Government of **Western Australia**
Department of **Health**

Intellectual Property Management in the WA Health System

Intellectual Property Guidelines

Research and Innovation Office
Clinical Excellence Division

health.wa.gov.au

Contents

Purpose

These Intellectual Property (IP) Guidelines outline recommended best-practice approaches to key aspects of IP management in the different entities of the WA health system: Health Service Providers and the Department of Health (the Department).

However, while these guidelines aim to provide a uniform and consistent approach to IP matters, each Health Service Provider is an independent statutory body, and will, within legislatively, legally and administratively prescribed activities, be responsible for the management, exploitation, commercialisation and disposition of IP developed within the entity, as well as the distribution of any benefits, whether financial, material, or otherwise, arising from such activities. Where applicable, and according to internal Health Service Provider processes, these activities will generally be overseen by the Health Service Boards.

These guidelines do not apply to contracted health entities that provide health services to the State, as these have their own IP provisions.

The recommended IP guidelines address:

- IP Ownership
- Employee Reward
- Conflict of Interest
- Categories of IP
- IP in Procurement
- Preserving Patentable IP
- IP Valuation
- IP Infringement
- IP Commercialisation
- Retention of Revenue
- Information and Communications Technology
- Aboriginal IP.

These guidelines complement supporting information provided in the document titled *Intellectual Property Management in the WA Health System: Intellectual Property Procedures.*

IP Ownership

The following is the recommended approach to ownership of IP developed by employees of the WA health system, either in the course of their work, or in the context of affiliation or collaboration with external organisations.

IP developed solely in the WA health system

IP developed by an employee of the WA health system will generally be considered to vest in their employer (Health Service Provider or the State of WA in the case of the Department) if:

- There is a clear relation to their work activities.
- It involves the use of facilities and resources (human and/or financial) of the employer.
- There is no collaborative, contractual or employment agreement or arrangement that specifies otherwise.

This position reflects the view that unless employment contracts specify otherwise, it is generally an implied term of such contracts that the products of an employee's service are for the benefit of the employer and not necessarily to be used by the employee for their own advantage

A general, non-legal, guiding principle that can be applied in considering whether the employee or the employer owns IP is to ask the question whether the IP would have been generated if the inventor/innovator had not been an employee of that entity of the WA health system.

This position on IP ownership is supported by the following considerations:

- IP Australia, which is the Commonwealth governing body for IP related to inventions, such as patents, states that the employer owns the IP created by an employee if it is related to the employer's business, unless the employment contract stipulates otherwise.
- The National Health and Medical Research Council states that IP created in the course of employment will generally be owned by the employer, unless the employee has a specific right to ownership.
- The New South Wales Department of Health has recently undertaken a thorough external review of their IP policy, and the updated policy has the following position on IP ownership: "As is the case under general law, this policy mandates that all IP created by employees of a public health organisation in the course of their employment is owned by the public health organisation. For the purposes of this policy, IP which is created by an employee through any significant utilisation of the resources of the organisation (e.g. funding, other employees, laboratory facilities, equipment, existing IP of the organisation) is taken to be created in the course of the employee's employment".
- The University of Western Australia IP policy states that that the university owns IP created by a university staff member pursuant to a contract of service to the university.
- The Curtin University IP policy states that ownership of all IP created by a member of staff in their course of duties will vest in the university, except where an agreement provides otherwise.
- The Murdoch University IP policy states that the university owns all IP created by its employees in the course and scope of their employment, or using university resources, facilities or apparatus.
- The Edith Cowan University IP policy states that the university will own all IP created by a staff member in the course of employment. This includes IP created by a staff member using university resources or participating in any project or program supported by funding obtained or provided by the university, as well as research being undertaken at the university in collaboration with any third party.
- The University of Notre Dame Australia IP policy states that this vests in the university when the IP is created in the course of employment or participation in a university project. In determining whether the IP was created in the course of employment the Vice Chancellor (or their delegate) will consider the duties of the employee as set out in their contract of employment, and whether the IP has been created by the use of University facilities, equipment or other resources supplied by the University.
- The IP policy of the Telethon Kids Institute states that the Institute will own any IP created by an originator: in the course of employment, engagement or involvement with the institute; created pursuant to a sponsored research agreement; created by significant use of the Institute's resources; and IP creation funded in any way by the institute.
- The Harry Perkins Institute of Medical Research uses the UWA policy.
- The *Western Australian Government Intellectual Property Policy 2015* (2015 WA Government IP policy) does not make reference to IP ownership, so by default leaves this to the different agencies to take a policy position.

This ownership position does not, however, preclude that under particular circumstances and agreements, the entity of the WA health system could potentially:

- Not make a claim over the IP.
- Share the IP rights with the employee(s).
- Assign the IP rights to the employee(s) or other relevant parties.

