidentiality section of the form.

#### Data custodian consultation

Prior to making the HREC submission, researchers should consult with the relevant data custodians to ensure:

* the Information required is available and able to be disclosed to the researchers
* resources required for the data custodian to provide the Information are available (i.e. meeting Queensland Health’s reasonable costs of giving the Information may require payment of a fee) (section 284(4)(a))
* any other local requirements requested by the data custodian are met

Please note: Data custodian signatures that are more than 12 months old will not be accepted. Researchers must request data custodians to re-sign their authorisations and include the date of re-signing if authorisation dates are more than 12 months old at time of submission.

A list of frequently used Queensland Health data custodian contacts can be found here: <https://www.health.qld.gov.au/__data/assets/pdf_file/0034/843199/data_custodian_list.pdf>

#### The application process

The applicant completes the PHA application form.

The project described in the PHA application form cannot deviate from the HREC approved ethics application / protocol.

Each data custodian provides authorisation by signing and dating section 6 of the PHA application form.

The CPI/PI signs the Undertaking of Confidentiality and the applicant emails the form to PHA@health.qld.gov.au with supporting documentation including:

* evidence of HREC approval (final approval letter)
* any relevant HREC amendment approvals

Provided all requirements of the PHA application are met, the Director-General of Queensland Health or their delegate will consider the PHA application and choose from the following (section 284):

* not make a decision yet and require the applicant to provide further information within a stated time to better inform a decision; or
* grant the application for a period and, potentially, subject to specified conditions and provide reasons for the conditions, and enter the details of granted PHA applications into a register (section 288); or
* refuse the application giving reasons for the refusal and notify the applicant of the decision

**Please Note:**

* All applications must be typed (hand-written applications will not be considered).
* All acronyms must be defined at first point of reference.
* All data custodian approvals must be within twelve (12) months of submission to the Office of Precision Medicine and Research (OPMR), Prevention Division.
* If there is a change to the reviewing HREC during the PHA approval period, the researcher must provide all documents submitted and approved by the alternate HREC. There must be assurance that the studies are one and the same.

#### The application must state the following:

* A description of the research that includes the purpose of the research and the methodology (section 282(2)(a)(i) & (ii)).
* The type of Information required and the reasons the Information is required (section 282(2)(b) & (c)).
* A description of how the privacy of any individual that could be identified from the Information will be protected (section 282(2)(d)).[[5]](#footnote-5)
* If the Information will be needed at intervals during the research and details of the intervals (section 282(2)(e)).
* The name of the person or entity proposing to conduct the research and the names of all persons who will be given the Information for the research (section 282(2)(f) & (g)).
* The duration of the research (section 282(2)(h)).

#### Notification of change of persons being given Information under grant of PHA application

The PHA requires that if the names of persons who will be given the information for the research changes from the names stated in the notice under which the PHA was granted, the person for the time being in charge of the research must give notice to the Director-General of Queensland Health or their delegate as soon as practicable after the change. In these circumstances, the CPI/PI must, as soon as practicable after the change:

* submit an amendment request using the original PHA application form with the change in researchers clearly highlighted or identified using track changes [refer to note in this section] and
* the CPI/PI must re-sign the undertaking of confidentiality and include the date of re-signing and
* email the amended application to PHA@health.qld.gov.au

**Please note:** A change in persons may require HREC approval and the applicant should contact the reviewing HREC for its requirements.

#### All other changes require a new PHA application

For all other changes a new application is required.

The same procedure as for the original application applies except that the CPI/PI should:

* submit a new application using the original PHA application form with changes clearly highlighted or identified using track changes and
* the CPI/PI must re-sign the undertaking of confidentiality and include the date of re-signing and
* provide a ‘clean’ (that is, not highlighted or tracked) copy of the changed application re-signed by the CPI/PI at the undertaking of confidentiality and include the date of re-signing and
* email the amended application to PHA@health.qld.gov.au

**Please note:** Amendments may need HREC approval - check with your HREC to discuss. Where required, a copy of the HREC amendment approval must be supplied.

