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

Intellectual Property Policy and Management in the WA Health System

- Current State Review
- Interjurisdictional Overview
- Options for a Future State IP Strategy

Research Development Unit
Clinical Excellence Division
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Contents

CURRENT STATE REVIEW

Introduction

The enactment of the Western Australian (WA) *Health Services Act 2016* (HSA) changed the governance structure of the WA health system, whereby the Director General of the Department of Health (the Department) became the System Manager, and the Health Service Providers (HSPs) were established as autonomous statutory authorities.

The HSA (Section 19) states that the WA health system is comprised of the Department, the HSPs and, to the extent that contracted health entities provide health services to the State, the contracted health entities.

Intellectual Property (IP) is a category of property which includes intangible creations of the human intellect, the rights to which may be protectable by law. As such it is an asset which can be generated, and needs to be appropriately managed, in the WA health system.

Previous to the HSA the Department was responsible for IP policy and management in the WA health system (excluding the contracted health entities). However the HSA confers functions and powers to the HSPs with respect to IP, which must be taken into account.

The current approach of the Department to IP is described in the Information Circular *Intellectual Property Management in WA Health* (IC 0228/15). Although this is a Mandatory Requirement under the System Manager's Research Policy Framework it needs to be updated in the context of the HSA.

The Director General of Health, in conjunction with the Health Service Board Chairs, has requested that a review be undertaken to determine the Current State of IP policy and management in the WA health system, which will then assist in the establishment of a Future State IP strategy which better reflects the roles and responsibilities of the Department and the HSPs under the HSA. It is noted that for the purposes of this review the term WA health system is only used to refer to the Department and the HSPs, and does not include the contracted health entities. These entities are private organisations which deal with IP independently of the public system.

The review has been undertaken by the Research Development Unit (RDU), Clinical Excellence Division of the Department.

The review also considers IP policy and management in other WA organisations which can interact with the WA health system, and that includes the contracted health entities, other Government agencies, the universities and the medical research institutes.

In order to place the outcomes of the review into the wider national context, the later section of this document, titled *Interjurisdictional Overview*, considers IP policy and management in other Australian jurisdictions, with a focus on health agencies.

Overarching Legislation and Policy

This section considers the overarching legislative and policy directions that relate to the WA health system (the Department and the HSPs).

National Legislation and Policy

- ### *Commonwealth Legislation*

Commonwealth legislation that is most relevant to IP policy and management in the WA health system includes the *Copyright 1968* and the *Patents 1990* Acts. The *Trademarks 1995* and the *Designs 2003* Acts are also of importance in some circumstances.

The Copyright Act is under the jurisdiction of the Australian Government's Department of Communications and the Arts. The Patents, Trademarks and Designs Acts are the responsibility of the Australian Government's IP Australia.

- ### *National Principles of IP Management for Publicly Funded Research*

These principles have been established by the National Health and Medical Research Council (NHMRC) and the Australian Research Council (ARC).

The principles provide guidance for the ownership, promotion, dissemination, exploitation and protection of IP generated through Australian Government funded research by public sector institutions.

In this context public sector institutions are defined as those which are majority funded by government, and include public hospitals.

The National Principles state that ownership and the associated rights of all IP generated as a result of Australian Government competitively funded research will initially be vested in the institutions receiving and administering the grants, and the Commonwealth organisations will not directly benefit from any commercial outcomes of the research funded through their financial support.

At present the HSPs of the WA health system are not administering institutions for such Commonwealth research grants, which include those from the NHMRC and the ARC. This means that any such grants that are awarded to staff of a HSP must be administered by an accredited organisation, which is generally a university or medical research institute. In such cases any IP generated through the research grant will not automatically vest in the HSP, but in the external institution.

The RDU understands that this situation arose because prior to the HSA the health services were not autonomous bodies, and as such were not eligible to be administrating institutions. It is now likely that the HSPs can apply for administering institution status, and thus could be in a position to own any IP resulting from research funded by the Commonwealth. Some government health agencies in other Australian states have such status.

It is noted, however, that in cases where an employee of the WA health system has an affiliation with an external organisation, such as a university, that organisation generally requests that they be the administering institution. Also, anecdotally at least, some researchers prefer to use universities or research institutes as the administrating institutions for their grant proposals, in the belief that the NHMRC will favour the academic status of these in their grant review process.

The NHMRC provides funding to research organisations under a Funding Agreement. This agreement states that the administering institution must adhere to an IP policy, approved by that institution's governing body, which has as one of its aims the maximisation of benefits arising from research.

The NHMRC does not differentiate between an institution-specific policy or an overarching policy across different institutions. This suggests that the HSPs of the WA health system could either have their own IP policies, or be subject to an overarching WA health system policy. It

could also be tested with the NHMRC whether the WA Government IP policy, described below, would be sufficient in this respect.

Western Australian Legislation and Policy

- ***Health Services Act 2016***

The HSA (Section 13.2.d) states that for the purposes of this Act, the Minister (for Health) may 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.

The HSA specifies (Section 19.2) the role of the Chief Executive Officer (CEO) of the Department (Director General) as the System Manager for the WA health system.

Under the HSA (Section 26) the Department CEO may issue Policy Frameworks that are binding on the HSPs (Section 27). Also (Section 28), the Department CEO may issue directions that require compliance with a matter set out in a policy framework.

Since the enactment of the HSA, IP management in the WA health system is under a Mandatory Requirement (Information Circular 0228/15) within the System Manager's Research Policy Framework.

With respect to HSPs the HSA refers (Section 36.3.f) to functions and powers, stating that a HSP may develop and turn to account any technology, software or other intellectual property that relates to its functions and, for that purpose, apply for, hold, exploit and dispose of any patent, patent rights, copyright or similar rights.

Regarding the exploitation of any patent, the HSA (Section 35.1) states that HSPs 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.

The HSA also states (Section 35.4) that when engaging, or proposing to engage, in a commercial activity, a HSP must ensure that:

a) The activity is consistent with its service agreements and any relevant policy framework.
b) The activity is likely to be of benefit to the WA health system.

Advice has been sought by the RDU from the Department's Legislative and Policy Implementation team and Legal and Legislative Services (LLS) as to whether the terms used in the HSA (turn to account, exploit and commercial activities) could extend to the HSPs establishing potentially high-risk IP-based commercialisation vehicles, such as spin-off companies, either independently or in conjunction with industry partners.

The advice received indicates that the HSPs are permitted to undertake activities that may give rise to profit. However, as the term "commercial activity" is not defined in the HSA, it is recommended that the HSPs seek legal advice on a case-by-case basis.

In this respect it is noted that the HSA (Section 36.3.c) states that a HSP may participate in any business arrangement and acquire, hold and dispose of, shares, units, or other interests in, or relating to, a business arrangement. A business arrangement is defined (Section 36.1) as a company, a partnership, a trust, a joint venture or an arrangement or agreement for sharing profits.

The HSA (Section 38) refers to transactions associated with a business arrangement which require agreement by the Minister/Treasurer.

- ***Other Relevant WA Legislation***

Other WA legislation that could potentially be of significance in IP policy and management in the WA health system includes, but is not necessarily limited to, the following:

The *Public Sector Management Act 1994*, which provides for the administration of the Public Sector of Western Australia and the management of the Public Service and of other public sector employment, and provides for related matters.

Interpretations of this Act and its Regulations could potentially be relevant to a number of aspects of IP policy and management in the WA health system, which might include the capacity of public sector employees to:

- Be externally employed, for example in spin-off companies arising from IP generated in (or in conjunction with) the WA health system, and to hold executive or board positions in such companies.
- Receive financial or non-financial rewards from their public sector employer for innovations they have developed, or inventions made, in the course of their work.
- Receive revenue from the commercialisation of IP that they have generated, or been involved in generating, in the course of their work in the public sector.

The *Financial Management Act 2006* can potentially influence the manner in which any revenue derived from the commercialisation of IP generated in the WA health system can be received and used.

The *State Trading Concerns Act 1916* could potentially be of significance for the commercialisation of IP generated in the WA health system. This is because it might limit the "Government of the State from carrying on, or establishing, a trading concern with the view of making profits or producing revenue, or of competing with any trade or industry…, or of entering into any business beyond the usual functions of State Government".

It is noted that the HSA (Section 35.6) states that a HSP is taken to be expressly authorised by Parliament for the purposes of the *State Trading Concerns Act 1916* Section 4(2).

The *Industry and Technology Development Act 1998*, which aims to encourage and facilitate the commercialisation of IP and other resources of Departments of the Public Service or of State agencies or instrumentalities.

- ***WA Government IP Policy 2015***

The *Western Australian Government Intellectual Property Policy 2015* is the responsibility of the Department of Jobs, Tourism, Science and Innovation (DJTSI), under the *Industry and Technology Development Act 1998*: https://www.jtsi.wa.gov.au/docs/default-source/default-document-library/industry-development---key-legislation---wa-ip-policy-2015.pdf?sfvrsn=a64e6c1c_2

The purpose of this policy is to guide WA Government agencies in the development, management and use of IP.

The Policy Statement requires that WA Government agencies will ensure that:

- IP created with government resources is identified, captured, suitably protected, responsibly managed, and transparently disposed of.
- IP rights are 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.
- Employees are recognised for their involvement in the development of IP.

The General Principles of the policy state that WA Government Agencies are required to:

- Manage IP under their control in a responsible, effective, efficient, fair and ethical manner for the Western Australian community as a whole.
- 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.
- Commercialise, transfer or dispose of IP in an open, accountable, timely and competitive manner consistent with Government legislation, policies and guidelines.
- 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.
- Periodically evaluate the overall effectiveness (including costs, risks and benefits) of their IP policies and practices.

The policy states that Government agencies are encouraged to develop agency-level IP policies in alignment with this Government policy to manage IP processes and stakeholder interaction.

The policy refers to *IP Policy Guidelines and Tool Kit*. However, communication by the RDU with the DJTSI in July 2019 informs that the development of these is currently on hold due to resourcing constraints.

Two IP principles that are of concern for the Government sector are IP ownership by innovative employees, and the reward of such employees. This is largely due to the considerable differences regarding how these are handled in the university sector, which has close relationships with a number of Government agencies, particularly in the WA health system.

The 2015 IP policy does not include consideration of IP ownership by employees.

With respect to employee reward, the 2015 IP policy refers to a 2012 review undertaken by the (then) Department of Commerce (now DJTSI) of the preceding *Western Australian Government Intellectual Property Policy 2003*.

This review recommends allowing for greater flexibility in recognition and reward for extraordinary achievement (where appropriate) via mechanisms such as endorsed net benefit sharing arrangements facilitated in consultation with a number of agencies, including Treasury.

Documents supporting the 2015 IP policy state that the 2003 sub-policy of *Encouraging Innovation by Government Employees - Procedures for the payment of monetary rewards to innovative Government employees* is still in effect.

This 2003 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 awards.

The 2003 rewards policy does not address any specific arrangements for the sharing of benefits of commercialisation between the inventors, the service units and the organisation. It states that any employee reward will be by an Act of Grace payment through the Treasurer, after approval by the *State Government Executive Council* (which consists of the Governor of the State along with the State Government Cabinet Ministers). This is currently capped at $250,000, unless approved otherwise by the Governor of the State.

It is noted, however, that the 2012 review of the 2003 IP policy revealed considerable contention in the WA government sector of the need for an employee reward structure.

It was concluded that, in respect to promoting a culture of staff rewards for invention and IP, the 2003 policy had not achieved any significant impact. It was stated that participant opinions on the merits of the strong focus on rewards and incentives were mixed. One range of participant views supported more flexibility and agency control over the levels of reward incentives, e.g. supporting more effort to develop an alternative discretionary ex gratia reward system. Another range of participant views considered that staff rewards and incentives should be defocused in the WA Government IP policy, and in some views, explicit mention should be removed altogether from this.

This aspect of the 2015 WA Government IP Policy therefore awaits further development.

IP Policy and Management: Department of Health

Research Development Unit

The RDU, which is located in the Clinical Excellence Division of the Department of Health, has since 2003 provided advice on, and operational assistance for, IP policy and management in the WA health system.

