

# Information for medical researchers – what are the first steps I should take to identify and protect Intellectual Property (IP) in my research?

## Purpose of this fact sheet

To assist Queensland Health (QH) employees who undertake medical/scientific research, to identify and protect intellectual property (IP) through the patenting process. It identifies the first steps that need to be taken before a patent application is made. In summary these steps are:

- Step 1: keep documentary evidence of the research
- Step 2: maintain confidentiality
- Step 3: search the 'Prior Art'
- Step 4: determine the most effective way to create public health benefits from the research
- Step 5: clarify:
  - who are the inventors
  - who owns the IP in the research
- Step 6: complete the QH "*Invention Disclosure Form*" and submit it to your Manager, Business Manager or Research Manager, and a copy to the IP Officer.

Further details of each step are set out below.

## 1 Keep documentary evidence of the research e.g. maintain lab books

The main purpose of keeping documentary evidence of the research is to be able to prove:

- who was responsible for the research
- when the research took place.

This documentary evidence will be particularly important if a patent application is eventually filed in the USA, and the application is challenged by competing research interests on the basis that they actually completed the research before you did. This is because the USA grants patents based on who can prove that they were the first to invent. This differs from most other countries which grant patents on the basis of who was first to file a patent application.

## 2 Maintain confidentiality: keep the research/invention confidential until it has been evaluated.

Generally, in order to secure IP rights via a Patent, you need to keep the research/invention secret until the IP is registered with an Australian Government department. This is because Patents have to be “new”. If your research is not kept secret before a Patent is filed, then your research will no longer be “new” and any opportunity to secure IP rights may be destroyed or at the least severely restricted.

Keeping your research secret means **NOT DOING** any of the following:

- presenting the invention or even key aspects of your research at a conference in any way i.e. orally, poster format or over a drink at the bar
- discussing the invention or research with people (who are not collaborators on the research) at a conference
- submitting an article for publication in a journal that discloses the invention
- using the invention or research commercially i.e. selling or even agreeing to sell any research results
- writing up the research in a thesis and then publishing the thesis
- discussing the invention with potential commercial interests and manufacturers, without a confidentiality agreement being in place.

You **CAN** however, disclose, demonstrate or discuss the invention/research with the following people in the following ways without destroying secrecy:

- other collaborating inventors working on the same project
- other employees of QH or collaborating researchers employer institutions who are in a role to assist in managing your research i.e. your Manager, Research Manager, Business Manager or the IP Officer etc
- professional consultants such as legal advisers and patent attorneys
- where you use the invention for reasonable trial or experiment only.

If you need to make your invention or research public (e.g. you wish to discuss your project with potential investors), there are two means which enable you to do so, while still maintaining the ability to register the invention/research as a patent. These are:

- disclosing *only* after filing a patent application; or
- using a Confidentiality Agreement. A QH Confidentiality agreement is available from your Research Manager or the IP Officer, via the email details at the bottom of this fact sheet.

Even after you (or QH) has filed a patent application, there are still some issues to be aware of if you want to publish your research: e.g.

- if a provisional patent application has been filed, then you *must not* publish any additional important information that was not included in the application. To do so may mean that you will lose protection for that information
- if further work is required e.g. to add data to the provisional application, it is not advisable to publish your research until after a *complete* patent application has been filed (i.e. 12 months after filing the provisional application)
- your strongest position will be when you do not publish your research, until the patent application itself is published by the Patent Office, approximately 18 months after the initial Provisional application was made. Publishing prior to this will enable any competing researchers to potentially better your research.

### 3 Search the Prior Art: identify if your research is actually new enough to be granted a patent by searching the “prior art”.

In order for your research to be patentable, it must be both new *and* an “inventive step” over the existing research in the field (i.e. the “prior art”). Therefore, you will need to know the current stage of research in your particular field. You do this by searching the “prior art”. This step will also ensure that your current/proposed research is not “reinventing the wheel”, thereby saving you time and resources.

Searching the “prior art” is a two-step process:

- *undertake a publication search* – a search of published journals. Check with your colleagues whether they have done a ‘literature review’ for the technology in question. Your library will be able to assist you with this search. If your research is the subject matter of an already published article, your research will generally not be patentable; and
- *undertake a patent search* – by using the European Patent Office website (because it’s easy and includes worldwide patents and patent applications). Short instructions that will assist you to identify what is going on around the world in regards to patenting activity in your research field are:
  - go to <http://ep.espacenet.com> (this is the European Patent Office website)
  - click on “Advanced Search”
  - enter a keyword relating to your research field in the “Keyword(s) in title” or “Keywords(s) in title or abstract” fields
  - click “Search”.

The following table sets out further step by step instructions that will assist you to find relevant information by using the *Advanced Search* option.