1. Glossary/explanations of terms

|  |  |
| --- | --- |
| Term | Definition |
| Confidential Information | Refer to the definition of ‘confidential information’ in s139 of the Hospital and Health Boards Act 2011 (Qld) which relevantly provides that ‘confidential information’ means information, acquired by a person in the person’s capacity as a designated person, from which a person who is receiving or has received a public sector health service could be identified. |
| Data linkage | Data linkage is a process that uses person-level identifying information (such as name, date of birth) to determine which records with a data source, or between multiple data sources, pertain to a particular individual.Queensland Health’s Statistical Services Branch data linkage team employs probabilistic methods to perform project-specific data linkage. Data output is provided with an anonymized person ID that the researcher may use to combine information from different sources, if applicable. |
| Information | Refer to the definition of ‘health information held by a health agency’ in Schedule 2 of the PHA – in general terms, the definition refers to information held by Queensland Health about a person’s health or the provision of a health service to a person, including a person who is deceased, which is capable of identifying the individual about whom it relates. In relation to a specific PHA application, Information refers to information which meets the definition in the PHA which is specifically requested in that application. |
| National Statement on Ethical Conduct in Human Research (the National Statement) | *The National Statement on Ethical Conduct in Human Research (2007) (as updated)* (published on <https://www.nhmrc.gov.au/guidelines/publications/e72>), developed jointly by the National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellor's Committee, which sets outs standards for the ethical design, review and conduct of research involving humans. It describes the roles and responsibilities of institutions, researchers, sponsors and ethical review bodies in conducting ethical research and applies whether the research is single centre or multi-centre. |
| Non-identifying information | Information that is not capable of identifying an individual – this kind of information will not include any identifiers such as name, address or Medicare number. |
| Re-identification | The process where non-identifying information, when used in various combinations, may be capable of identifying an individual. An example would be datasets that hold date of birth and an area code in an area consisting of 200 residents. Factors assisting in identifying data include presence of rare characteristics, accurate and complete information and newness of information. |
| Waiver of consent | When neither consent nor an opt-out approach is appropriate to obtain information that is capable of identifying an individual, the requirement to obtain consent may sometimes justifiably be waived. When an HREC grants a waiver of consent for research conducted prospectively or retrospectively, research participants will characteristically not know that they, or perhaps their tissue or data, are involved in the research. Please see Chapter 2.3 of the National Statement for further information. |

### Application Form for Chapter 6, Part 4 of the *Public Health Act 2005*

Note: where boxes are provided, at least one requires a tick

There are 10 parts to this form and all must be completed and submitted

#### Application Type

☐ Initial ☐ HREC approval letter attached

☐ Amendment No \_\_\_\_\_\_\_\_ Reference number of initial PHA grant\_\_\_\_\_\_\_\_\_\_

☐ HREC amendment approval letter attached where appropriate, for example, if changes to the protocol or changes to information requested have occurred (check with the HREC for guidance)

#### HREC information

|  |  |
| --- | --- |
| Name of Reviewing HREC |  |
| HREC Approval Number(also insert HREC approval number in page header) |  |
| HREC approval expiry date (or if no expiry date then indicate that approval is ongoing and provide the due date of annual report to HREC) |  |
| Project name(also insert Project name in page footer) |  |

#### Applicants

Coordinating Principal Investigator (CPI) / Principal Investigator (PI)
(Please note: CPI/PI must be the person to whom the HREC approval is addressed)

| Title  | eg Dr, Mr, Ms | Name |  |
| --- | --- | --- | --- |
| Institution and Position Title |  |
| Postal Address |  |
| Telephone |  | Email |  |

Contact person for notices (if different from CPI/PI)

| Title  | eg Dr, Mr, Ms | Name  |  |
| --- | --- | --- | --- |
| Institution and Position Title |  |
| Postal Address |  |
| Telephone |  | Email |  |

All researchers or persons being given the Information (insert more rows if required)

| Title and Name of Person | Position Title | Name of Institution |
| --- | --- | --- |
| e.g. Dr, Mr, Ms |  |  |
| Title and Name of Person | Position Title | Name of Institution |
|  |  |  |
| Title and Name of Person | Position Title | Name of Institution |
|  |  |  |

#### Locations where project will be conducted

| e.g. RBWH, PAH  |
| --- |

#### Description of the HREC approved research

Please answer the following questions in the space below.