The following is a brief description of the evolution of this activity from 2003 to the present.

The Western Australian Government Intellectual Property Policy and Best Practice Guidelines were launched in **2003** by the then Department of Industry and Resources (now DJTSI).

In the same year the Department established a Senior Policy Officer position in the RDU, with duties that include (at approximately 0.5 FTE) providing policy direction, operational support and advice on IP across the WA health system. This position is ongoing.

Also in 2003 the Department established the *Intellectual Property Management Group* (IPMG) in order to oversee the implementation of the Government IP policy in the WA health system. This group consisted of representatives of the executive of the Department, the HSPs, the Department's LLS, medical researchers and the (then) Department of Industry and Resources (now DJTSI). The RDU provided secretariat, operational and financial support to this group.

As part of this work the RDU undertook a *Review of IP Asset Management and Commercialisation in the WA Department of Health*.

In **2004** the RDU issued an Operational Directive titled *Intellectual Property Management in the State Health System*. This directive was supported by a web-page on the Department's internet site, with information on a range of aspects of IP management.

The RDU has provided an IP advisory service to the sector since then, frequently taking enquiries regarding IP identification, protection and management. Where necessary the RDU liaises with the Department's LLS to provide appropriate information and assistance.

In **2006** the membership of the IPMG was modified to link with the *State Health Research Advisory Council*, which had been established by the Department in 2005.

In the context of this new focus the RDU, in conjunction with an external consultant (Atamo Pty Ltd), prepared a document entitled *Developing a Coordinated Approach to IP Management Across the Health Sector in WA*.

The IPMG functioned until 2008, after which, 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 associated 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.

Membership of the MRCF in WA is co-funded by the Department and 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, when appropriate, assisting the generators of the IP in preparing a funding submission to the MRCF. The consultant also assists in the processing of the submissions by the MRCF.

This activity has resulted in a number of potential investments being presented to the MRCF from different HSPs, with two very significant funding commitments being made: *OncoRes Medical* and *Respirion Pharmaceuticals*, which are further considered later in this document.

In **2015** the (then) Department of Commerce (now DJTSI) issued a revised version of the *Western Australian Government Intellectual Property Policy*.

Like some other government health agencies in Australia (Victoria and South Australia), the WA Department of Health does not have a stand-alone IP policy, and uses the 2015 WA Government IP Policy.

Since the *Health Services Act* **2016** IP is managed in the WA health system through a Mandatory Requirement of the System Manager's *Research Policy Framework*, which is in the form of an Information Circular (0228/15) *Intellectual Property Management in WA Health.*

This document states that (at the present time) the RDU is the primary contact point for IP matters across the WA health system. It informs that the RDU can assist by:

- Providing general advice on IP management, and assisting with specific questions and issues related to IP developed in the WA health system.
- Obtaining expert advice on IP valuation and paths to commercialisation (including establishment of recording, reporting and non-disclosure procedures).
- For materials protected by copyright and which have potential commercial value (e.g. software, training manuals, patient or business management tools, etc.), assisting with the establishment of licence agreements prepared in conjunction with LLS or the State Solicitors Office (SSO).
- Obtaining Executive authorisation for progression of IP through commercialisation stages.
- Provision of funds, subject to approvals, for the limited support of very early stage commercial development of IP (e.g. establishment of a business case, assessment of commercial value, assistance in reaching the proof of concept stage, initial patent attorney costs and provisional patent application costs).
- Providing template IP clauses to be included in contracts with external parties. Any modifications to standard IP clauses should be prepared and approved by LLS or SSO.
- Providing the opportunity to support commercial IP development through the MRCF, which can provide early stage seed funding for the commercialisation of IP generated in the WA health system.

This Information Circular is supported by a series of documents on the WA Health IP website, which include: *IP Management in WA Health*; *Procedures for the Protection and Commercialisation of WA Health IP*; *IP Policies*; *IP Resources* and an *IP Registration and commercialisation checklist*: https://ww2.health.wa.gov.au/Articles/F_I/Intellectual-Property

In **2017** the RDU, in conjunction with LLS, prepared a consideration of IP ownership by, and reward of, innovative employees of the WA health system. This was undertaken in response to specific concerns of some of the HSPs regarding these matters, particularly in case of joint appointments, such as Clinical Academic positions. The considerations taken into account follow.

- Staff of the WA health system are sometimes involved, either directly or indirectly, in the generation of IP through their work activities and their participation in research.
- IP can also be generated by staff who have some form of university affiliation, such as Clinical Academics, who are concurrently employed by the WA health system and the University of Western Australia (UWA). Other WA health system staff have part-time employment relationships with universities, medical research institutes, or other organisations. In addition, some WA health system staff have adjunct (non-employment) academic titles with the universities.
- The relationship between the different parties that might be involved in the generation of IP by such persons is very complex. This is because not only are potential IP rights of the WA health system and external organisations involved, but also those of the individuals and other parties that might have contributed to the generation of IP. These can include other institutions collaborating in the initiative, funding agencies and corporate bodies, which can be at the local, national and international levels.
- In Australian law the ownership of IP in an employee-employer relationship is relatively clear in the case of Copyright, where this is generally vested in the employer. However, Australian law does not explicitly give ownership of IP to the employer in the case of invention and patenting. This has been a point of considerable discussion and contention, both locally and nationally.
- The landmark 2010 High Court decision on the *University of Western Australia v Gray* case has found that an employer has no automatic rights over the inventions of an employee, without an express, or implied, term in the contract of employment. It was decided in this judgement that a duty to undertake research does not carry with it a duty to invent, nor necessarily provide employers with the benefit of the inventions.
- In the case of the WA health system, standard employment contracts generally do not refer to the requirement to invent, ownership of inventions or to other intellectual property matters, and indeed even research would not routinely be included as a duty.
- This presents a situation whereby WA health system employees who claim to have generated IP in inventions outside of their prescribed duties, whether in their own time or not, could well argue that they personally own the IP, and that the WA health system has no claim over this, irrespective of whether there is a relationship between the IP generated and the work activities or environment of the person.
- The use of work facilities or resources, or the creation of an invention “on work time” do not, in themselves, give the employer any claim to ownership of IP in that invention. The employer may, however, have rights to take disciplinary action if it was not appropriate for the employee to use those facilities or resources to create the invention on work time.
- In such a situation it is preferable for the employer and employee to come to an agreement which takes into account the IP rights of the employee, the employment and contractual arrangements in place and the possible influence of the work environment on the development. Consideration could be given to any operational value the development might have to the activities of the employer, and to the sharing of any net benefits that

the invention might engender. It is suggested that such considerations would be on a case-by-case basis, and not necessarily be subject to enforceable policy.

- It is noted however, that as referred to earlier, the 2015 WA Government IP policy does not directly address IP ownership or benefit sharing by public sector employees, but falls back on the associated 2003 employee rewards policy, which unfortunately does not provide an effective mechanism for allowing this. Any other means of rewarding innovative employees could be subject to potential constraints imposed by the *Public Sector Management Act 1994*.
- With particular reference to Clinical Academics, who are concurrently employed by the UWA and by the WA health system, the WA Health System-Medical Practitioners (Clinical Academics) *AMA Industrial Agreement 2016* was registered in the Western Australian Industrial Relations Commission on 30 June 2017. This agreement does not contain any provision related to IP.
- The UWA IP Policy contains a clause that specifies that the university owns IP created by a university staff member pursuant to a contract of service to the University. The UWA refers to this policy statement in its employment contracts.
- This means that WA health system staff who have employment relationships with the UWA have agreed that UWA will own any IP that they develop, whether in the context of the university or the WA health system. Such staff also have a right to a share of any net proceeds that might arise from commercialisation of IP generated through the UWA, and this share can be greater, and more easily accessible, than that contemplated by the government employee awards policy of 2003, which is still in effect.
- In different forms and manners, this principle would also apply to the other WA universities with which staff of the WA health system could potentially interact.
- The HSA refers to IP in the context of HSP functions and powers, but does not address issues regarding IP ownership.
- Ideally, into the future, the WA health system should consider incorporating appropriate IP clauses in all new, and renewed, employment contracts. This would have to be considered internally at multiple levels, and in consultation with other relevant government agencies, such as the DJTSI, which is the agency responsible for the 2015 WA Government IP policy, as well as the Departments of Treasury and Finance, the SSO, and the Public Sector Commission, amongst others.

Other Sectors of the Department of Health

As part of the review activity of the RDU in establishing this Current State document, relevant sections of the different Divisions of the Department were consulted.

These divisions are: Clinical Excellence; Public and Aboriginal Health; Purchasing and System Performance; and Strategy and Governance.

In general terms this consultation revealed that the different sectors of the Department have a reasonable appreciation of the importance of IP in their operational activities. This was particularly evident in the area of contracts for services with external providers. Examples were given where inappropriate, or even absent, IP clauses in such contracts resulted in disagreement over IP ownership of the products of the contracts. This has caused problems in having access to the products of those services, or unanticipated use by the external providers of the products. Significant resistance by the external providers to the IP clauses in Department template service agreements for contracts was also found, particularly where the providers saw potential commercial value in the outputs of the services. Examples were also given where there was a lack of clarity around ownership of IP developed by Department staff, either directly or indirectly related to their employment.

The different sectors of the Department recognised the role of LLS, or when required SSO, in assisting with IP matters, but were generally less aware of the assistance that the RDU could provide. It is felt that this internal consultation process increased the profile of the RDU in this respect.

IP Policy and Management: Health Service Providers

The RDU obtained information on IP policy and management in the HSPs of the WA health system by various means, which included:

- A series of nine written guiding questions (Appendix 1) was provided to the Chief Executives (CEs) of the Child and Adolescent Health Service (CAHS), East Metropolitan Health Service (EMHS), Health Support Services (HSS), North Metropolitan Health Service (NMHS), South Metropolitan Health Service (SMHS), PathWest Laboratory Medicine WA (PathWest) and the WA Country Health Service (WACHS).
- It is noted that the guiding questions were not limited to determining the views of the HSPs on the Current State of IP, as the opportunity was taken to include consideration of aspects of a possible Future State IP strategy.
- Written responses to these questions were provided by the HSPs to the RDU. PathWest did not answer the individual questions, but provided a letter regarding those that were particularly relevant to them. The CE of SMHS also provided a letter which complemented the responses to the individual questions.
- The HSP CEs named persons with whom personal consultations with the RDU could be held. These consultations were aimed at clarifying any points regarding the written responses, as well as providing the opportunity for the HSPs to further discuss the IP review with the RDU. The RDU also met with the CEs of WACHS and PathWest.
- The RDU held consultations with relevant groups within the HSPs: Research Directors, Human Research Ethics Committee Chairs and Research Governance Officers.
- The RDU has also gathered information from researchers in the HSPs in discussions that have occurred outside the current review process.

Responses by HSPs to guiding IP questions

The following is a compilation of the written responses of the HSPs to the nine guiding IP questions.

- ***1: Current IP capacity and capability of HSPs***

CAHS

There are opportunities to improve both capacity and capability for IP briefing and management at CAHS.

Currently:

IP matters are managed in accordance with WA Health policy.

Requests for legal advice on IP matters are received from time to time by CAHS' General Counsel (State Solicitor's) officer.

Relevant IP expertise is a gap. When research projects are reviewed by CAHS Human Research Ethics Committee (HREC) or the Research Governance team, the possibility of any IP issues are identified and further information/clarification sought from the study team if applicable.

IP queries are also directed to the RDU (Dr Neil Lynch) as the drafter and owner of the WA Health IP policy and guidelines. The RDU is also the administrator of various research grant schemes funded by WA Health and have a requirement that any grant funded research project involving a number of collaborators has an IP agreement in place prior to the release of any funds.

EMHS

The EMHS does not employ anyone with specific IP expertise within its health service. IP matters that require legal advice are filtered through the EMHS General Counsel to the State Solicitor's Office or through specialist companies if required.