The advice of the Department's Legal and Legislative Services (LLS) or the State Solicitors Office (SSO, which where applicable, also refers to the General Counsels assigned to Health Service Providers) should be sought in situations where IP ownership is either not inherently evident or is not agreed to by the employee and the employer. This includes situations where the 2010 *University of Western Australia v Gray* High Court of Australia decision on IP ownership might be invoked in regard to differentiating between duties to undertake research, and to invent.

In situations of uncertainty or disagreement regarding IP ownership it is recommended that the WA health system entity and the employee seek to come to an agreement which takes into account possible IP rights of the employer and employee, the employment and contractual arrangements in place and the possible influence of the work environment on the generation of the IP. Consideration could be given to any operational value the IP might have to the activities of the employer, and to the sharing of any net benefits that commercialisation of the invention might engender (see *Employee Reward*, below).

In this respect the different entities of the WA health system should consider including appropriate IP clauses in new or renewed staff employment contracts. This will, however, have to be considered in the context of any terms of, and possible restrictions included in, established employment Awards or Agreements.

In cases where employees of the WA health system work across different entities of this system (particularly between different Health Service Providers) the ownership of the IP will generally be shared between these services, according to the relative input of these to the development of the IP.

Although the different entities of the WA health system will have individual ownership of IP rights (subject to any claims by external organisations) it is important to ensure that the benefits of this IP extend, in one way or another, to the whole of the WA health system in order to maximise the public value of this to WA. This could include the sharing of any products of the exploitation of the IP, or in the case of commercialisation of the IP, access to the product at preferential rates (where this is possible).

It is important that claims over IP ownership do not become barriers to productive and beneficial co-operation across the different entities of the WA health system.

IP developed in conjunction with external organisations

Whether the entity of the WA health system is the sole and outright owner of the IP can depend upon various factors, including:

- When WA health system employees developing the IP have additional formal employment relationships with external organisations, such as universities and medical research institutes, which have their own IP policies and claim ownership of IP rights.
- The employment relationships of any non-WA health system co-developers of the IP, in which IP ownership might be claimed by their employer.

- Possible IP arrangements applied by funders of the work that resulted in the development of the IP. This is particularly the case in industry-sponsored clinical trials, but can also apply to other forms of funding support.

Some relevant considerations include:

- When employees of the WA health system have employment relationships with external organisations it is often difficult to determine whether all, or part, of the IP was developed in the WA health system or in the external organisation.
- Generally, if a WA health employee claims that some or all of the IP was developed through, or in conjunction with, an external organisation, they should provide evidence of this, such as: certified lab books (where applicable); research grant agreements; funding contracts; clinical trial agreements, or other sources of financial support that were available to the external organisation to undertake the work.
- It should be established whether the staff member is named as a participant in such agreements, and whether the work funded through these could have resulted in the IP being developed.
- Where it is established that the IP was developed in the WA health system in conjunction with an external organisation, the proportion of the IP that would correspond to these entities should be determined according to the relative input (intellectual, funding, resources, facilities, amongst other inputs) of the parties into the development of the IP.
- Some employees of the WA health system have adjunct titles with universities and medical research institutes. Adjunct titles do not signify an employment relationship with the organisation granting these. However, some organisations may claim IP rights over the work of persons having adjunct titles, without those organisations actually contributing to the generation of the IP. This position is not considered to be acceptable to the WA health system.
- Some universities and medical research institutes have established *Research Access Agreements* with Health Service Providers, which include consideration of IP ownership.
- IP ownership must be considered on a case-by-case basis, and advice should be sought from the Department's Research and Innovation Office (RIO; formerly Research Development Unit) and LLS or SSO before any work is commenced.
- IP ownership by students from universities who conduct research or related activities within the WA health system should also be considered on a case by case basis, generally in conjunction with the RIO and/or, as required, LLS or SSO. This is because the universities generally vest any IP developed by students during their academic activities in the student. However, when there is potential for the development of significant IP the universities generally require students to enter into an IP agreement that specifies ownership conditions. Such agreements need to be taken into account in relation to work undertaken in the WA health system.
- Research Access Agreements between Health Service Providers and universities or research institutes can include consideration of IP ownership in work undertaken by students.

IP in the evolving innovation ecosystem

The are many initiatives that aim to stimulate and develop innovation in the WA health system, and that can involve a wide range of external participants.

Such initiatives can present challenges with respect to potential claims of IP ownership by the participants.

An example of this are Hackathons, for which there are, under the Department's ICT Governance and Strategy directorate*, WA health system Hackathon Guidelines*.

These guidelines state that a clearly defined strategic approach to IP management arising from such events is required to ensure that the WA health system benefits appropriately from any commercialisation activities.