	What	How
1	Advanced Search	<ul style="list-style-type: none"> <li>The “<i>Advanced Search</i>” option provides several search fields to narrow the search results.</li> <li>Extra information is available in a small “<i>Quick Help</i>” box on the bottom left of the screen to help you navigate the system.</li> </ul>
2	Database choice	<ul style="list-style-type: none"> <li>In the “<i>Select patent database</i>” field, choose the “<i>worldwide</i>” database option.</li> </ul>
3	Search fields - Numbers	<ul style="list-style-type: none"> <li>The most accurate method of searching is by a “<i>Publication/application/priority Number</i>”, if known. Be mindful that the correct number format (i.e as stipulated to the right of each search field) is used otherwise no results will be yielded.</li> </ul>
4	Search Fields - Keywords	<ul style="list-style-type: none"> <li>Known keywords (i.e. based on the given patent topic) can be inserted either in the “<i>Keyword(s) in title</i>” field or the “<i>Keywords in title or abstract</i>” field for a broader result.</li> </ul>
5	Search fields – Applicant/Inventor	<ul style="list-style-type: none"> <li>These fields can be used separately, or in conjunction with each other, or in conjunction with the other fields for maximum search efficiency.</li> <li>The preferred search option is the use of the inventor’s last name and the known applicant for accurate results.</li> </ul>
6	Search results	<ul style="list-style-type: none"> <li>The “most relevant” document(s) will come out as the relevant result(s).</li> <li>Click on the title of the patent/patent application to open up further information.</li> <li>A document-specific page will appear and the document can now be perused online under several layers of detail: <ul style="list-style-type: none"> <li><i>Bibliographic data</i> (always available)– general patent information – including a link to “INPADOC patent family” (in red) which leads to ALL of the registered affiliated documents to this patent, including national phase applications, the PCT document, and the original provisional application in some instances.</li> <li><i>Description/Abstract</i> (may not be available) – a useful synopsis of the patent</li> <li><i>Claims</i> (may not be available) – this is where to find the relevant claims of the document.</li> <li><i>Original Document</i> (always available) – The original patent document. This is where the full application will be found, together with the patent examiners report (describing patentability/prior art – see 7)</li> <li><i>Inpadoc Legal Status</i> (may not be available) – all the relevant legal information can be inferred from the information on this site. Specific descriptive documents that decipher the meaning of the Inpadoc legal codes may be found in the “<i>Quick Help</i>” menu as a downloadable document.</li> </ul> </li> </ul>
7	Search Report	<ul style="list-style-type: none"> <li>A useful document published with the patent is the “<i>Search Report</i>”.</li> <li>This is available under the “<i>Original Document</i>” tab at the end of the patent/patent application. Click on the arrow at the top of the document to go to the end page.</li> <li>This document is a report from the Patents Office as to whether the patent application is considered new and inventive when compared with the “<i>Prior Art</i>”.</li> <li>Reading this report carefully, will give you important information as to the current stage of research in your particular field.</li> <li>A letter assignment determines how important a listed document is. An “X” or a “Y” listing are the main ones to be concerned about. An “A” listing, may be for a cited document with non-key disclosure. In addition, the correlation of the documents to any given patent claim is also given (i.e. the cited document may not relate to a complete document).</li> </ul>

This preliminary search will not be comprehensive. If the invention is to be patented, a more precise search should be undertaken by a patent attorney. This search will be more detailed, and is more likely to identify any 'prior art'. If you would like assistance with undertaking a preliminary search, contact the Intellectual Property Officer via the contact details at section 8 below.

## 4 Determine the most effective way to create public health benefits from the research

Basically, there are two pathways that can be taken to create public health benefits from your research:

- placing the research in the “public domain” by freely publishing without taking steps to protect the research (e.g. via a patent application); or
- the commercial path, where steps are taken to obtain proprietary property rights over the research (e.g. via a patent application), and these property rights are then provided to a commercial firm(s) to provide the necessary incentive for the firm to invest funds into the research in order to:
  - undertake further research to confirm results and/or to package the research into products and or services
  - obtaining regulatory body approvals
  - manufacture products based on the research; and eventually
  - distribute and market the products to end users to create health benefits.

In general, the commercial path would be the most effective when the following conditions are met:

- the research needs to be incorporated into a manufactured product and the product needs to be distributed through existing channels to the health consumer; (compare this to a new method of treatment which (although being patentable in some countries), needs only to be published widely to create the desired public health benefits
- there is a unmet need for the product/service
- the market for the need is large
- there are no similar substitute products already on the market that provide the health benefits of the research
- substantial additional \$\$\$ are required to either prove the research or/and to package the research into a useable product
- the research and patented property rights provide an opportunity to existing companies operating within the specific field/industry.

## 5 Should the commercial path be suitable then clarify a) who are the inventors? and b) who owns the IP in your research?