The EMHS has identified a gap in its ability to deal with IP matters and the need to have a comprehensive framework covering IP.

HSS

HSS' current capability to effectively deal with IP matters is considered low. HSS does not have persons employed with specific IP expertise beyond some staff members with an academic knowledge.

HSS has not specifically engaged in the development of IP guidelines or standard operating procedures, nor does it have an IP management group.

If specialist IP advice is required, this would be sought through the Department's LLS who provide legal advice to HSS via a bureau service.

HSS has recently updated its Compliance Framework to include a requirement for every Executive Director to provide assurance or identify a gap in relation to their business unit's compliance with the *PSC Circular 2009-30: Government Intellectual Property Policy*.

NMHS

NMHS has very limited IP experience. Previously support has been provided by the Department.

The Executive Director Safety, Quality, Governance and Performance is responsible for the Research portfolio at NMHS and has some limited involvement in IP.

Support is limited and often person dependent.

NMHS recognises the need for IP support, however there is no current plan to have a dedicated IP resource at this time.

NMHS has access to General Counsel advice, although their expertise is not commercial or IP specific.

If required NMHS would outsource or request support from the Department.

NMHS has recently conducted a Research Review that focused on ethics and governance, but is developing Risk Based Research Monitoring Procedures.

PathWest

As a small HSP, PathWest has very limited capability to develop and manage IP matters independently, and nor is it necessarily desirable. Whilst PathWest envisages that a new position such as a PathWest Research Governance Officer may provide a degree of contact or

liaison between individual researchers and the Department regarding IP, this position would be more of a 'conduit' than active involvement, with the expectation that the Department provides the necessary policies and operational guidance in managing individual IP matters.

IP is an important concern for PathWest, given the strong research culture and exploration of cutting-edge technologies. In the relatively short time that PathWest has been a standalone HSP, questions around how IP is managed have arisen several times.

SMHS

SMHS Officers provide limited review and advice for research contracts involving IP issues. SMHS refer IP matters to their general counsel and executive members with expertise and experience in these areas of law as necessary.

(From CE's letter) There is a requirement, if intellectual property is to be protected, to have access to funding to lodge the relevant protective instruments. The cost of this aspect is not trivial and remains outside the present funding capability and capacity of the SMHS.

WACHS

For any research-related IP matters that are identified prior to research commencing at WACHS sites, the WACHS Research Governance Coordinator reviews and complies with the WA Health IP policy and with endorsement from the Executive Director Medical Services seeks advice from the RDU and/or LLS regarding the need for a review of any IP agreement. It is not often that this occurs, given that WACHS only has a very small number of funded research/clinical trials involving IP matters and IP ownership where issues arise. WACHS relies on support from LLS and the RDU particularly to ensure consistency in IP approaches in research.

- ***2: Possibility of enhancing IP capacity and capability of HSPs***

CAHS

CAHS supports the development of additional expertise and capability in IP matters for all of the WA health system, with consideration of the current state outlined above.

EMHS

The EMHS is not in a position to fund any additional positions. The EMHS utilises its General Counsel position and the State Solicitor's Office for legal advice and where appropriate will refer matters on should specialist advice be required.

The EMHS is of the view that any IP framework and management should sit under the HSP, as the owner of the IP.

HSS

HSS is currently undergoing a business transformation program. This program aims to build essential foundations for HSS as a Statutory Authority and transform some of the existing business processes to improve efficiency and effectiveness for customers. This activity is the main focus of HSS improvement initiatives at the current time.

At this point, HSS is not in a position to fund additional resources with IP expertise, and would not consider doing so until a review is undertaken of whether or not this would be a cost-effective activity for the organisation. Similarly, HSS do not currently have funding earmarked for IP protection activities.

At this point, HSS would prefer that IP matters be managed with guidance from subject matter experts from within the Department.

NMHS

NMHS is not currently in a position to fund any additional IP staffing, although would consider up-skilling the research monitoring role to be able to address the less complex queries.

NMHS would prefer that the IP matters are managed collaboratively with the Department, the NMHS Research Strategy Committee and the Executive Sponsor.

There is no specific NMHS funding relating to IP protection, seed funding or business cases for commercialisation. NMHS has a number of IP Agreements with UWA in which resources (use of hospital facilities etc.) contribute to the research.

SMHS

No funding is currently available within the SMHS budget for an IP specialist or funding for IP protection. This is a specialised and complex area and SMHS would not currently have the volume of work to justify a full time or part time FTE. Current arrangements whereby SMHS seek advice within the organisation, from SSO and the other HSPs, provides adequate support. The majority of IP is retained by the commercial sponsors or the collaborating universities under their existing agreements.

It is acknowledged that a central resource at SMHS that deals with all IP issues including research would be most efficient and cost-effective. Organisations in other jurisdictions have specifically operated sections that deal with the IP/commercialisation matters for research funding, IP protection and commercial development.

As the research effort expands, particularly into basic research to supplement the current applied focus, it is envisaged that the need for this function within the HSP will expand. This will need to cover both the IP and contractual issues that emanate from participation.

WACHS

Given the limited research projects and instances where WACHS requires advice on IP matters, preference is for IP matters to be managed by WACHS in conjunction with existing policy and resources in the Department (such as the RDU and or LLS). WACHS does not have funding available within the Research Governance Unit for additional staffing resources for IP matters nor is this warranted when WACHS can seek specialist advice from Department on a small number of projects per year. WACHS cannot comment on access to funding to cover the costs of IP protection, commercialisation and seed funding, however current research activity would not warrant this at this stage.

With the recent establishment of the *WACHS Research and Innovation Strategy 2018 - 2023* whereby the directions include becoming a global leader in country health research, building research capacity and capability, and investing in research resources and infrastructure, the future requirements of IP resourcing for WACHS will need to be enhanced to support the strategy. It is unlikely, however, that there will be a large increase in research projects that can be commercialised.

- ***3: Need for uniformity and consistency***

CAHS

CAHS' view is that it is important that there is an over-arching WA Health IP policy. Research often occurs across HSPs and involves one or more universities or institutes – it would make IP matters easier to manage if all HSPs operated under the same mechanism. For example,

having a single WA Health IP agreement template would seem sensible in such circumstances. There would be increased efficiency for IP management within the public health sector if IP knowledge and expertise resided centrally.

EMHS

The EMHS would support being responsible for its own IP.

HSS

HSS believes that IP management is the responsibility of each HSP as a Statutory Authority as ultimately IP ownership would vest with the employing authority (on behalf of the State of WA), provided sufficient contractual clauses are included in employment contracts.

Without further information, it is suggested that the management of IP is a matter that each HSP should deal with individually, with support and guidance from subject matter experts within the Department as required. This would allow each HSP to manage their IP in a manner that suits their individual requirements.

However, should the review identify tangible benefits associated with a system-wide approach, this is something HSS would happily consider. This is likely to be the case, as mentioned above, where there are matters that cross HSPs.

NMHS

NMHS would support an over-arching WA health system IP policy and associated guidelines.

PathWest

Uniformity and consistency in IP policy, management and operating procedures is desirable across the WA health system. The Department as System Manager is best placed to provide this expertise and function.

SMHS

This is crucial as many projects are multi-site or researchers work across multiple sites and there needs to be a consistent policy and process. As a statutory authority it is incumbent on the organisation to protect its IP and maximise “return”, both reputational and commercial, for this asset. There needs to be a clear framework for organisations to operate within.

A WA Health framework developed in collaboration with HSP representatives would be most beneficial.

(From CE’s letter) It is imperative that there is a universal framework across the WA health system that covers all employees.

WACHS

WACHS strongly supports an over-arching WA health system IP policy including standardised operational guidelines/procedures, and consider uniformity and consistency regarding this issue and greater research processes to be very important across all health services.

- ***4: Need for individual HSP IP policies***

CAHS

As per response above.

EMHS

(Specific response not provided)

HSS

If a need was identified, HSS would undertake the development of a local IP policy that aligns to the requirements of the WA Government IP Policy.

NMHS

There should be a consistent approach across the WA health system in relation to IP management to facilitate cross-HSP research. If a HSP specific policy is required site specific procedures can be put into place.

SMHS

It is crucial that SMHS have their own IP policy that operates within their overall framework.

WACHS

WACHS' current research activity does not warrant WACHS having its own individual IP policy at this stage, as any issues are effectively managed by the overarching WA Health IP policy.

With the introduction of the WACHS Research Strategy this year, it will be important for WACHS to be consulted on IP policy if an overarching WA Health IP framework remains. As the Strategy develops, WACHS may choose to develop its own policy, particularly as it relates to staff incentives for research. However, guidance from the Department on consistent approaches to managing employee rewards would be beneficial given the movement of staff amongst HSPs.

- ***5: Role of the Department as System Manager***

CAHS

As per response above.

EMHS

The EMHS does not believe there is a need for a system wide involvement in IP. However, the Department will have a role in ensuring there is no system-wide risk.

HSS

One area of benefit could be some oversight of existing WA health system protected/ commercialised IP. As mentioned above, HSS would welcome an opportunity to discuss the benefits associated with some elements of a system-wide approach if that is what the review uncovers.

Otherwise, if no tangible benefits for the Department or HSPs can be demonstrated, IP policy and management should be left to individual HSPs to address as they see fit, in line with the WA Government IP Policy.

NMHS

The system manager should have a role in developing a mandatory policy in this space and should facilitate HSPs in developing appropriate local procedures to ensure HSPs are protected and are able to optimise opportunities.

PathWest

Should a 'system manager' model for IP be put in place, PathWest would welcome these issues being explored collaboratively between the Department and the HSPs.

SMHS

SMHS believe that the Department should provide a consistent overall framework for all HSPs to operate within.

It may also be necessary for involvement in resolving conflict of interest with the education sector.

WACHS

It is important for the Department to be consulting with each of the HSPs when updating their IP policy so all IP issues experienced amongst the different HSPs can be incorporated into the policy and any related procedures. It may not require a mandatory policy from the Department but guidance on employee benefits would provide a more consistent approach across health. Guidance on IP sharing with external parties, particularly universities, would also be useful.

- ***6: Importance of IP commercialisation to HSPs***

CAHS

CAHS currently has limited access to specialised commercialisation advice and expertise (other than the Department and CAHS General Counsel).

Given limited IP is known to have arisen from research within CAHS, it is unclear as to whether it would be worthwhile for CAHS to establish or participate in revenue generation. CAHS is aware that other research institutions have done so but not sure about a HSP participating in such enterprises. CAHS knows of the existence of the Medical Research Commercialisation Fund but has had no experience, and hence no views, about the Fund

EMHS

The EMHS believes there have been missed opportunities with respect to commercialisation of IP and revenue generation in the past.

The EMHS would consider the option of establishing spin-off companies but this would require more advice and consideration.

The EMHS is not clear how the Medical Research Commercialisation Fund works and does not believe it is well communicated.

HSS

Based on current information available, it is unlikely HSS has taken advantage of IP that has arisen. Especially in the ICT space, there is likely to be a number of opportunities that could have been commercialised or protected in some manner.

Having said that, there is a need to balance the interests of patients and patient safety with the benefits of commercialisation. For example, HSS often develops bespoke solutions to meet a particular clinical IT requirement. However, such products are often needed immediately to improve patient safety or treatment which does not leave sufficient time to undertake an IP

commercialisation or protection activity. This is especially the case in relation to patents where disclosure of an invention renders a patent application invalid in most circumstances.

NMHS

Although NMHS has taken advantage of some commercialisation of IP there have been a substantial number of missed opportunities.

NMHS does not have access to in-house commercialisation expertise.

NHMS is not entirely sure (it would need to understand the cost benefit) whether it would establish a spin-off company, but does not see why it would not if given the opportunity.

Some of NMHS Senior Researchers have experience with the Medical Research Commercialisation Fund. Unable to identify how many at this stage.

SMHS

The balance between this aspect and the more traditional academic is complex, but SMHS should not resile from this and from the obligation to maximise the benefit from IP to the State. Models within other jurisdictions can provide examples of both what works and that which constricts IP commercialisation.

