

CHI

Centre for Healthcare Improvement

Office of Health and Medical Research

Legal Requirements of Fellowships

Senior Clinical Research Fellowship

Clinical Academic Fellowship

Health Research Fellowship

*To be read in conjunction with Legal Requirements of
Fellowships*

Office of Health and Medical Research

Queensland Health

April 2011

Tomorrow's Queensland:
strong, green, smart, healthy and fair

Toward 
Tomorrow's Queensland

 **Queensland**
Government

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Legal Requirements of Fellowships

Prepared by the Office of Health and Medical Research | December 2010

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1 Purpose of document

This document provides important information about the Health Research Fellowships which form part of the Health Research Program. The Legal Requirements of the Fellowships document should be read in conjunction with the with the relevant Fellowship guideline document.

The **Health Research Fellowship Program**, administered by the Research Programs Unit of the Office of Health and Medical Research (OHMR), will provide \$20.55 million in funding over four years. It was established by the Queensland Government to retain, develop and recruit outstanding health and medical researchers. (<http://www.health.qld.gov.au/ohmr/html/funding/funding.asp>)

2 Applicants are to inform themselves

It is the applicant's responsibility to:

- read and familiarise themselves with this legal requirements document, and all other documents referenced within this document
- carry out their own investigations into the feasibility of the proposed position
- seek professional advice as is appropriate to an arrangement of this type.

3 Privacy and conduct

Fellows are required to comply with:

- the privacy requirements applying to Queensland Health under Information Standard 42A (<http://www.qgcio.qld.gov.au/SiteCollectionDocuments/Architecture%20and%20Standards/Information%20Standards/Current/is42a.pdf>)
- the Privacy Act 1988 (Cth) (http://www.austlii.edu.au/au/legis/cth/consol_act/pa1988108/)
- the Queensland Health Code of Conduct (http://www.health.qld.gov.au/about_qhealth/cc.asp)

4 Application process

4.1 The OHMR discretion in the application process

The OHMR may in its absolute discretion:

- cancel or vary the process set out in the Funding Guidelines including any timeframes and selection criteria
- cancel, supplement, modify or replace the Funding Guidelines
- extend the time for submission of applications
- decide not to proceed with any of the submitted applications.

4.2 Confidentiality

Queensland Health will treat all information received in confidence. All information provided during the application process is received and accepted by Queensland Health in confidence, subject to any applicable statutory exception.

It is the responsibility of the OHMR, the review panel, assessors, referees and other persons involved in the selection process not to disclose any personal confidential information to which they become privy as a result of exercising their responsibilities to the OHMR.

Information including the names of successful fellows, their administering health facility, the title and summary of the research project and the fellowship amount may be made available publicly and for regular reporting and evaluation purposes.

Details of unsuccessful applicants are to remain confidential.

Documents held by the Queensland Government are subject to the [Right to Information Act 2009](#) and will be retained as required under the [Public Records Act 2002](#).

4.3 Commissions and incentives

An applicant must not give or offer to Queensland Health or any officer or employee of Queensland Health, or to a parent, spouse, child or associate of an officer or employee, any inducement, gift or reward, which could in any way influence Queensland Health's actions in relation to an application.

If the OHMR discovers at any time that an applicant has not complied with this Section, the OHMR may not consider that application.

4.4 Incomplete, false or misleading applications

If the OHMR believes that omissions or inclusion of misleading information are intentional, it may take such action as it deems appropriate (which may include exclusion of the application or termination of the fellowship) and may also refer the matter for appropriate legal action.

Examples of false or misleading information in an application include, but are not restricted to:

- providing fictitious track records
- falsifying claims in publication records (such as describing a paper as accepted for publication when it has only been submitted).

4.5 Contact with the review panel members or assessors

Applicants, or persons acting on their behalf, may not contact the review panel members in relation to their application. If they do so, the application may be deemed ineligible and therefore excluded from further consideration.

5 Intellectual property

The ownership, use and commercialisation of intellectual property (IP) created during the term of a research fellowship managed by the Office of Health and Medical Research, will be determined by contractual arrangements between Queensland Health (QH), the relevant research institute, and the successful recipient.