The Participant Terms and Conditions specify that the participants will retain IP that they own in any ideas or material presented, developed or submitted during the course of the event, unless agreed separately with the event coordinator. These also state that any dispute between participants regarding IP is to be resolved independently, without the involvement of the event coordinator. It is recommended that advice be sought from LLS or SSO regarding allocation of IP arising from the event.

Employee Reward

The 2015 WA Government IP policy states that Government agencies should recognise, and as appropriate reward, employee achievements – including "outstanding extraordinary outcomes".

WA Government rewards policy

The *2015 WA Government IP policy* does not specify how employee recognition and reward should be actioned. However, this policy is under the responsibility of the Department of Jobs, Tourism, Science and Innovation (DJTSI) and documents of this agency state that the 2003 policy of *Encouraging Innovation by Government Employees - Procedures for the payment of monetary rewards to innovative Government employees (*2003 WA Government employee rewards policy) is still in effect.

This rewards policy considers: who may receive rewards; form of rewards; factors relevant to the choice and level of rewards; source of funds for the payment of rewards; and approval and granting of rewards.

The policy states that rewards can only be paid once the Government Agency receives revenue from the commercialisation of an IP asset. This will, therefore, be contingent upon the appropriate approvals being obtained for the particular case at the time that such revenues are actually available.

This policy states that a monetary reward can be requested through an Act of Grace payment, which must be made in accordance with the (currently applicable) *Financial Management Act 2006.* Under the *Financial Management Act 2006* an act of grace payment of up to $250,000 may be made if the payment has been authorised by the Treasurer. An act of grace payment exceeding $250,000 can only be authorised by the Treasurer with approval from the Governor.

The *2003 WA Government employee rewards policy* also states that decisions on payments of rewards to innovative Government employees must be made by the relevant Minister, on recommendation of the person's employer.

It is noted that this policy only refers to "Government Agencies". Under the *Financial Management Act 2006* the term "agency" includes a "statutory authority", and thus is applicable to the Health Service Providers.

Health Services Act 2016

The 2015 WA Government IP policy states that agencies are encouraged to develop agency-level IP policies in alignment with this policy to manage IP processes and stakeholder interaction, such as employee incentives and reward systems where appropriate, or promoting a commercialisation opportunity.

In addition, the 2003 WA Government rewards policy states that Government agencies that regularly develop, manage and commercialise IP may wish to develop and put in place agency-specific procedures or policies to provide additional guidance in relation to the provision of rewards.

In this respect, the *Health Services Act 2016*, in Section 36(5)(b), states that a Health Service Provider may make any *ex gratia* payment that it considers to be in the interest of that Health Service Provider.

If a Health Service Provider considers that the reward of innovative/inventive employees is "in its interest" these *ex gratia* payments could potentially be a means of providing this.

Advice should be sought on a case-by-case basis from LLS or SSO before making an *ex gratia* payment under the provisions of the *Health Services Act 2016* for the purposes of employee reward.

Distribution of revenue

The *2003 WA Government employee rewards policy* does not address the proportion of any revenue derived from successful commercialisation that the inventors/innovators might receive.

The distribution of revenue resulting from commercialisation of IP in other Australian health jurisdictions, and in the WA universities, has been considered in an accompanying document titled *Intellectual Property Policy and Management in the WA Health System: Current State Review; Interjurisdictional Overview; Options for a Future State IP Strategy, September 2019*.

The interjurisdictional overview shows that commercialisation revenue, net of costs, is often shared between the developers of the IP, the service unit in which they work and the host organisation, typically on a 1/3:1/3:1/3 basis, although this can vary.

Sharing arrangements could be considered by the Health Service Providers on a case-by-case basis, and it is recommended that this be reviewed by LLS or SSO, and if necessary, by the Departments of Treasury and/or Finance.

Conflict of Interest

The potential benefits to the WA health system of undertaking of research, innovation and commercialisation are evident. Equally evident is that the undertaking of these activities by

employees of the WA health system should not be primarily driven by the potential for personal gain.

The System Manager's *Managing Conflicts of Interest Policy Framework* states that Conflict of Interest (CoI) arises when a staff member's official duty is directly affected or impacted by their personal or private interests. Such potential or perceived CoI must be declared and managed through the established processes.

With respect to research, the *National Statement on Ethical Conduct in Human Research 2007 (updated 2018)* states that a CoI exists where a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research. Such potential or perceived CoI should be declared in the process of obtaining ethical and governance approval for research.

Categories of IP

When managing contractual agreements, collaborations or partnerships, the following categories of IP might be involved:

Background IP

This is pre-existing IP that is individually owned by the parties, and which is brought into the proposed arrangement. It is important to acknowledge and agree upon on each party's background IP, and any conditions or restrictions on its use during, and subsequent to the completion of, the work.