WACHS

WACHS' current research activity to date has not involved commercialisation of IP or revenue generation.

- ***7: IP ownership and rewards for employees***

CAHS

Employee reward and recognition is highly important at CAHS, appreciating that the appropriate governance exists around any future mechanisms for IP ownership in particular.

CAHS considers that IP generated within the health service may vest in both CAHS and the inventor/innovator. It is feasible that employment contracts within CAHS may include IP clauses but this would need to be investigated further.

EMHS

The EMHS believes that any IP generated in the health service and the potential of offering the reinvestment of this to the service or staff member could be considered. However, this would need to be done so on a case by case basis.

The EMHS believes it is feasible to include IP clauses in employment contracts, particularly for Clinical Academic/joint appointments.

HSS

In general, IP ownership should vest with the employing authority where an employee has been employed for an 'inventive' purpose. In HSS' case this is likely to be applicable to the IT Application Developers in particular. However, to ensure this is the case, it is important to have relevant clauses included in employment contracts. Similarly, moral rights waivers may also be required in some circumstances.

Employees should be celebrated for their inventiveness rather than provided with a reward, especially where they are employed for an 'inventive' purpose.

NMHS

Any IP generated in NMHS should generally vest in the service if HSP resources have been utilised to support the research.

NMHS is not aware of current legal opinion on ownership issues and does not have access to legal advice for the specific focus of IP ownership issues.

NMHS would seek advice from Human Resources on the need for IP clauses in employment contracts before committing to this.

Employees should be rewarded but via support/re-investment in their ongoing research activities rather than individually.

SMHS

Any framework or policy must give considerable thought and prominence to the situation where a member of staff has invented or created something that is of commercial value. SMHS should support researchers through the process and enable them to retain part of the proceeds from net revenue raised through the commercialisation process. This is about respecting staff and encouraging them to pursue innovative ideas and bring them to life. Other jurisdictions/organisations have considered this matter with the distribution being determined by the service department head so that all participants in the research teams know their relative share of the "pool" to be distributed to employees. It is imperative that both the organisation and department have a share of proceeds for future development, seeding and support of research activities.

However, consideration needs to be given to the form of any benefit as the issuance of "rights" or "future" shares at nominated prices may distort the focus of an organisation's employees even though it is in the interest of the commercialising body who has acquired the right to the IP.

With respect to ownership of IP it is acknowledged that there should be clear provisions in employment contracts if the employees are potentially going to be involved in the development of IP. The IP must reside with the institution, especially if the researcher is generating this as part of their employment. If the HSP decides to commercialise the IP and generates net financial returns then there should be some recognition to the staff involved.

Any IP developed through sponsored or university research would be managed through agreements with the respective organisation and ownership of IP generated should be specifically articulated in the contract or agreement.

(From CE's letter) The issue of employee rewards is extremely vexed and unless handled with a degree of dexterity and nuance can result in aberrant behaviour to maximise personal gain and ultimately distort the research focus and thus outcomes.

The employment contract needs a clear and unequivocal statement regarding the ownership of intellectual property being vested in the employer. Any transfer of employee to the organisation will also require the employment contract to articulate any pre-existing issues that may conflict with the ownership of intellectual property developed whilst the individual is an employee of the organisation. This will be particularly problematic, although none-the-less crucial, with respect to clinical academic staff.

WACHS

The Research and Innovation Strategy for WACHS includes a direction to build the capability of research staff. It may be beneficial in future to ensure there are employee rewards for staff involved in research, however, it is likely that other benefits such as time to do research would be more important to research staff in WACHS.

- ***8: Relationship with external organisations***

CAHS

This is of particular importance to CAHS given the interagency approach to many research endeavours, in particular the collaborative work with TKI.

EMHS

The EMHS is supportive of collaborating with external organisations.

HSS

Due to the nature of HSS' work having a corporate focus, HSS does not routinely engage with research institutions. This may be applicable where HSS engages with an external third party to assist with the development of a new or innovative solution to meet an identified IT need.

NMHS

Substantial research is conducted within and across NMHS with many opportunities for commercialisation.

NMHS has a significant number of missed opportunities to date.

Robust IP agreements are integral with respect to commercialisation.

Although not currently available, NMHS would ideally like to build in-house capacity (within the monitoring position) in relation to IP, even if only to provide researchers with advice on where to access legal opinion, awareness of key risks and solutions associated with IP and commercialisation.

PathWest

Effective management of IP is critical for PathWest. PathWest has a well-established and respected research track record and a large number of collaborative projects with universities and other organisations.

SMHS

This aspect has not received the consideration it warrants. The issue of who owns the IP from joint University/SMHS employees has not been fully considered and is an area of potential dispute.

There are also issues surrounding "Custom and Practice" within Western Australia that need to be unpacked so there are clear guidelines that determine how this should be managed. This is particularly evident with respect to individual research foundations and the relationship with the Harry Perkins Institute.

(From CE's letter) The progress of intellectual property protection and commercialisation will require clear and unequivocal agreements with participants in the research community including all Universities, the Harry Perkins Institute and the independent research foundations that exist to foster research.

WACHS

Fostering and facilitating relationships with external organisations to encourage research is extremely important to WACHS. All IP matters require research agreements which are directed to the RDU and or LLS who have the specialised expertise to review and provide guidance on the issues. Only when satisfied that these agreements are acceptable can it be signed off by the Executive Director Medical Services and commence within the health service. WACHS relies on this guidance from the Department to ensure consistency in approach with external parties. It would be beneficial for the system for research partnerships with external parties to have a consistent approach across health services such as is currently the case with clinical trial research agreements.

- ***9: Other issues***

CAHS

IP matters in relation to one of CAHS' partners, in particular TKI, is of interest to CAHS. For example, a Research Access Agreement exists around access to Perth Children's Hospital patients and facilities by TKI researchers however does not encompass issues of IP that arise from research projects involving CAHS. There is in-kind support provided to TKI researchers by CAHS, including ethical and site review.

Another issue for consideration is the IP created as a result of a contract, or when CAHS buys a service and IP is created – separate to a research focus.

EMHS

Need to consider Digital and Data Innovation including Information Technology

HSS

While it is understood that the main way IP is generated across the WA health system is through medical research, the IP review should look at all forms of IP that may potentially be developed.

SMHS

For SMHS the issue of publication approval needs to be documented more clearly and expectations articulated as this is currently indeterminate. This may result in the employing and sponsoring organisation not receiving due recognition in the published article. In other jurisdictions research performance encompasses not only publications but patents held.

The interactions of clinicians with both universities and private organisations need consideration, particularly from the perspective of what is permissible in the employment context.

Overview of information from Health Service Providers

The following is an overview of the written responses of the HSPs to the nine guiding IP questions, supplemented by personal consultation with the RDU. This overview focuses on the Current State of IP policy and management in the HSPs. Some of the guiding questions were also aimed at obtaining views of the HSPs that inform the subsequent section of this document, titled *Options for a Future State IP Strategy for the WA Health System*, and are not considered in detail here.

- None of the HSPs have formally defined policy statements on IP. Most of the HSPs refer to the Department's IP guidelines and/or the WA Government IP policy.

- There is very limited IP capacity, capability or expertise in the HSPs. Although there might be a certain degree of academic and experiential awareness of IP in the HSPs, this does not necessarily translate to effective action with respect to IP matters.
- None of the HSPs have defined pathways of IP management or approval processes. There are no designated IP contact points in the HSPs that are widely known to internal staff and external organisations.
- Research Governance officers in the HSPs may identify potential IP issues in research initiatives, but do not have the capacity to independently address these.
- Some HSPs (CAHS, EMHS, NMHS and SMHS) have SSO General Counsels situated in their services, but these persons are required to deal with a large volume of general legal work, which can take precedence over IP matters. Also, the General Counsels do not necessarily have specialised IP expertise.
- These circumstances have resulted in difficulties in managing IP both internally within the HSPs, and in their relations with external organisations. These difficulties relate mainly to IP ownership in situations of collaborative research and shared or joint employment arrangements, as well as in cases of IP developed by employees, either directly or indirectly, in the context of their work activities.
- Some of the HSPs feel that there have been potential commercialisation opportunities that have been missed by not having the capacity to effectively deal with IP.
- The cost of IP protection by patenting can be relatively high, and for some HSPs this is a significant barrier to this being undertaken. There is no available internal funding to develop potentially promising IP through to proof-of-concept and early-stage commercial development.
- Although IP generated in some HSPs has been further developed through the MRCF this is being led by external organisations, rather than by the HSPs themselves. Given that the Department is a Public Partner in the MRCF the more direct participation of the HSPs in such initiatives might be considered.
- All of the HSPs recognise that the above findings are gaps that ideally should be filled.
- None of the HSPs feel that they have the human or financial resources to enhance their IP capacity into the near future.
- From the information gathered it appears that across the WA health system the only employment position which specifically includes IP policy and management responsibilities in the Job Description, is that of the Senior Policy Officer in the RDU. The effective time allocation to IP in this position is approximately 0.5 FTE.
- A number of HSPs have used, or are aware of, the IP assistance that the Department provides, through the RDU and/or LLS, and it is their preference to utilise these services. This is particularly the case in HSPs that do not generate large quantities of IP, and in which it is considered to not be cost-effective to have dedicated internal IP resources.
- Irrespective of the presently limited capacity of the HSPs to deal with IP they are responsible for any IP that is generated in their services, and are the owners of this IP (subject to the considerations described earlier in this document, and that include possible involvement of external organisations, contractual clauses, and employer-employee relationships).
- Consistency in IP policy and management across the WA health system was generally considered to be advantageous, particularly by clinicians and researchers whose activities cross different HSPs.

Examples of IP outcomes in the WA health system

The following are recent examples of IP matters arising in the WA health system for which the Department, in particular the RDU and LLS, has provided support to the HSPs.

OncoRes Medical Pty Ltd

OncoRes Medical is an early-stage medical device company that is developing patent-protected technology in collaboration with researchers at UWA, the Harry Perkins Institute of Medical Research and breast cancer surgeons in the WA health system.

The surgeons are currently undertaking trials of this technology, which aims to provide the capacity to better interoperatively differentiate between tumour and normal tissue.

In order to provide OncoRes with the required freedom to operate in the commercial space, the RDU liaised between the UWA, the Department's LLS and the different HSPs involved in the clinical aspects of the development (SMHS, NMHS and EMHS) to establish agreements whereby any IP rights that the HSPs had in relation to the technology were assigned to the UWA, which is a founding partner in OncoRes.

In exchange for this assignment of IP rights the HSPs will receive a share in any financial benefit that might result either from the on-selling of the technology, or from any revenue generated by its commercialisation.

The MRCF has made a funding commitment of up to $6 million to the further development of the OncoRes initiative.

In addition, OncoRes has been awarded a project grant by the Commonwealth's Cooperative Research Centres program.

In 2018 OncoRes was named joint winner of the Pitch@Palace Global 3.0, held at St James's Palace, London.

In 2019 OncoRes was voted as having the best Value Proposition at the Medtech Innovator Accelerator program in the USA. OncoRes was the only Australian representative of 818 applicants to the program

Respirion Pharmaceuticals Pty Ltd

A group of respiratory physicians in CAHS, in collaboration with the Telethon Kids Institute (TKI), has developed an adjuvant treatment which promises to assist in the antibiotic treatment of children with cystic fibrosis.

The Department's RDU and LLS assisted in developing an IP assignment agreement that has been made between CAHS and the TKI which allows TKI freedom to operate in the commercial space, and which specifies benefits that will accrue to CAHS in the event of the successful commercialisation of the technology.

The MRCF, along with Commonwealth's Biomedical Translation Fund, which provides companies with venture capital through licensed private sector fund managers to develop and commercialise biomedical discoveries in Australia, has committed up to $20 million to further develop and commercialise the technology.

In addition, the MRCF has indicated that this initiative has been approved for a $US3 million Therapeutics Development Award from the US Cystic Fibrosis Foundation.