Generally, QH will seek the following outcomes via the terms of the contract:

- IP will be owned by the institute (e.g. university or medical research institute)
- the institute will bear all costs of IP protection, management and commercialisation
- QH will retain rights to:
 - a) use the IP for QH's internal service delivery purposes
 - b) receive revenue from commercialisation commensurate with QH's contribution to the research project.
- Contractual arrangements will be determined with the relevant research institute and the successful recipient, subsequent to the awarding of the fellowship.

6 Compliance with laws

All research undertaken by the applicant, unless otherwise specified, must comply with all applicable statutory requirements, government codes, policies or guidelines and any current Australian Standard, and where an Australian Standard does not exist, the relevant and current International Standard will apply.

Research conducted as part of the fellowship must be consistent with:

- the National Statement on Ethical Conduct in Human Research (2007)
http://www.nhmrc.gov.au/files_nhmrc/file/publications/synopses/e72-jul09.pdf
- Australian Code for the Responsible Conduct of Research
http://www.nhmrc.gov.au/files_nhmrc/file/publications/synopses/r39.pdf
- Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research <http://www.nhmrc.gov.au/publications/synopses/e52syn.htm>
- TGA Good Clinical Practice Guidelines
<http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf>

7 Approvals and clearances

Fellowship funds cannot be provided unless the applicant/s submits documentation that demonstrates that relevant approvals and clearances have been obtained.

Clearances will cover the life of the fellowship and may need to be renewed during the award.

The fellow will advise the OHMR, within six months of a fellowship offer being made, whether or not relevant ethics approvals have been obtained.

Non-compliance with the above requirements within six months of the offer of the fellowship may render the grant null and void.

Relevant approvals may include:

- research involving animal experimentation (http://www.nhmrc.gov.au/health_ethics/animal/index.htm)
- research involving the use of recombinant DNA, teratogens or carcinogens (<http://www.oqtr.gov.au>) and (<http://www.nohsc.gov.au>)
- research involving humans.

7.1 Research involving humans

Queensland Health requires assurance that research involving humans has been reviewed and is approved by the relevant Human Research Ethics Committee (HREC) as complying with the *National Statement on Ethical Conduct in Human Research (2007)*, the *Australian Code For The Responsible Conduct of Research (2007)* and any other regulations or guidelines relevant to HRECs prescribed by the Principals of Good Clinical Practice applicable in Australia; and if applicable, the Therapeutic Goods Administration.

Human research, in this context, includes research involving any human tissue, no matter what the source, and also includes research in which there is any intervention (physical or psychological) in the normal lives of humans. Projects supported by Queensland Health must conform to the general principles outlined in the National Statement.

7.2 Human embryo research

Relevant legislation includes Research Involving Human Embryos Act 2002 (Cth), Prohibition of Human Cloning for Reproduction Act 2002 (Cth) and Research Involving Human Embryos and Prohibition of Human Cloning for Reproduction Act 2003 (Qld).

These acts establish a strong regulatory framework to prohibit certain unacceptable practices including human cloning for reproduction, and regulate activities that involve the use of certain human embryos created by Assisted Reproductive Technology or by other means.

Applications which involve the following may require a licence under the Research Involving Human Embryos Act 2002 (Cth):

- the use of excess Assisted Reproductive Technology embryos
- the use of human eggs
- the creation of embryos other than by fertilisation of a human egg with a human sperm or use of those embryos.

Further information regarding research using human embryos can be found from the National Health and Medical Research Council (<http://www.nhmrc.gov.au/research/embryos/index.htm>).

8 Contractual relationship with OHMR

The Funding Guidelines and the Legal Requirements documents for the Health Research Fellowship Program are not intended to give rise to any contractual relationship upon an application being submitted.

The applicant and Queensland Health do not enter into a binding legal relationship unless and until a subsequent agreement is executed between Queensland Health and the applicant.

No applicant will be entitled to claim compensation or loss from Queensland Health for any matter arising out of the application process, including but not limited to any failure by Queensland Health to comply with the relevant Funding Guidelines.