You (with the assistance of your Research/Business Manager and/or the IP Officer) will need to clarify who will own the IP in your research in order to determine who has the responsibility to manage the IP. There are several possibilities:

- if your research project was undertaken by you in the course of your employment with QH, the IP will initially be owned by the State of Queensland and managed by QH
- if you have undertaken your research project with employees of another entity (ie a University), the IP may be jointly owned by QH and the University. If so, it will be necessary to involve the University IP & Commercialisation office in regards to clarifying ownership and management of the IP
- if you have undertaken the research outside the course of your employment, then you may be the owner
- where IP is created for QH by external consultants/contractors, IP ownership may have been clarified in a contract. Prior to the initiation of any research project, IP issues should be clarified in an appropriate agreement
- different rules apply to students. Generally the student will own any IP created in a research project. Within QH, IP issues involving students are stipulated in the students "Student Placement Agreement".
- if your research project has been funded by grants, there may be conditions imposed by the granting entity regarding ownership of IP. For researchers supported by grants from the NHMRC, you will find the NHMRC's Interim Guidelines – Intellectual Property Management for Health and Medical Research (at the website in the "What can I read" section below) helpful in regards to identifying your responsibilities and obligations.

The steps to take to clarify ownership are:

- identify the IP created
- identify the authors/creators/inventors of the IP
- identify whether the creation of the IP is in accordance with:
  - your position description; or
  - any special projects that you have been instructed by your manager/director to do.
- your Manager, Research Manager/Business Manager or the IP Officer will be able to provide further assistance regarding clarifying ownership.

## 6 Complete the QH "Invention Disclosure Form":

If you have: a) kept your research confidential; b) undertaken an attempt to confirm that your research is new and an "inventive step" over the "prior art" by undertaking searches of existing publications and patents; c) identified that the commercial path would be most effective to create health benefits from your research; and d) begun to clarify the ownership issue, then the next step is to report these issues to your Manager, Business Manager, Research Manager or the IP Officer using the QH "Invention Disclosure Form".

The QH *“Invention Disclosure Form”* serves to capture key information from you in order to answer the following questions:

- what is it? - to describe the benefit of the invention in terms able to be understood by the lay person
- who is/are the inventor(s)? – who are the people who have made an inventive contribution to the invention that will be named as inventors on any patent or design application and may qualify for allocation of financial rewards
- who owns it? – ownership determines who has the initial responsibility for the project i.e. who should initiate any patenting, who pays the bills, which confidentiality agreement to use if needed etc. Ownership is determined by the employment arrangements of the nominated inventors
- is there commercial potential? - an invention will not be patented (by QH) where there is no commercial potential to cover the costs
- can and should it be protected? – is the best way to create health benefits via protecting and commercialising the IP.

The QH *“Invention Disclosure Form”* form is available from the QH IP website at: [http://www.health.qld.gov.au/ohmr/html/rcpu/intel\\_prop.asp](http://www.health.qld.gov.au/ohmr/html/rcpu/intel_prop.asp) or from the IP Officer, via the email details at the bottom of this Fact sheet.

## 7 What happens next?

The QH *“IP Identification Form”* form will initially be evaluated by your Manager, Business Manager/Research Manager with the assistance of the IP Officer if required, to confirm some of the key foundation issues such as:

- who is/are the inventor(s)?
- who owns the IP?
- is it really new and inventive compared to the prior art?
- is there really commercial potential?
- what is the most effective way to protect the IP? and importantly
- is IP protection the most effective way for QH to create public health benefits from your research?

It may be necessary to seek advice from IP professionals such as legal advisors, patent attorneys and your collaborating researchers commercialisation advisers.

If the evaluation determines that:

- the commercial path is the most effective means to create public health benefits;
- the research has a high probability of being patented; and
- QH is an owner of the IP in the research; then

QH will look to fund the filing of a patent application covering the research.

## 8 Who should I speak with?

Contact:

- your Manager, Business Manager or Research Manager
- the Intellectual Property Officer, Office of Health and Medical Research, Centre for Healthcare Improvement, phone: 3234 1479 or e-mail: [ip\\_officer@health.qld.gov.au](mailto:ip_officer@health.qld.gov.au). (that's IP underscore Officer)

## 9 What can I read?

The National Health and Medical Research Council (NHMRC) "*Interim Guidelines for Intellectual Property Management for Health and Medical Research*" (particularly Appendix 2); and

The "*National Principles of Intellectual Property Management for Publicly Funded Research*" both of which are available on the NHMRC website at: <http://www.nhmrc.gov.au/grants/policy/ipmanage.htm>

Chapters 1 and 2 of The Queensland Public Sector Intellectual Property Guidelines at: <http://203.210.126.185/dsdweb/v4/apps/web/secure/docs/1620.pdf>

IP Australia <[www.ipaustralia.gov.au](http://www.ipaustralia.gov.au)>

## 10 Document Custodian

Principal Project Officer (Intellectual Property)

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Website: [http://www.health.qld.gov.au/ohmr/html/rcpu/intel\\_prop.asp](http://www.health.qld.gov.au/ohmr/html/rcpu/intel_prop.asp)



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