Ownership of IP by a HSP

An employee of a HSP was a member of a group of Australian researchers which was awarded a grant from the NHMRC. The primary administering institution for this grant was an Eastern States university, but it was initially considered appropriate that a WA university would be the sub-administering institution for the WA component of the grant. However, the WA university maintained that they would own any IP that might result from the research, even though they

were: i) only to administer the grant funds, and have no intellectual or functional input into the research to be undertaken; and ii) the HSP employee only held an adjunct title with the university, which does not confer any university employment status.

This situation was brought to the attention of the RDU which then undertook discussions with the parties involved, and it was finally decided that the HSP would be the sub-administrator of the WA component of the grant funds, and have access to any IP generated, in accordance with a multi-institutional agreement with the primary administering institution.

IP associated with medical equipment

An engineer in a HSP developed a small piece of medical equipment which, because this was prior to the enactment of the HSA, was patented in the name of the State of WA, through the Department.

This initiative was discussed with the MRCF but this organisation declined to invest in the development. They did, however, make contact with a manufacturer of medical equipment, who expressed interest in acquiring the IP.

The Department's RDU and LLS undertook extended negotiations with the manufacturer, and a draft agreement was reached whereby the company would purchase the IP by paying an up-front amount, and then provide the WA health system with the product at reduced cost, as well as paying an ongoing royalty on sales revenue.

However, the agreement was not executed because it appears that the business was then sold to a private equity firm, and sometime later was placed into liquidation.

The business has now been purchased by another manufacturer of medical equipment, and it is now probably appropriate that the patent be transferred from the State to the HSP, which could then consider approaching the new owner to determine whether there is still interest in the product.

Multi-Institutional Agreement

In 2016 a clinician working in a HSP was awarded a NHMRC grant to further develop a medical device that was invented by biomedical engineers in a WA university.

As a number of institutions were involved in this grant, for which the WA university was the administering institution, a multi-institutional agreement (MIA) between the different parties was required to be signed, prior to the NHMRC providing the funding. This MIA was based on a standard template that the NHMRC has used nationally for a number of years.

The university provided the HSP with a copy of a MIA in February 2017. As this was after the implementation of the HSA, and the agreement contained an IP clause that could impact on revenue distribution after potential commercialisation of the device, the HSP requested that the RDU work with the Department's LLS to review the MIA prior to signing.

For a number of reasons, that appear to include lack of familiarity of some of the involved parties with such matters, this MIA was not signed by the HSP until June 2018. This 17 month delay exposed the university and the HSP to significant risk in meeting development milestones which could trigger further investment into the project.

Ownership of IP by an employee of a HSP

A nurse employed by a HSP had an idea for a simple device which might assist in the handling of patients in the clinical area in which she worked. She discussed this with her immediate managers, and developed a prototype, which she tested in the service.

The nurse then obtained a patent for this device in her private capacity, and found a manufacturer who expressed interest in this.

Given that questions arose regarding the ownership of the IP associated with the device, the nurse contacted the RDU, and this was considered in conjunction with the Department's LLS.

The legal advice indicated that there was nothing in the job description, employment contracts and agreements for the nurse that required her to invent, and she had not been instructed as part of her work duties to invent. As such, the HSP would have very little chance of claiming ownership over this invention (this refers to the *University of Western Australia v Gray* case).

In consultation with LLS the RDU suggested some possible options that the HSP could consider in this case, and that were based on the IP ownership paper described earlier in this present document. The RDU is given to understand by the nurse that the HSP had not progressed this matter with her.

Other Organisations interacting with the WA health system

Consultation was undertaken by the RDU with other organisations that, directly or indirectly, are of relevance to IP policy and management in the WA health system.

Contracted Health Entities

Under the HSA (Section 19) the WA health system includes contracted health entities that provide health services to the State under public-private partnership agreements with the WA State Government.

There are currently two contracted private health entities included in the WA health system, which could potentially have interaction with public system in the area of IP: Ramsay Health Care (RHC) and St John of God Health Care (SJGHC)

The *Joondalup Health Campus* is managed by RHC and is comprised of the Joondalup Private Hospital and a co-located hospital which provides public patient services.

Personal communication by the RDU with the office of the National Research Manager of RHC has indicated that their IP policy is out of date, and currently under review. Any IP matters that arise are being dealt with by their legal office.

The *St John of God Midland Public Hospital* is operated by SJGHC. This organisation has a *Research Handbook 2019*, which includes a research governance framework and guidelines for conducting human research. IP policy is not specifically addressed in this handbook, but IP is referred to in a number of research ethics and governance templates and guidelines. The RDU has been informed in personal communication with SJGHC that IP matters are referred to their legal counsel.

Department of Jobs, Tourism, Science and Innovation

- ***Industry Development***

The Industry Development team of DJTSI has been involved in public sector IP policy since the late 1990s, and is responsible for the current *Western Australian Government Intellectual Property Policy 2015*. This policy is considered in detail earlier in this present document.

Part of the approval of this policy by the WA Government was an authorisation for the (then) Department of Commerce (now DJTSI) to review impediments impacting on the IP Policy's

effectiveness, and endorsement of a project to design a new net-benefits sharing program (which is also referred to earlier in this present document).

The Industry Development team advised that due to significant staff reductions, the above two projects have been placed on hold.

Similarly, the 2015 WA Government IP policy refers to *Best Practice IP Policy Guidelines and Tool Kit*, but this resource has not been developed.

The Industry Development team pointed out that the present Labor Government's *Plan for Jobs – the Innovation Economy* states that the government will explore and develop revenue streams through the commercialisation of State Government IP, and indicated that they were anticipating greater support for this activity.

- ***Chief Scientist and Director of Science and Innovation***

The Chief Scientist of WA and the Director of Science and Innovation of DJTSI were consulted by the RDU regarding the review IP policy and management in the WA health system. Both were highly encouraging of this initiative, and recognise the importance of IP the innovation pipeline, and the potential value to WA of successful commercialisation of outcomes of scientific research.

Department of Justice – State Solicitor's Office

The RDU met with the Assistant State Solicitor, along with the SSO General Counsels who are situated in CAHS, EMHS, NMHS and SMHS.

This group noted that they deal with a significant volume of legal work which arises in the HSPs, and which could take precedence over IP matters of lower priority. Also, the General Counsels do not necessarily have specialised IP expertise, and seek advice when necessary.

This group agreed to work in conjunction with the RDU on IP matters, where appropriate and as required, and generally felt that consistency in IP policy and management across the WA health system would be desirable.

The RDU is currently assisting the SSO in consideration of ownership of IP generated by employees of the WA health system.

Department of Primary Industries and Regional Development

Department of Primary Industries and Regional Development (DPIRD) is an amalgamation of the former Departments of Agriculture and Food, Fisheries and Regional Development.

For a number of years the (then) Department of Agriculture and Food had a very active IP management structure. This was, however downgraded over time, and is presently operating with significantly reduced resources. This IP capacity is currently being enhanced and contact has been made by the RDU with DPIRD to explore possible complementarity of functions in the area of IP, which could be of benefit to both organisations.

The Research Development and Innovation Directorate of DPIRD generously provided the RDU copies of their *Intellectual Property Policy* and *Intellectual Property Management Manual*, both of 2017, and which are for internal DPIRD use only. These documents will assist in informing the RDU in the next phase of its activities, which is developing options for a Future State IP strategy for the WA health system.

Landgate

Landgate is a WA Government agency which has a significant IP portfolio, and has informed the RDU that it is currently developing a comprehensive IP Framework, Policy, Strategy and Register. It is anticipated that once complete Landgate will make this material available to the RDU to assist in informing the development of options for a Future State IP strategy for the WA health system.

Other Government Agencies Approached

The RDU approached some other WA government agencies that it considered to potentially have relevance to the IP policy and management in the WA health system. These included the Department of Treasury, the Government Chief Information Officer and the Public Sector Commission. These agencies indicated that at the present stage they had little to add to the information being gathered by the RDU.

WA Universities, Medical Research Institutes and Other Organisations

The IP policies and practices of WA universities and medical research institutes are considered in detail in the second part of this present document (*Interjurisdictional Overview*).

However, as these organisations have strong links to the WA health system in the area of IP they were consulted by the RDU as part of the present determination of the Current State of IP policy and management.

All five of the WA universities (UWA, Curtin University, Murdoch University, Edith Cowan University and University of Notre Dame Australia) and the two major medical research institutes (TKI and the Harry Perkins Institute for Medical Research) were provided with a series of questions regarding their IP relationship with the WA health system (Appendix 2).

These organisations provided written responses to these questions, which are held on file by the RDU. This information was complemented by the RDU undertaking personal consultations, either individually or in groups, with different representatives of the organisations. Some discussions have been held outside the context of the current review, but directly relate to the questions asked in the consultation.

The Western Australian Health Translation Network (WAHTN) was also consulted in this context. The WAHTN is a consortium of the Department, WA teaching hospitals, all five WA universities, major medical research institutes and other health-related entities. The WAHTN has been accredited by the NHMRC as an Advanced Health Research and Translation Centre.

It is noted that the Australian Medical Association WA was invited to provide input into the IP review, but no response was received to multiple contacts.

A brief overview of the information gathered follows.

- All organisations reported having multiple and varied interactions with the WA health system that directly, indirectly or potentially relate to IP.
- This was often at the level of research collaborations, contracts for services, shared or joint academic and clinical appointments (including adjunct titles), post-graduate student research projects, undergraduate student placements, and research grant funding received from the Department, amongst others.
- Some organisations have had IP interactions with the WA health system that have led to outcomes with commercialisation potential.

- Some organisations feel that on occasion the WA health system has been excessively demanding with respect to issues regarding IP ownership and benefits sharing, and that there is what they perceive to be a lack of clarity in this respect.
- Some organisations feel that the level of administrative, governance and operational complexity of the WA health system has impeded the timely resolution of IP matters, which have on occasion put the outcomes of these at significant risk.
- It was remarked that the IP clauses of some the Department's template contracts for services are not conducive to the potential commercialisation of outcomes of these services.
- Concern has been raised regarding the constraints around benefit sharing by employees of the WA health system generating IP, but also working for, or in collaboration with, an external organisation.
- Some of the organisations have had dealings with, or are aware of, the activity of the RDU and the Department's LLS in the management of IP across the WA health system.
- Whilst some issues were raised regarding the previous approach that the Department has taken to some IP matters, concern was expressed that, with the devolved WA health system under the HSA, IP management could become fragmented, and that clear contact points and pathways of communication or decision making have not been established. This concern extends to the possibility that each HSP could potentially have its own individual IP policy, and that there might not be consistency across the system.

As might be expected, this information reflects the particular interests of the external organisations, and does not necessarily take into account the present circumstances and requirements of the WA health system.

INTERJURISDICTIONAL OVERVIEW

Introduction

The following is an overview of IP policy and management in different Australian jurisdictions that has been undertaken in order to inform new directions and strategies that could be applicable in the WA health system, under the provisions of the HSA.

This overview focuses primarily on IP policies and practices of the government health agencies of selected Australian states, and considers these in the context of national and state-wide approaches. It also includes relevant WA organisations that can potentially be involved in the generation of IP in the WA health system, such as the universities and medical research institutes.

The overview considers:

- The organisational structures of the different state health systems.
- State Government IP policies.
- Government health agency IP policies.
- Other relevant Australian organisations.

Within these considerations any stated positions on two key IP principles that are of relevance to the WA health system, IP ownership and employee rewards, are highlighted.

This information was compiled by the RDU with the assistance of Ms Emma Wolke, Student Intern (Science and Law), University of Notre Dame Australia (WA).

New South Wales

New South Wales Public Health System Structure

The New South Wales (NSW) public health system is managed by the Department of Health, under the *Health Services Act 1997*. Within this, management is organised into eight metropolitan Local Health Districts (LHDs), seven rural and regional LHDs, two speciality networks and the St Vincent's Health Network (collectively referred to as Public Health Organisations: PHOs)

These entities are responsible for managing their respective public hospitals and health services, and each division (to varying extents) has its own governance, with separate Boards and policies.