Third party IP

This is IP that is to be used in the work but is not owned by any of the participating parties. A clear right to the use of such IP is required. It is important for all participants in the work to disclose, discuss, agree to and document any third party IP that will be used.

New IP

Ownership of new IP (also referred to as Activity or Project IP) should be agreed to, and documented by, the parties before the work commences. There are different options to consider relating to the level of ownership of the IP, which can include:

- Sole (outright, exclusive) ownership: where upon agreement with the other parties one of these will have sole ownership of the IP.
- Licence: where one of the parties retains ownership of the IP but grants an exclusive or non-exclusive licence, which can be conditional, to the other parties to use the IP.
- Joint ownership: where the partners agree to share ownership of the IP in equal, or unequal parts. In the latter case this is usually based on agreement regarding the financial, operational, structural or intellectual contribution of each party to the development of the IP.

IP in Procurement

IP needs to be considered in all procurement and contract or grant management activities that are undertaken in the WA health system.

The establishment of a preferred IP ownership position by the WA health system from the outset will provide guidance for external providers and contractors, and allow IP to be proactively managed throughout the period of engagement.

The WA health system generally uses commercial or community services contracts and grants, which include standard clauses relating to IP ownership.

Commercial Contracts

The WA health system uses a number of standard form contract documents for the procurement of goods and services, which include terms relating to ownership and use of IP. In particular, the *Request Conditions and General Conditions of Contract, August 2019* (General Conditions) available from the Office of the Chief Procurement Officer, specified by the State Government's Department of Finance, is used for a significant part of the WA health systems procurement activities.

Clause 23 of the General Conditions refers to IP rights.

Two options for IP ownership are provided:

Ownership by the customer

Clause 23.1 vests IP ownership in the State or Customer (which could be a Health Service Provider), and provides that the State or the Customer grants to the Contractor a revocable, royalty-free, non-exclusive licence to use the New Material to the extent necessary to provide the Services.

Ownership by the contractor

Clause 23.2 vests IP ownership in the Contractor, and grants to the Customer an irrevocable, perpetual, royalty-free, non-exclusive licence to exercise any or all of the rights of an owner of IP rights in the New Material.

The contract documents recommend that legal advice be obtained on which option is preferred for the particular case, and for the entity of the WA health system contracting the services.

Commercial Grants

Commercial grants, which can include Research Grants, are managed under the *WA Health System Commercial Grant Framework Guideline* (Office of the Chief Procurement Officer), and the IP ownership clauses are effectively the same as for commercial contracts, only they have different numbers: Clauses 14 and 15.

Variation of Funding Agreements

When clearly justified, variations can be made to contract or grant funding agreements, after consultation with LLS or SSO.

Examples of where this might be appropriate are clauses 23.2 and 15 of the standard contract and grant funding agreements, respectively.

These clauses vest IP ownership in the recipient of the funding, but require that the recipient grants to the provider of the funding (e.g. an entity of the WA health system) an irrevocable, perpetual, royalty-free, non-exclusive licence *to exercise any or all of the rights of an owner of IP rights in the New Material* (our emphasis).

In practice, there are situations where there are valid reasons for the recipient of the funding not agreeing to the terms of this clause, particularly in cases where the funding outcomes have commercial potential.

In this respect the 2015 WA Government IP Policy states that responsible IP asset management by Government agencies may involve commercialisation, assigning IP rights to developers in return for concessions in development costs and licensing, allowing other WA government agencies to use the IP, or applying appropriate open access license conditions to the release of government information.

On a case-by-case basis, and in consultation with LLS or SSO, it could be considered whether contract clause 23.2 and grant clause15 be varied to state that the IP vests in the recipient of the funding, but that the funder is granted a royalty-free license to use any of the IP generated that falls within the scope of its normal activities. In the case of entities of the WA health system this could include, but not necessarily be limited to, activities related to healthcare provision, teaching, training and research.

These normal activities would, however, not include the potential commercialisation of the outcomes of the funding, and it would generally be specified that in such cases the funder and the recipient of the funding should reach a separate agreement whereby the parties would negotiate in good faith, and use all best endeavours, to reach agreement so as to fairly share in any returns derived from the commercialisation of the IP. This would be apportioned on the basis of the contribution of the respective parties to the overall outcomes of the activities. This could include the inventive contribution to the activities, as well as financial contributions, whether cash or in-kind, or any other form of contribution. Once again, this would be considered in consultation with LLS or SSO.