Funding for the project will not be released until a contract or memorandum of understanding (MOU) has been signed by all parties nominated on the application.

8.1 Change of circumstances

If an applicant's circumstances change after submission of an application for a fellowship or during the course of a fellowship, the fellow will notify the OHMR immediately.

The notification will detail the change in financial and administrative functions of the fellow and effects of the change on the fellow's ability to undertake the fellowship.

Failure of a fellow to advise the OHMR within three months of a change of circumstances could result in the fellowship being terminated.

8.2 Termination of Contract

Queensland Health may withhold payments or terminate the contract if there is:

- failure to comply with visa or registration requirements
- failure to participate in program review activities and submission of annual financial and progress reports
- failure to advise of change of circumstances relating to position
- failure to adhere to terms of funding agreement
- professional misconduct.

8.3 Payments

All payments are to be allocated in accordance with the contractual arrangements between the applicant, the Queensland government funded health care facility and Queensland Health.

Payments will be made from Queensland Health to the Health Service District to be distributed to the fellow as outlined in the contractual agreement.

Unless otherwise agreed payments will be conditional upon the approval and clearance requirements outlined above and the receipt of the annual financial and progress reports.

9 Assessment

As part of the peer review process, the OHMR reserves the right to consult external assessments from experts in the field. The external assessors, not nominated by the applicant, agree to assist the OHMR on the basis of confidentiality, and as such their identity will not be disclosed to applicants.

The Health Research Fellowship applications are considered against the selection criteria by an independent review panel that recommend and endorse the successful Fellowship recipients.

Due to the limited time commitment of the external review panel, the OHMR is unable to provide individual feedback.

The OHMR will not enter into any oral or written correspondence about the selection decisions.

The selection decision will be final.

10 Reporting obligations of Fellows

Fellows will be required to submit to the OHMR reports outlining their progress including the following:

10.1 Annual financial report

The Annual Financial report documents that the funding has been used for the purpose as outlined in the agreement. The annual financial report must be submitted by 31 August each year of the fellowship by the Finance Officer of the applicant's health facility and/or university/institute. A final financial statement is to be submitted within three months of completion of the fellowship.

The non-receipt of the Annual Financial Report will impact on the release of the fellowship funding for the following payment period or could lead to termination of the fellowship.

10.2 Annual progress report

An annual progress report will be due twelve months following commencement of the fellowship.

The report must outline progress of the research project against the milestones and aims of the Health Research Fellowship Program and is to be submitted to the OHMR. Annual progress reports will be reviewed by the Executive Director of the OHMR.

The non-receipt of the annual progress report may result in the withdrawal of funding for the following payment period.

Additional information may be requested to complete the review. A one hour interview may be requested at the discretion of the Executive Director of the OHMR.

10.3 Final report

The final report is to enable the OHMR to assess whether the objectives of the fellowship have been achieved, and to gather information for the OHMR's internal performance measurement.

The final report must be submitted within three months of completion of a fellowship, or termination of the fellowship.

11 Dissemination

To maximise the benefits from research, findings should be disseminated as broadly as possible to allow access by other researchers and the wider community.

The OHMR encourages fellows to consider the benefits of publishing data from the research project in an appropriate medium of their institution or externally.

Publication related to the fellowship of any description should be identified in the annual and final reports.

The OHMR should also be notified immediately when work is submitted for publication in peer reviewed or other journals or presented at conferences to enable press releases and announcements to be made in an appropriate manner.

Further information can be found in the *Australian Code for the Responsible Conduct of Research* (<http://www.nhmrc.gov.au/publications/synopses/r39syn.htm>).

It is expected that successfully appointed fellows will make time available during their fellowships to publicly present their research findings or other outputs to audiences including the OHMR, Queensland Health and external researchers.

12 Advertisement

Successful applicants, their departments or institutes must not make any public announcement or advertisement in any medium in relation to the application process without the prior written approval from the OHMR.

13 Further Information

Further information regarding the Health Research Fellowship may be obtained from:

Research Programs Unit, Office of Health and Medical Research.
Phone number: (07) 3405 6121
or email: ohmr@health.qld.gov.au