New South Wales State Government IP Policy

NSW has an *Intellectual Property Management Framework for the NSW Public Sector 2005*, which is the responsibility of the Premier's Department.

This framework includes:

- A set of mandatory *Intellectual Property Principles* which all Government sector agencies must implement.
- A non-mandatory *Better Practice Guide* that identifies better practice in the management of IP, and includes advice and information on the creation, use, protection and commercialisation of IP.
- An *IP Resource Kit*, which provides information on IP categories, key contracts, relevant legislation, policies and websites.

- A *Summary Guide* which includes IP Principles, Better Practice Checklist and Advisory Signposts.

The IP Principles state that all NSW State Government agencies are to develop IP policies based on the framework, which support their core functions and service delivery outcomes. Each agency should develop an implementation strategy for their IP policy, and a strategic plan through which IP assets are managed in a transparent manner. Then, ongoing risk management assessments should be conducted by an IP officer/team.

The framework vests ownership of IP created by government employees with the State.

Commercialisation is suggested to be commenced in conjunction with the NSW private sector (if consistent with core functions of the agency).

The framework does not include a rewards system for employee innovation.

New South Wales Public Health System IP Policy

There is a *NSW Department of Health Policy on Intellectual Property Arising from Health Research in Public Health Organisations, 2005*.

This policy applies to all NSW PHOs and states that these must have an IP policy which is consistent with the Department of Health policy.

The policy requires that all PHOs that are involved in health research establish an IP Committee, which should include: the CEO of the organisation; Director of Finance or a senior finance employee; senior research officer; specialist legal advisor; and a secretariat.

The policy states that all IP created by employees in course of employment is owned by the PHO.

The policy contains a formula for distributing proceeds of commercialisation: after deduction of any associated costs, the net commercialization proceeds are to be distributed with 1/3 to each of the: creator; source department within the PHO; and the PHO.

Additionally, the policy requires that the creator signs a written agreement before receiving any payment from the commercialisation whereby they relinquish any future claims on the ownership of IP.

Agreements with third parties, such as clinical academics, visitors and students are outlined. Fair agreements on rights of IP created are encouraged to be established before project commencement, taking into account the rights of the creators.

NSW Health commissioned a major review of health and medical research in 2012. The management of IP was considered and several issues were raised, with the most relevant being the lack of a mechanism for reaching timely multiparty agreements regarding IP ownership and management. Although these are addressed in the *NSW government IP framework*, most NSW medical research institutes were found to have their own IP policies, and a standard approach was difficult to achieve. This led to the loss of some potential investors, who were concerned about the risks surrounding IP ownership.

This 2012 review suggested that where research is funded by the NSW government the State Government IP framework should be utilised. Multiparty agreements should also be based on the protocols outlined in the government framework.

Communication by the RDU with the NSW Office for Health and Medical Research (NSW OHMR) indicates that the 2005 IP policy is still applicable but is currently under review.

The NSW OHMR has confidentially provided the RDU with a draft copy of a revised version of the IP policy. The major addition to the 2005 IP policy is that NSW Health will establish a Central Office which will provide oversight and assistance in relation to the commercialisation of IP, as may be requested by a PHO or IP Committee.

New South Wales Local Health Districts

The following is a brief description of information found on IP policy and management for some of the NSW LHDs:

- ***Sydney LHD (SLHD)***

The Research Strategic Plan (2012-2017) of the SLHD, under the title of *Intellectual Property*, states that the NHMRC requires research institutions to have policies approved by their Governing Body relating to the ownership, protection and exploitation of IP. A number of researchers noted that the SLHD lacks an IP policy. Lack of legal agreements and clear policies about the LHD's claim to ownership and associated rights for IP renders both researchers, relevant Institutes and the LHD vulnerable. This then means that IP is determined on a case-by-case basis, which can slow commercialisation, publication and funding opportunities and could potentially involve significant legal entanglement. The SLHD could develop relevant local policies to ease these issues for researchers in the District. The NSW Office of Health and Medical Research has undertaken to develop an intellectual property framework that promotes greater opportunities to commercialise these innovations.

However, the SLHD Research Ethics and Governance Office, in its 2018 direction on IP, still refers to the *NSW Department of Health Policy on Intellectual Property Arising from Health Research in Public Health Organisations, 2005*, which is presently being updated.

- ***North Sydney LHD (NSLHD)***

The NSLHD has an Office of Commercialisation, which is linked with Hospital and Health Services IP NSW Ltd (previously Biomed North), and is responsible for the management and commercialisation of IP that is produced by researchers working at any of the Area's ten hospital campuses (note: Hospital and Health Services IP Ltd is described more fully later in this overview).

- ***Central Coast LHD (CCLHD)***

The Research Governance Framework for the Responsible Conduct of Research 2013 states that the CCLHD supports the management of IP in accordance with the NSW Health Policy. It also states that a CCLHD IP Policy is under development, but has yet to be released.

- ***Mid North Coast LHD (MNCLHD)***

The MNCLHD Research Roadmap states that the NSW Health Policy is followed as its IP policy.

- ***St Vincent's Health Network***

St Vincent's Health Network comprises of St Vincent's Hospital Sydney Limited as the affiliated health organisation in respect of three recognised establishments under the *Health Services Act 1997 (NSW):* St Vincent's Hospital; Sacred Heart Health Service; and St Joseph's Hospital.

There is a *St Vincent's & Mater Health Sydney Intellectual Property Policy (2006)*, and this refers to the over-arching NSW government IP policy.

The intention of the policy is to ensure that staff has clear understanding of their IP obligations (protection and ownership) and their requirement to notify the IP Committee of any potential IP rights. It also intends to provide a framework for fair distribution of rewards from commercialisation.

It is stated that the entity owns the IP rights created by a staff member in course of employment. It also owns any rights created by non-staff members if done so using the entity's resources in the course of health research. The policy makes clear that this is irrespective of whether this was during employment or not, as entity resources should only be used in course of employment. To confirm this ownership, written assignments of IP rights must be obtained from staff.

Research with outside collaborators is encouraged; however, an agreement as to distribution of benefits must be reached before commencement of project.

The policy states that there is a need for specific agreements for sharing rewards, however as a starting point, at least 10% should be deducted for ongoing management and other costs, and any profit will be shared in thirds between the inventor, the Department and the entity.

Queensland

Queensland Public Health System Structure

The Queensland (QLD) public health system is managed by the Department of Health, under the *Hospital and Health Boards Act 2011*. Within this, management has been organised into 16 Hospital and Health Services (HHS), which are statutory bodies that are independently and locally controlled by a Hospital and Health Board.

Queensland State Government IP Policy

QLD has the *Queensland Public Sector Intellectual Property Principles 2013*, which is the responsibility of the Department of Science, Information Technology, Innovation and the Arts. These principles are applicable to all QLD Government agencies, and the agencies are encouraged to develop individual IP policies that reflect their own needs and objectives, consistent with relevant government policies and requirements.

The principles encourage State Government agencies to manage their IP responsibly, and have risk management plans that include: regular review of IP; rigorous IP record keeping; protecting IP rights; minimising infringement risk; using IP assets to enhance service delivery.

IP management principles include: record keeping; acquisition, use, sharing, commercialisation, disposal and public access to IP; identifying and recording ownership of IP; monitoring and protecting IP; and developing IP commercialisation pathways.

Agencies should also make decisions about licensing and commercialisation so that State obtains maximum benefit.

The policy also includes several steps for IP assessment: define the type and form of IP; conduct a licensing review; select the most appropriate licence; check IP principles and relevant policies and standards; and obtain approvals for release.

It describes steps for IP commercialisation, including: perform IP pre-assessment; seek expert opinion; prepare a business case; obtain approval of the business case; convert IP and plan to achieve appropriate licensing returns.

The principles refer to IP ownership, and state that agencies must consider and address ownership of IP where it is commercially valuable, and is created as a result of employment or in relation to a contractor or outside consultant. It also states that in particular agencies should be aware that the "duty to research" does not automatically imply a "duty to invent", which needs to be expressly stipulated and managed contractually (this refers to the *University of Western Australia v Gray* case, described in more detail later in this overview).

The QLD Government has a *Rewards for Creating Commercially Valuable Intellectual Property 2007 policy*.

The policy provides that the State may grant a reward to an employee under certain conditions: positive revenue has been obtained from the IP asset; the asset has been created during course of employment with the State; the asset has resulted from a project in the Business Case; and the employee's ongoing work performance is satisfactory.

Reward may include cash payment, and will be determined by the relevant Chief Executive. It can be up to 33% of the total positive return but cannot exceed $20,000 per employee per year and $100,000 total per employee. It will not exceed $500,000 total benefits to a group of employees. This may, however, be altered under special consideration.

Communication by the RDU with the QLD Department of Health has indicated that this rewards policy is currently under review.

Queensland Public Health System IP Policy

The QLD Department of Health has a one page document titled *Intellectual Property Policy 2015*, which in single lines gives a high-level overview of IP management.

This is accompanied by an *Intellectual Property Standard 2015* which very briefly outlines positions and responsibilities of: developers of IP; IP Officers; Project Managers; Directors; and the Director General.

A series of short documents are listed under the title of *QLD Health Intellectual Property (updated 2016)*, which include: What is IP? and Department of Health IP Policy and Standard.

There is an *IP ownership Assessment Form (2017)* which aims to assist QLD Health in determining whether IP is owned by the State, an employee, or whether there is joint ownership.

Reference is made to a more extensive document entitled *Ownership and Protection of IP created by Queensland Health Employees and Others 2010*. However, in personal contact with the RDU the Health Innovation, Investment and Research Office of the QLD Department of Health has advised that this document is under review, and is no longer applicable.

It appears that the reason for this is that the above documents only refer to the QLD Department of Health, and not to the HHSs.

The Health Innovation, Investment and Research Office have however, confidentially provided the RDU with information on *IP Deeds* that have been established between the Department of Health and the HHSs. In general terms these deeds establish licence conditions under which the Department of Health and the HHSs can reciprocally use IP owned by each other.

The QLD Department of Health has a policy on the *Management of IP Purchased by Queensland Health 2010*. This policy is to assist QLD Health employees to identify and manage IP issues that arise when external organisations/consultants create IP for use within the Department.

There is also a fact-sheet titled *Information for medical researchers- what are the first steps I should take to identify and protect IP in my research? 2010*. This is to assist QLD Health employees who undertake research to identify and protect IP through the patenting process.

- ***Metro North Hospital and Health Service***

Metro North HHS has a document titled *Procedure, Metro North HHS-wide, Research: Intellectual Property 2017*.

This document includes consideration of: ownership, recording and protection of IP; collaborating with, and using IP of, others; sharing the proceeds of IP; transfer to employees; and determination of ownership.

Under this policy ownership of IP is, subject to a number of criteria, vested in Metro North HHS, although this can be varied by the Executive Director, Research. With respect to benefits sharing of commercialisation, this is set at 1/3 for each of: the inventor(s); the clinical department involved; and the Metro North Office of Research. It is noted that the restrictions imposed by the State Government IP policy appear not to be enforced, and may be related to the fact that the Government policy is currently under review.

Victoria

Victoria Public Health System Structure

The Victorian (VIC) public health system is managed by the Department of Health and Human Services (DHHS), under the *Health Service Act 1988*. Within this, the management has been organised into 19 Public Health Services, which are incorporated public statutory authorities under Government-appointed Boards. The Act also refers to Public Hospitals, Denominational Hospitals and Multipurpose Services.

In 2017 the VIC DHHS was restructured on a portfolio basis, whereby the Health and Wellbeing Division was formed, and which has the responsibility for policy, strategy and commissioning of services in Victoria's primary prevention, secondary and tertiary healthcare system.

Victoria State Government IP Policy

VIC has a *Whole of Victorian Government Intellectual Property Policy 2012*, under the responsibility of the Department of Treasury and Finance.

This policy states that all VIC Government agencies must implement the IP policy, and that this must be supported by the allocation of appropriate resources. The agencies are encouraged to appoint IP coordinators to be responsible for day to day administration of the IP policy.