As a point of comparison to the above considerations, the Commonwealth Government's *Simple Grant Agreement 2020* states that the IP rights created under the agreement should belong to the grantee, but that the grantee will provide to the Commonwealth a permanent, non-exclusive, irrevocable, royalty-free license (including a right to sub-license) to use, reproduce and adapt the activity material.

In addition, the Commonwealth Government's *Australian Research Council* refers to commercialisation in the following (abridged) terms: "Each Party must advise the other Party immediately if the Developing Party has produced or created IP that does, or may have, a commercial application. To the extent that any IP is capable of commercialisation, a commercialisation strategy will be agreed in good faith by the Parties with the intention that commercialisation revenue shares between the Parties will reflect their contributions to that IP".

Community Services Contracts and Grants

The *Delivering Community Services in Partnership Policy 2018* does not have specific IP requirements, and only states that IP must be managed appropriately.

Preserving Patentable IP

Good ideas shared before they are protected by patent could result in the loss of the IP asset. The following points should be taken into account in this process:

- Employees of the WA health system who could potentially develop patentable IP should ensure that they do not unnecessarily disclose critical information, either internally or externally, at the professional, personal or social levels.
- Information should only be shared on need-to-know basis.
- Confidentiality or non-disclosure agreements should be used when sharing of information is required. This can be in the context of research, collaboration and partnership agreements, and contract and tender documents (templates available from the RIO).
- Mark all sensitive documentation with 'Commercial-in-Confidence'.
- Use security measures, such as password protection and multi-factor authentication.
- Track and record parties who come into contact with confidential information.
- Disclose the invention to the WA health system IP Advisory Committee (IPAC: see accompanying document *WA Health System IP Procedures*), and act promptly to protect IP after its creation.

IP Valuation

When considering the value of IP it is important to look beyond monetary value and also consider its strategic importance to the WA health system and its possible public benefit. One question that can be asked is whether the IP is essential, complementary or surplus to the needs of the WA health system.

IP that has potential commercial or social value should be reviewed by the IPAC and, as necessary, an Ad Hoc IP Expert Group (see accompanying WA health system IP procedures document). Some points that are relevant to the assessment of the value of the IP include the following:

Does the IP have significant health and social benefits? What is the public value of the IP, including economic, social and environmental considerations? How reliant might the public become on this IP? Is the public benefit preserved or enhanced by formally registering and possibly commercialising the IP?
Does the IP have an important role in the services and functions of the WA health system? Is there a need for the WA health system to have continued access to, or control of, the IP?
What has been the cost of developing the IP? What is the cost of replacing it? Is further development required, and what would be the cost of this? Are there alternatives that are functionally equivalent, and what is the cost of these? How does the performance of the new IP compare with alternatives? What is the cost of maintaining the IP?

What is the nature of the IP? Is it generic enough that it will be useful to other entities without much adaptation or further development? Or is it quite specialised? Will other entities be interested in using, buying or licensing the IP? What is the approximate market size for the applications of the IP?
Will the IP be formally registered, e.g. as a patent? Does the entity of the WA health system have the rights necessary to commercialise the IP?
How would the monetary value of the IP be determined: *Cost approach:* what is the cost of reproducing or replacing the IP? Considerations include labour, overhead, redevelopment of the IP, any associated profit or incentive? *Market approach:* what is the price or licencing costs of comparable IP in the market? *Income approach:* what is the estimated future income that could be generated by the IP asset over its effective lifetime?

IP Infringement

Infringement of Other's IP

Staff of the WA health system must undertake strict due diligence to avoid infringing IP that is owned by other parties.

This means ensuring that:

- Any material, product or process (or part thereof) that is developed in the WA health system has not been previously developed, and protected in some manner, by another party.
- The use in the WA health system of any material that has been produced by another party does not infringe their IP rights.

In a case that such infringement is identified by a staff member, and this cannot simply be resolved at the operational level, they should advise their relevant supervisor, and the IP contact point for the entity. The IPAC should be advised of this, and the ad-hoc IP expert group may be consulted as necessary.

Registered IP

For registered IP, in particular patents, searches can be conducted on publicly accessible databases such as:

- IP Australia.
- US Patent and Trademark Office
- European Patent Office
- World Intellectual Property Organisation

Unregistered IP

For unregistered IP, such as copyright, there are no publicly accessible databases. Ensuring appropriate use of such material should be approached by:

- Being aware of the licence conditions of any in-licensed material.
- Being aware that copyright protection can still applicable even if the material does not have a copyright statement attached.

- Seeking written authorisation to use material when requested in a copyright statement. In cases where this is not possible, it is recommended not to use that material.
- Acknowledging the owners of copyright when their material is used.
- Advice of LLS or SSO should be sought when considering the provisions of the *Copyright Act (Cwth) 1968* regarding the nature, duration and ownership of copyright, infringement of copyright, and acts not constituting infringement of copyright.