**Please note:** information provided here must not deviate from the HREC approved protocol.

**5.1 Describe the research project including the research objectives and expected outcomes**

|  |
| --- |

**5.2 Outline the methodology** (include the number of patients required and justification for this number as well as for the date range for the data items and if any patients aged <18 years)

|  |
| --- |

**5.3 Justify the use of Information and how the benefits of the project (to the public) outweigh the risks for the individual/s whose Information will be used**

|  |
| --- |

#### Description of the data items required (Information) and data custodian/s authorisation

|  |  |
| --- | --- |
| **Cohort Scope** (Define the patients for whom data are requested (e.g. age range, sex)) |  |

***Please copy and paste the entire table below and corresponding data custodian authorisation for each data source (i.e. copy and paste 6.1 and 6.2 together for each data source).***

**6.1 Data**

|  |  |
| --- | --- |
| **Data source**(only **one** source per table (e.g. one table for AUSLAB; one table for medical records; one table for CIMHA)) |  |
| **Data description**(describe characteristics that define the requested patient records/events (e.g. inclusion and exclusion criteria; date range of patients’ presentation and/or interaction with Queensland Health)) |  |
| **Data item/s to be given to researchers** (only data items from the data source listed above with each data item on a separate line) |   |
| **Date range**(specific start date and specific end date are required (e.g. 01/01/2004 to 31/07/2014), approval cannot be given outside the HREC approval period and the dates must correspond with the date range in the HREC approved protocol) |  |
| **Frequency of request**(interval when data custodian will supply the data (e.g. once; six monthly; specific dates)) |  |
| **Data items to be used for linkage** (if applicable) |  |

**6.2 Data custodian authorisation for the aforementioned data items (collectively,** **Information)**

Data custodian declaration:

I have considered this application and have seen all the relevant documents (including the HREC approval letter) that are required for this research and confirm that our unit is able to provide the data services indicated in this application within present resources.

In supplying the Information for an approved research project, no warranties are made as to: the fitness of the Information; the appropriateness or validity of the proposed research methods; or the appropriateness of the purpose for which the Information is being given.

| **Repository name** |  |
| --- | --- |
| Data custodian to list any special conditions or limitations that may be applied as a condition by the decision-maker (e.g. cost per record or whether authorisation is dependent on availability of staff at the time of data request): |
| Data Custodian Name |  |
| Position |  |
| Unit |  |
| Hospital / Facility |  |
| Signature of data custodian |  | Date |  |

Signature of data custodian must be no more than twelve (12) months old at time of submission to the Director-General’s delegate.

1. Data Linkage

**7.1 Is data linkage required for this project?**

 [ ]  Yes [ ]  No

**7.2 Have you consulted with the data linkage service?**

 [ ]  Yes [ ]  No

**7.3 Who is linking the data?**(If Queensland Health please name the department/branch undertaking the linkage)

|  |
| --- |
|  |

1. Privacy and confidentiality

**8.1 In what form will the Information be disclosed to you?**

[ ]  Electronic [ ]  Paper [ ]  Both paper and electronic

**8.2 Who is giving the information to you (including the name of the relevant person/s giving the information and to whom the information is given).**

|  |
| --- |

**8.3 How will the privacy of any individual that may be capable of being identified from the Information or its use in combination with other information be protected?**

|  |
| --- |

**8.4 How will Information security be maintained, throughout its entire research pathway?**

|  |
| --- |
| (e.g. where will the information be transferred to (including name of institutions and physical locations) and by whom, the method/software that will be used to transfer the information, how it will be shared and with whom) |