The policy comprises of three components: IP Policy Intent and Principles; IP Policy Guidelines; and IP Policy Operational Tools.

The policy intent and principles document refers to: the management of State owned IP; State commercialisation of IP; procurement of goods and services (that might result in IP being generated); funding and grants (that might result in IP being generated); the use of IP belonging to others; and identification and recording of IP.

The IP Policy Principles specify that: the State manages IP in ways that are consistent, transparent and accountable; the State grants rights to IP with the fewest possible restrictions; the State may exercise its IP rights restrictively, depending on privacy, public safety, security, law enforcement, public health, commercialisation and compliance with law; the State owns IP

created by its employees in the course of their employment; the State is not in the business of commercialisation of IP, and does not create IP in order to generate financial return.

The Intellectual Property Guidelines for the Victorian Public Sector (Version 1) 2015 address: management of IP; granting rights to State IP; State procurement; commercialisation of State-owned IP; funding and grants; moral rights; third party IP; and compliance and reporting.

No evidence was found for the existence of a current *IP Policy Operational Tools* document.

Victoria Public Health System IP Policy

Communication by the RDU with the Victorian Department of Health and Human Services (VIC DHHS) Office of Health and Medical Research indicates that this organisation does not have an IP policy, other than compliance with the State Government policy. In fact this Government policy states that in the past some departments and agencies have developed their own formal IP management policies, to deal with their specific business needs. These policies may need to be amended for consistency with the (Government) IP policy.

The VIC DHHS also indicated that IP issues are generally dealt with by their legal services on a case-by-case basis.

The DHHS *Policy and Funding Guidelines 2016* state that IP developed by public health services vests in those services, unless otherwise specified, and that those services grant to the State of Victoria a license to the IP rights, as if the State was the owner. No employee rewards policy was found.

The Peter MacCallum Cancer Centre is a Victorian Public Hospital which has an intensive research effort (almost 25% of total staff involved), and has a *Distribution of IP Corporate Procedure*. This procedure assigns 30% of IP generated to the inventors, 20% to other key staff, 20% to the laboratory or division and 30% to the organisation.

South Australia

South Australia Public Health System Structure

The South Australia (SA) public health system is managed by the Department of Health, under the *Health Care Act 2008*. Within this, management has been organised into five Local Health Networks, supported by Governing Councils.

While these networks are vested with their own responsibilities, the State Government continues to be responsible for planning, funding, management, policy development and research.

South Australia State Government IP Policy

The *South Australian Government IP Policy 2017* is under the responsibility of the Department of Premier and Cabinet, and applies to all public sector agencies.

This policy states that generally, IP generated, or acquired in the course of government business is owned by the Government. It also states that agencies may commercialise IP if the benefit outweighs that of public open access to such IP.

The policy suggests that innovative government employees may receive appropriate incentives and rewards, that do not exceed a third of any net financial return, and that comply with financial thresholds.

South Australia Public Health System IP Policy

The SA Department of Health states in a 2016 *Policy Directive* that it is a mandatory requirement that the Department complies with the State Government IP policy.

This directive specifies that any net returns form commercialisation should be shared equally between the inventors, the institution and the Medical Research Fund.

Comparison of Different State Jurisdictions

The material provided in the present document has been compiled into a comparison between the different state jurisdictions, including WA, which is summarised here, and in the table that follows.

The State Government IP policies of SA and WA have relatively recently been updated. Those of NSW, QLD and VIC are less up-to-date.

VIC, SA and WA Departments of Health use the State Government IP policies, rather than having agency-specific policies, although WA has a Mandatory Requirement (currently under review).

The IP policies of the NSW, QLD and WA Departments of Health are presently under review.

No consistent approach was found across the different government health agencies for the IP polices of the equivalents of WA's HSPs. In some cases the HSPs had their own policies, in others they used those of the corresponding State Governments or Departments of Health, or seemingly had none at all. Communication by the RDU with the Departments of Health of some key States indicated that IP policy and management was generally not considered to be a particularly high priority with respect to the activities of the HSPs.

Ownership of employee-generated IP is claimed by NSW, VIC and SA. However, this could potentially be challenged in the light of the *University of Western Australia v Gray* decision. QLD takes this decision into account. WA handles this on a case-by-case basis.

With the exception of VIC, the jurisdictions considered have some form of employee rewards policies or statements. The QLD and WA rewards policies are currently under review.

The following table summarises the IP policies of the different jurisdictions.

Summary of Intellectual Property Policies in Selected Australian States

	NSW	QLD	VIC	SA	WA
Is there a State Government Policy in place?	Yes: *Intellectual Property Management Framework for the NSW Public Sector 2005.*	Yes: *Queensland Public Sector Intellectual Property Principles 2013.*	Yes: *Whole of Victorian Government Intellectual Property Policy 2012.*	Yes: *South Australian Government IP Policy 2017*.	Yes: *WA Government Intellectual Property Policy 2015.*
Is there a Department of Health policy?	Yes: *NSW Department of Health Policy on Intellectual Property Arising from Health Research in Public Health Organisations 2005* (under review).	Yes: *but currently inactive: Ownership and Protection of IP created by Queensland Health Employees and Others 2010* (under review).	No: State Government policy applies.	No: State Government policy applies.	No: State Government policy applies, but IP currently managed under Mandatory Requirement: *Intellectual Property Management in WA Health 2015* (under review).
Do Health Service Providers (or equivalents) have their own IP policies?	Some HSPs have own IP policies, but not mandated.	Some HSPs have own IP policies, but not mandated	No: State Government policy applies.	No: State Government policy applies.	No: Currently as for Department of Health.
Who owns IP under these policies? (State/employer or inventor (s)	State and/or employer.	As agreed contractually	State and/or employer.	State and/or employer.	Not mandated.
Is there an Employee Benefits/Rewards policy or	Yes, in Department of Health policy.	Yes: *Rewards for Creating Commercially Valuable Intellectual*	Not specified.	Yes, in State Government policy.	Yes: *Encouraging Innovation by Government Employees- Procedures for the*

	NSW	QLD	VIC	SA	WA
framework in place?		*Property 2007* (under review).			*payment of monetary to innovative Government employees 2003*.
What is the benefit sharing ratio and is there a financial limit on employee benefits?	• 1/3 Employee. • 1/3 Work area. • 1/3 Organisation.	1/3 employee, max $100,000 total per employee or $500,000 for group of employees.	N/A.	Rewards to employees do not exceed a third of any net financial return, and that comply with financial thresholds.	No benefit sharing ratio specified. Max $250,000.

Other Australian Government Agencies

IP Australia

IP Australia is the Government agency responsible for management of the: *Patents Act 1990; Trade Marks Act 1995; Designs Act 2003* and the *Plant Breeder's Rights Act 1994.*

IP Australia provides general information on key aspects of IP management and commercialisation. This includes the Australian IP Toolkit for Collaboration, a joint project between the Department of Industry, Innovation and Science and IP Australia, and which is designed to facilitate, simplify and improve collaboration between researchers and industry.

Advice given on *IP Ownership: IP Created by Employees* 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. It also states that special rules may, however, apply to inventions made by university teachers or researchers, as may be prescribed in the IP policies of their institutions.

No advice was found on employee reward.

Department of Communications and the Arts

This Department is responsible for the *Copyright Act 1968* and the *Circuit Layout Act 1989*.

It has established *IP Principles for Commonwealth Entities 2016*. The general principles state that: Commonwealth entities are responsible for managing IP in their control or custody in an effective, efficient and ethical manner and that entities should periodically evaluate overall effectiveness, including costs and risks, and benefits of the policies they have in place for the management and use of IP.

It also states that commercialisation should be no more than an ancillary part of the activities, and should not become a core business activity.

This Department has also issued an *Australian Government IP Manual 2017*. This very extensive manual (267 pages) provides policy direction and operational directions for the Commonwealth entities on IP management and commercialisation.

Although directed to Commonwealth entities, this manual is relevant to other government agencies.

Productivity Commission

The Australian Productivity Commission produced an *Inquiry and Report on Intellectual Property Arrangements 2016*. This report made a number of high-level and wide-ranging recommendations for improving IP arrangements at the national level, and that referred to inventor rewards, the Australian patent system, copyright, commercialisation, enforcement, policy and governance, international commitments and reform.

WA Universities

The University of Western Australia

The UWA was subject to a landmark decision by the High Court of Australia in 2008 on the multi-million dollar IP ownership case: *University of Western Australia v Gray*. In this ruling it was decided that an employer has no automatic rights over inventions of an employee, without an express, or implied, term in the contract of employment. It was decided in this judgement that

a duty to undertake research does not carry with it a duty to invent, nor necessarily provide employers with the benefit of inventions. After appeals by the UWA, this decision was finally ratified in 2010.

As a result of this decision Australian universities have moved towards including IP ownership clauses in their employment contracts. However, information obtained by the RDU indicates that such IP clauses are not regularly included in the employment contracts of staff of the WA health system. This means that claims of ownership by the agencies of IP generated by their employees could potentially be contestable.

The UWA has a *University Policy on Intellectual Property 2014*, and this policy states that the university owns IP created by a university staff member pursuant to a contract of service to the university.

The UWA also requires that staff involved in a research project sign *a Sponsored Research Deed Poll* which assigns all IP rights that might arise from a research project to the university. It is noted that this requirement also applies to people who have Adjunct (non-employment) titles with the university. This is of relevance to the WA health system because a number of staff have such titles, and consequently are required to assign IP rights to the university, despite the fact that they have no employment status with this organisation.

Ownership of IP in projects involving third parties will be determined by a prior agreement with those parties to the project.

The university may, in relation to IP it owns, at its election: commercialise the IP; offer the IP to the creator, gratis or on commercial terms; offer the IP to others, gratis or on commercial terms; or release the IP to the public domain with or without conditions.

The policy includes several IP related definitions, followed by a *Policy Statement* which addresses: ownership of IP created by a university staff member; ownership of IP created by a student; duties of fidelity and disclosure; license to use teaching materials and scholarly works; moral rights; participation in centres and institutions; other external collaborations; trademarks and business names; pre-existing IP; use of university personnel, facilities, equipment, insignias, trademarks and names; management of IP; and disputes.

This policy was due for review in 2017.

The UWA also has a policy on *Reward and Recognition and Discretionary Allowances and Payments*, which is aimed at recognising and rewarding outstanding performance of employees.

The UWA has the following commercialisation revenue sharing schedule:

Cumulative Net Revenue	Originator	UWA
Up to $100,000	85%	15%
Over $100,000	50%	50%*

*68% of this share is provided to the school or centre in which the IP was developed and 32% to the university.

The UWA has also established a *Commercialisation Pathway,* and a *Pathfinder proof of concept fund*, which can provide seed funding for early-stage commercialisation opportunities.

The UWA uses a *Multi-Institutional Agreement* (MIA) when other collaborating organisations, such as WA HSPs, are involved in research funded by the NHMRC.

Regarding the ownership of IP that arises from collaborative research the MIA states that the Parties agree that all rights, title and interest in the Project IP (except for copyright in a Student thesis) will be owned solely by the Party, or jointly by the Parties, that contribute to its development or creation. In the case of jointly owned Project IP the relevant Parties will own the Project IP as tenants in common in shares proportionate to their respective intellectual contributions to the development or creation of that IP.

Regarding commercialisation, the MIA states: (the Parties) will negotiate in good faith and using all best endeavours to agree the terms of any program of commercialisation arising from the Project IP so as to make fair and equitable arrangements to meet any costs associated with the protection and registration of the Project IP and to share in any commercial return associated with the Project and the Project IP.

Curtin University

Curtin University has an *Intellectual Property Policy 2017*. The purpose of this policy is to determine ownership of IP, and it 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.

It also states that when the university decides to commercialise the IP the net revenue will be shared between the university and the originators. Where the university decides not to commercialise the IP ownership may be assigned to the originators.

Curtin also has a set of *IP Procedures 2017*, in order to facilitate the identification, protection, management and commercialisation of IP. Amongst other provisions, these procedures state that the originators will receive 50% of any commercialised IP.