Non-infringement under this Act includes: fair dealing for the purpose of research or study, and copyright subsisting in works shared for healthcare, or related purposes.

Infringement of WA Health System IP

To maintain the operational or commercial value of IP developed in the WA health system, it is important to monitor IP usage in order to mitigate potential infringement and take appropriate steps against infringers.

Staff of the WA health system should inform their supervisors and the IP Contact Point (see accompanying document *WA health system IP Procedures*) of their entity of any breach, or suspected breach, of their entities' IP rights.

If the infringement cannot be easily resolved at the local level, the IPAC should be informed of this, and the advice of the LLS or SSO should be sought. If necessary, a relevant member of the ad hoc IP expert group may be consulted by the IPAC.

With respect to copyright, although this protection is automatic, it is important that this be affirmed through the following statement, which should be attached to the material (note: there are two options, depending on whether copyright is claimed by a Health Service Provider or the Department):

- © (either) *Name of Health Service Provider* (or) *State of Western Australia (WA), represented by the Department of Health*
- "Copyright to this material belongs to the *[Health Service Provider or State of WA]* under the provisions of the Copyright Act 1968 (C'wth Australia). Apart from any fair dealing for personal, academic, research or non-commercial use, no part may be reproduced without written permission of the *[Health Service Provider or State of WA].* The *[Health Service Provider or State of WA]* is under no obligation to grant this permission. Please acknowledge the *[Health Service Provider or State of WA]* when reproducing or quoting material from this source".

This statement can, where appropriate, be accompanied by the following disclaimer:

"All information and content in this material is provided in good faith by the *[Health Service Provider or State of WA]*, and is based on sources believed to be reliable and accurate at the time of development. The *[Health Service Provider or State of WA]* and their respective officers, employees and agents, do not accept legal liability or responsibility for the material, or any consequences arising from its use."

It is noted, however, that apart from copyright, there are other forms of protection, such as Creative Commons licensing, that allow certain flexibility in the use of the material by other parties, and that is determined by the type of license applied. This form of licensing is encouraged under the provisions of the *WA Whole of Government Open Data Policy* and the *Australian Governments Open Access and Licensing Framework (AusGOAL).*

In the case of computer software, that is automatically protected by copyright, there is also the option of making this available through open-source licensing, whereby the source code or design can be used, modified and or shared under defined terms and conditions. An example of this is the commonly used MIT (Massachusetts Institute of Technology) licence.

Whenever the formal protection or registration of IP developed in the WA health system is considered, this should be in consultation with LLS or SSO.

IP Commercialisation

Relevant Policy and Legislation

WA Government IP Policy 2015

This policy encourages commercialisation through the following statements:

- IP rights be allocated to optimise the economic, social or environmental benefits for the State from the use, commercialisation and disposal of the IP.
- Employers and employees are encouraged to meet core operational objectives through creativity and innovation, which may result in valuable and useful IP being developed and commercialised.
- Respond to opportunities to 'unlock' IP for commercial use and further exploitation by the private and non-for-profit sectors where this involves acceptable risk.
- Consider IP development and commercialisation as an ancillary non-core business activity, except where commercial activities or research driven solutions are an integral aspect of an agency's objectives.

Health Services Act 2016

The *Health Services Act 2016* enables the Minister and the Health Service Providers to develop and turn to account any technology, software or other intellectual property and apply for, hold, exploit and dispose of any patent, patent rights, copyright or similar rights.

Regarding the exploitation of any patent, the *Health Services Act 2016* states that Health Service Providers may earn revenue by engaging in commercial activities that are not inconsistent with, and do not have an adverse effect on, the performance of its other functions. It also specifies that when engaging, or proposing to engage, in a commercial activity, a Health Service Provider must ensure that the activity is consistent with its service agreements and any relevant policy framework, and that the activity is likely to be of benefit to the WA health system.

The *Health Services Act 2016* also states that a Health Service Provider may participate in any business arrangement and acquire, hold and dispose of, shares, units, or other interests in, or relating to, a business arrangement, where a business arrangement can be a company, a partnership, a trust, a joint venture or an arrangement or agreement for sharing profits. The *Commercial Activity Policy* of the System Manager specifies that Health Service Providers must seek legal advice from LLS or SSO prior to engaging in a commercial activity.

General Considerations

Commercialisation of IP can be an expensive and a high-risk process, and entities of the WA health system considering this should avail themselves of specialised professional advice on,

for example, IP protection, due diligence on IP rights and the determination of freedom to operate, and the preparation of business cases and commercialisation plans.

The actual development costs of IP are not the only costs incurred when taking a product to market. Funding can be required for the undertaking of pilot or proof-of-concept studies and possibly clinical trials, as well as product registration with regulatory authorities.