1. Checklist

This checklist is provided to help in submitting your application (all boxes require a tick before submission).

| [ ]  | Does the PHA application title match the HREC approval letter title? (Section 2) |
| --- | --- |
| [ ]  | Have you included the HREC reference number, expiry date and attached a copy of the HREC approval letter and all HREC amendment approvals? (Section 3) |
| [ ]  | Have you listed all people who will be given the requested Information and their institution/s? (Section 3) |
| [ ]  | Have you answered all sections clearly and provided documents to support your application? |
| [ ]  | Have you listed all data repositories, data items, and data dates required? (Section 6) |
| [ ]  | Have you specified how privacy, confidentiality and Information security will be maintained? (Section 8) |
| [ ]  | Do you have relevant data custodian/s authorisation for all Information required? More than one data custodian authorisation may be required. (Section 6) |
|  | If all the above boxes are ticked, please proceed to Section 10 and sign the undertaking of confidentiality. |

1. Coordinating Principal Investigator / Principal Investigator undertaking of confidentiality

In the course of being, as relevant, given, holding, using or further disclosing Information for research purposes in relation to this application, if granted, I acknowledge that:

* I will be given Information which, if inappropriately dealt with or managed or insufficiently secured may cause loss or damage to individuals, public or private facilities or communities.
* I will not disclose Information in any publication whatsoever (including, for example, any report or communication disclosed to persons or entities other than those listed in a grant of this application).
* I will not use Information for any purpose other than for performing the specific activities detailed in my application if granted.
* I will ensure that the Information is not disclosed to any person or entity other than those listed in a grant of this application and is kept confidential.
* I will ensure that the Information is securely stored such that it cannot be accessed by any person or entity other than those authorised to be given the Information as listed in a grant of this application, including in relation to disposing of it securely.
* I agree to submit a further application to amend this application, if granted, or a new application (as applicable) if:
	+ I seek additional information (this includes but is not limited to, additional data from the same data sets, new data sets and new sites)
	+ I want to extend the time period for the grant of this application, if granted
	+ another researcher not listed in a grant of this application, if granted, seeks to be given Information for the purposes of the research listed in the grant of application, if granted.

In signing this undertaking, I will take all steps necessary to ensure that all researchers, including myself, involved in the research given Information described in this application, if granted, will adhere to the obligations specified above and the conditions set out in a grant of this application, if granted. I believe that the public interest benefits of this research outweigh the public interest detriments, including maintaining confidentiality and privacy of patients who may be identified by the Information, and will provide for increased knowledge and improved health outcomes (section 284(2)(a)(i)).

I also acknowledge that if this application is granted by the Director-General of Queensland Health as chief executive under the Public Health Act 2005, or delegate, the research project must satisfy a Research Governance review process prior to commencement of the research.

|  |  |
| --- | --- |
| Signature |  |
| Coordinating Principal Investigator / Principal Investigator Name (please print) |  |
| Date |  |

Please note. This section cannot be signed by any person other than the person nominated as CPI/PI at section 3.

1. Refer to the glossary in section 10 for terms defined in this document. [↑](#footnote-ref-1)
2. References to sections in legislation without reference to another Act are references to the PHA. [↑](#footnote-ref-2)
3. Research is not, of itself, a ‘health service’ under the *Hospital and Health Boards Act 2011*. [↑](#footnote-ref-3)
4. To avoid breaching the law, it is strongly recommended you obtain legal advice regarding your project before seeking to use s150 of the *Hospital and Health Boards Act 2011* for research purposes. [↑](#footnote-ref-4)
5. Given s279A(b), the phrase ‘any individual identified’ in section 282(2)(d) is taken to mean ‘any individual that could be identified from the information’. [↑](#footnote-ref-5)