The possibility of funding such costs is generally explored through a variety of avenues, such as:

- The participation of private venture capital companies, "Angel" investors and philanthropists.
- Australian Government programs such as *Accelerating Commercialisation*, the *Biomedical Translation Fund*, the *Biomedical Translation Bridge Program*, *BioMedTech Horizons* and the *Medical Technology and Pharmaceuticals Growth Centre* (MTPConnect).
- WA Government programs such as the *New Industries Fund*.

The following documents can assist the entities of the WA health system in undertaking commercialisation:

- *Understanding Commercialisation*, prepared by the Australian Government's IP Australia.
- *The How, What, When and Why of Commercialisation*, prepared by the NHMRC.
- *Guide on IP Commercialisation*, prepared by the World Intellectual Property Organisation.

Any proposed commercialisation of IP developed in an entity of the WA health system (Health Service Provider or Department) should be submitted to the IPAC through the IP contact points, in order to have the initiative reviewed by the ad-hoc IP expert group in order to consider the provision of funding to assist in IP protection, establishment of high-level business cases or commercialisation pathways.

Commercialisation Strategies

Commercialising IP usually follows a "route to market" or a "commercialisation pathway" that has been established by, or for, the developer of that IP.

Commercialisation strategies that are referred to by IP Australia include:

IP assignment

IP assignment (or outright sale*)* transfers IP ownership from the developer of the IP to another entity which will undertake the commercialisation process, under an arrangement whereby the original developer of the IP receives financial benefit. This is often through an up-front lump-sum payment and/or the ongoing payment of a percentage of any net-of-costs revenue (royalty) generated by the commercialisation. In some circumstances this might include preferential pricing of the eventual product for the original developer, and future user, of the IP.

In determining the amount of a lump-sum payment, some factors that might be taken into account include:

- The direct and indirect costs of the development and protection of the IP.

- The estimated value of any existing products in the market, with a loading for the added value that is anticipated to be conferred by the innovative IP.
- A consideration of the potential profit that the commercialising entity might gain over the market life of the product.

In the case of a royalty, the percentage can be based on the estimated relative contribution of the parties to the commercialisation.

Compared to other commercialisation strategies, assignment has the advantage of being less onerous to the original developer of the IP, but it often delivers lower financial returns because the commercialisation costs and risks are borne by the assignee.

IP out-licensing

Licensing the use of IP to another entity is a common commercialisation strategy, particularly when the IP developer does not have the capacity or the desire to undertake a complex and costly commercialisation process. Through licensing agreements the other entity has the right to use the IP, under agreed terms and conditions, in exchange for an up-front lump sum payment and/or royalties.

IP Australia recommends that the following points be considered in establishing licence agreements:

- Whether the rights are granted exclusively to one licensee, or whether these can also be granted to other entities (non-exclusive licences).
- Whether sub-licensing by the licensee is allowed.
- The “territory” (e.g. country) that the licence applies to.
- Any limitations to the application (use) of the IP.
- Any time limitations that apply.
- Any lump-sum payment that might be paid by the licensee.
- Any royalties that may be paid by the licensee.
- Any performance obligations (e.g. development milestones and minimum sales) that are imposed upon the licensee.

Other strategies

There are other commercialisation strategies that might be appropriate in some particular circumstances.

Start-up businesses: These are business entities that are newly created by the organisation which developed the IP in order to commercialise that IP. If the start-up is created by partitioning it off from an existing organisation it is referred to as a “spin-off” business.

The *Health Services Act 2016* does not preclude the creation of a start-up business by Health Service Providers. However, this should consulted with LLS or SSO, and be carefully and professionally evaluated in terms of potential costs, risks and benefits. In addition, such a business arrangement would require approval of the Minister for Health and the Treasurer.

In-House or *First-to-Market commercialisation*: These strategies could apply when the IP is embodied in a product that is, or is close to being, market-ready without requiring major investment for further development.

These strategies would, however, typically result in significant expenditure associated with product registration, manufacturing, marketing, distribution and ongoing management, that

might be prohibitive for a WA health entity to undertake. These strategies are probably more appropriate to commercial situations where such expenses may either be outsourced or embedded in business-as-usual costs.

Medical Research Commercialisation Fund

In 2009 the Department became a Public Research Partner in the Medical Research Commercialisation Fund (MRCF).

The MRCF was established in 2007, and invests in early stage development and commercialisation opportunities emanating from Australian medical research institutes and hospitals. It is supported by the Governments of Victoria, New South Wales, Western Australia, Queensland, South Australia and New Zealand, and is managed by Brandon Capital Partners.

Brandon Capital Partners is also a licensed private sector venture capital fund manager for the Australian Government's Biomedical Translation Fund (BTF), with the responsibility of screening investment proposals and making venture capital investments on behalf of the BTF.

The membership of the Department in the MRCF is presently co-funded with DJTSI. These two departments also fund a part-time commercialisation consultant, whose role is to be the conduit between the WA health system and the MRCF. Effectively this consultant assists in the identification of IP with commercial potential, analysing commercial and non-commercial aspects of this and, where appropriate, assisting the developers of IP in preparing funding applications to the Investment Review Committee of the MRCF. Access to the MRCF can be made through the RIO.

There is no binding obligation that WA health system entities present potentially commercialisable IP to the MRCF for consideration, but it is suggested that this be discussed with the RIO as a possible option.

Retention of Revenue

Revenue derived from the commercialisation of IP by a Health Service Provider can be received into that Health Service Provider's Special Purpose Account, established under Section 64 of the *Health Services Act 2016*. This means that IP commercialisation revenue can be retained by the Health Service Providers.

With respect to the Department, the *Financial Management Act (Net Appropriations) Determination 2015* allows the retention of revenue received from the commercialisation of IP up to a total of $15,000 annually. Above this amount the revenue would be credited to the Consolidated Account of the State. However, upon request, the Treasurer can consider approving the Department to retain the money in such cases.

Information and Communications Technology

Information and Communication Technology (ICT) can generate IP, and this is generally dealt with in the same manner as IP resulting from any other form of development. In this respect, the Australian Government's IP Australia states that there are three main forms of official protection of computer-related IP: patents, copyright and circuit layout rights.

Software

Software in Australia is automatically protected by copyright, which includes source code, executable code and data banks and tables. However, Australian patent law enables a diverse range of software to gain patent protection, providing the software inventions are industrially applicable.

Open source software is a form of licensing where the source code is publicly available with relaxed or no restrictions on its use or modification.
However, generally for software to qualify as open source, users must be able to freely (in relation to rights, not payment) copy, study, adapt, improve and distribute the source code of the software.

One of the key elements of open source licences is that any changes, improvements or adaptations to the code base must themselves become subject to the same open source licence. Some common examples of open source licences include Creative Commons licences and the GNU General Public License.

Hardware

Physical devices that highly innovative and/or novel, or are significant improvements on previous devices, can be patented. This includes complete computer systems or computer components such as disk drives, memory chips, bus architectures and accessories.

Circuit layouts

Circuit layout rights automatically protect integrated circuits, which are defined as the three-dimensional location of active and passive elements and interconnections making up an integrated circuit. Circuit layouts are generally not patentable in Australia.

Aboriginal IP

A WA health system policy position on Aboriginal IP will be developed in accordance with the Australian Government's IP Australia current initiative to establish a comprehensive and culturally appropriate approach to the indigenous knowledge of Aboriginal and Torres Strait Islander people.

This follows a 2018 discussion paper titled *Indigenous Knowledge: Issues for Protection and Management* and a 2018-19 consultation report titled *Protection of Indigenous Knowledge in the Intellectual Property System.*

IP Australia has also developed an *Indigenous Knowledge Work Plan 2020-21* (which will be progressively updated) that outlines a range of initiatives aimed at supporting protection of indigenous knowledge in the IP system. An example of this is the report titled *Estimating the Market Value of Indigenous Knowledge,* which IP Australia commissioned from the Australian National University's Centre for Aboriginal Economic and Policy Research.

These IP Australia documents should be taken into account by the WA health system in dealing with matters that involve Aboriginal IP.

In addition to this, the requirements of the *WA Health Aboriginal Health Impact Statement and Declaration* must be met to ensure that the needs, interests of, and potential impacts on, Aboriginal clients and employees are considered and appropriately incorporated when developing a new or revised policy, strategy, program, practice, procedure or health initiative.

Further Documentation

These IP Guidelines complement supporting information contained in the document titled *Intellectual Property Management in the WA Health System: Intellectual Property Procedures.*

They also relate to the supporting document titled *Intellectual Property Policy and Management in the WA Health System: Current State Review; Interjurisdictional Overview; Options for a Future State IP Strategy.*

Frequently Used Acronyms

Department	Department of Health Western Australia
DJTSI	Department of Jobs, Tourism, Science and Innovation
Entities (of the WA health system)	The Health Service Providers and the Department of Health
IP	Intellectual Property
IPAC	WA health system Intellectual Property Advisory Committee
LLS	Legal and Legislative Services
MRCF	Medical Research Commercialisation Fund
RIO	Research and Innovation Office (formally Research Development Unit)
SSO	State Solicitor's Office (which, where applicable, also refers to the General Counsels assigned to Health Service Providers)
WA	Western Australia

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