This IP policy also states that in the case that the university establishes a spin-out company to commercialise IP, the originators of the IP may be recognised by the issue of shares in that company.

Of relevance to the WA health system is the fact that a number of its employees have Adjunct (non-employment) titles with Curtin University. In this respect the IP policy states that the ownership of any IP created during the course of an adjunct appointment will be determined by consultation between the university and the adjunct appointee (*RDU note*: no reference is made to consultation with the employer of the appointee).

Murdoch University

Murdoch University has *Intellectual Property Regulations 2007*.

These regulations state 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.

They also state that contributors to Murdoch IP will receive a 50% share of net revenue derived from commercialisation, and the university 50%.

Edith Cowan University

The Edith Cowan University (ECU) has an *Intellectual Property Policy 2017*. This 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.

A document titled *For Research Staff - Research Journey: Intellectual Property Deeds; Staff Intellectual Property* states that all ECU academic staff involved in funded research projects are requested to complete an IP Deed confirming assignment of IP ownership to the university.

With respect to benefit sharing arising from successful commercialisation, it is stated that 50% of net revenue will be distributed to the creators of the IP, and that the other 50% will be shared amongst the creator's School or Centre, and the university's Strategic Initiatives Fund for investment in research or commercialisation.

University of Notre Dame Australia

The University of Notre Dame Australia has an *Intellectual Property Policy 2006*. With respect to IP ownership this policy states that this vests in the university when the IP is created in the course of employment or participation in a university project.

The policy also states that in determining whether the Intellectual Property 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 Intellectual Property has been created by the use of University facilities, equipment or other resources supplied by the University.

With respect to the sharing of benefits arising from successful commercialisation, the IP policy states that the creators will receive 85% of the first $50,000 of net revenue; 65% of the next $100,000 and 50% of all cumulative net revenue thereafter.

The remainder of any net revenue will be apportioned to the university, and distributed in the following manner: a significant portion will be provided to the employee's School or Division, and any remaining net revenue apportioned to the university will be set aside for other activities, including research and commercialisation.

WA Medical Research Institutes

Two of the largest WA medical research institutes have been taken into consideration in this present review: the Harry Perkins Institute for Medical Research (HPIMR) and the TKI.

The HPIMR does not have its own IP policy, but being affiliated with the UWA vests IP ownership in that university, and consequently uses its IP policy.

The TKI has an *IP policy 2017*. This policy has a number of relatively standard Principles relating to: Confidentiality; Agreements; Non-disclosure; IP Protection, amongst a number of others.

Of particular relevance is the principle of Ownership of IP. This principle states that the TKI 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. This is a very wide-ranging claim to ownership, and should be taken into consideration when external parties, such as the HSPs, undertake work in partnership or collaboration with the institute.

With respect to employee rewards, the TKI IP policy has a Distribution of Royalties principle, which states: The Net Royalty (derived from commercialisation) is to be divided equally between the Institute and the Originator or if there is more than one Originator, then the total royalty payments to the Originators shall be fifty per cent (50%) of the Net Royalty per annum and paid

to each Originator according to the proportion of each Originator's contribution to the creation and development of the IP.

Miscellaneous

Hospital and Health Services IP Ltd

Hospital and Health Services IP Ltd (HHSIP) is a group that states that its aim is to develop and promote hospital IP, including patient care improvements, operational efficiencies, revenue and other beneficial outcomes. It states that it operates through the IP Offices and Offices of Commercialisation of hospitals in NSW, QLD, VIC and ACT. The HHSIP is referred to earlier in this document, in reference to the North Sydney Local Health District.

This company also states that since 1992 it has managed and commercialised knowledge contracts and IP assets involving more than 6,000 hospital practice and patient care improvement projects, which have returned more than $75 million in revenue from IP productization *(sic)*, commercialisation and industry partnerships.

It is noted that various inconsistencies have been found in the information provided by this company.

Indigenous IP

Indigenous IP is a matter that should be taken into appropriate consideration in the WA health system.

In this respect IP Australia, which is the federal government's body that oversees most IP matters in Australia, issued a 2018 paper titled *Indigenous Knowledge: issues for protection and management*. This paper explores the relationship between tradition-based knowledge of Aboriginal and Torres Strait Islander peoples and issues of IP, cultural heritage and economic empowerment.

This paper refers to a number of key issues, one of which is of particular relevance to the health sector: the use of indigenous knowledge relating to genetic resources.

This section of the paper states: Indigenous skills, techniques and other knowledge relating to bush foods, medicinal plants and other genetic resources remain largely unprotected. More and more, this knowledge is used and commercialised for scientific research and development. Within the access and benefit sharing framework of Australia's biodiversity laws, patent laws, research funding initiatives and protocols, positive scientific collaborations have emerged for Indigenous people. More and more, Indigenous people are asserting their rights to Indigenous Knowledge and pushing for recognition of their meaningful contributions. However, much can still be done to safeguard Indigenous Knowledge in research and from unauthorised use and commercialisation.

It is noted that in the course of conducting this present overview the RDU found little reference to indigenous IP in the policies of the different WA organisations considered. The Edith Cowan University does, however, have the following statement in its *Intellectual Property Policy 2017*: Where the creation of the University Intellectual Property involves the traditional interests or property of Indigenous peoples and/or the use of traditional knowledge, the University will take all reasonable steps to consult with the relevant groups within the University, including relevant Indigenous Australian staff, to ensure that any decisions taken on the protection, development and Commercial Exploitation of that Intellectual Property conforms with the relevant Indigenous protocols and ethical guidelines.

OPTIONS FOR A FUTURE STATE IP STRATEGY

Introduction

The outcomes of the *Current State Review* and *Interjurisdictional Overview* have been considered by the RDU in order to assist in informing the establishment of a Future State IP strategy for the WA health system, which reflects the roles and responsibilities of the Department and the HSPs under the HSA.

The RDU formulated the following possible options for an IP strategy, which were provided to the Health Executive Committee (consisting of the Director General and the Assistant Directors General of the Department, and the Chief Executives of the HSPs) for consideration.

Possible Policy Options

1) Only adhering to the *Western Australian Government Intellectual Property Policy 2015.*

2) A Mandatory Requirement under the Research Policy Framework.

3) An overarching WA health system IP policy.

4) Individual HSP IP policies under an overarching IP framework.

5) Stand-alone HSP IP policies.

These options are further explored in the following.

1) Only adhering to the WA Government IP Policy

The 2015 WA Government IP policy is considered in detail in the *Current State Review* (page 4).

This policy applies to all Government agencies, and it encourages the development of agency-level IP policies, in alignment with the Government policy, to manage IP processes and stakeholder interaction.

As described in the *Current State Review* (page 10), the HSPs were invited to respond to a series of guiding questions on IP policy and management in their services. In addition, the RDU conducted personal consultations with relevant representatives of the HSPs.

One of the questions, described in further detail below, included the possibility of the WA health system simply adhering to the WA Government IP policy.

None of the HSPs gave particular consideration to this option, and in personal consultation by the RDU it was found that this policy was generally considered to provide high level direction, but did not give effective operational guidance.

The *Interjurisdictional Overview* showed that the VIC and SA Departments of Health do not have their own IP policies, but adhere to their respective State Government IP policies.

Irrespective of the IP strategy adopted by the WA health system, the WA Government IP policy will still overarch this.

2) A Mandatory Requirement under the Research Policy Framework

The HSA specifies the role of the CEO of the Department (Director General) as the System Manager for the WA health system.

Under the HSA the Department CEO may issue Policy Frameworks that are binding on the HSPs. Also, the Department CEO may issue directions that require compliance with a matter set out in a policy framework.

The Information Circular (0228/15) titled *Intellectual Property Management in WA Health* is currently included as Mandatory Requirement in the Research Policy Framework.

As presented in the *Current State Review*, the HSPs provided responses to the following question: *What importance do you see for the Department as the System Manager being involved in, and overseeing, IP policy and management across the WA health system? For example,* do *you feel that certain critical aspects of IP policy and management should be directed through a Mandatory Policy?*

The responses are presented on page 15 of the *Current State Review*.

A mandatory policy was supported by one of the HSPs, and conditionally by two others, but was not given particular consideration by the remainder.

3) An overarching WA health system (non-binding) IP policy

One of the questions asked of the HSPs in the *Current State Review* was: *How important to you is uniformity and consistency in IP policy, management and operating procedures across the WA health system? For example, would you support either an over-arching WA health system IP policy, standardised operational guidelines/procedures etc? If not, what approach would you take in dealing with IP matters that cross different HSPs?*

The responses of the HSPs to this question are presented on page 14 of the *Current State Review*.

These responses show that five of the HSPs were strongly supportive of an overarching (whole-of- system) IP policy, while one expressed qualified support, and one was not supportive.

This policy would be non-binding, and during the course of the *Current State Review* the question was raised as to whether such a policy is permissible under the HSA, or if this can only be through a binding Policy Framework, or a Mandatory Requirement within this.

The RDU consulted on this point with the Department's LLS, the Board Support and Policy Frameworks Branch and the Governance and System Support Directorate, as well as the SSO.

The advice received indicates that a non-binding overarching policy is permissible under the HSA.

4) Individual HSP policies under an overarching IP framework

In this context a Framework would provide direction and guidance over a set of individual policies.

As presented in the *Current State Review*, the HSPs provided responses to the following question*: What importance do you give to your health service having its own individual IP policy: for example in comparison with simply abiding by the existing WA Government IP Policy, or by an overarching WA health system policy.*

The responses of the HSPs to this question are presented on page 15 of the *Current State Review*.

One of the HSPs stated that it was essential to have an individual IP policy, albeit this being under an overarching IP framework, and another was conditionally supportive of this same position. The remainder were not supportive of individual IP policies.

During the course of the *Current State Review* the question was raised as to whether the HSPs can make decisions on IP matters based on an overarching policy or framework, or if they require individual HSP policies for this.

Advice on this question was also asked of the legal and policy advisors referred to in Option 3 above, and the response was that the HSPs do not require individual policies upon which to base their IP decisions.

This advice also indicates that a HSP can, if so desired, have separate provisions under an overarching framework for IP matters that are relevant to its particular service, or can have individual policies under such a framework.

The *Current State Review* shows, however, that at the present time and into the short- to medium-term future it would be difficult for the HSPs to develop, manage, update and ensure compliance with, individual IP policies. This is due to limitations in IP capability, capacity and expertise, as well as financial constraints, in the HSPs.

In addition, some of the HSPs noted that individual IP policies could potentially be a barrier to cross-HSP collaboration. This was a particularly important concern for clinicians and researchers who conduct their activities in more than one HSP.

As described in the *Interjurisdictional Overview*, the NSW Department of Health has recently undertaken a review of its IP policy, and is in the process of completing an update of this. NSW Health has provided the RDU with a final draft of the updated policy. It is stated that “This policy applies to all public health organisations within the meaning of the Health Services Act 1997 (Area Health Services)”. It also states that “All public health organisations which are involved in health research must have an intellectual property policy which is consistent with this policy”. The *Interjurisdictional Overview* showed that a number of the NSW equivalents to the HSPs have IP statements, but do not have fully developed IP policies.

5) Stand-alone HSP IP policies

Given the considerations presented in the points above, this option would not be that which is preferred by most of the HSPs, and consequently is not developed further here.

Approved Option

In its meeting of 11 September 2019 the Health Executive Committee approved Option 2, with the minuted words of: “HEC members agreed to a Mandatory Policy with clear flexibility”.

It is noted that under this policy the individual HSPs would still be responsible for their IP, as per the functions and powers conferred by the HSA (Section 36.3.f): a HSP may develop and turn to account any technology, software or other intellectual property that relates to its functions and, for that purpose, apply for, hold, exploit and dispose of any patent, patent rights, copyright or similar rights.

IP Support to HSPs

The *Current State Review* provided two guiding questions to the HSPs regarding their current and potential future capacity to deal with IP matters:

What is the current capacity/capability of your health service to effectively deal with IP matters? and *What importance do you give to enhancing the capacity/capability of your health service to effectively deal with IP, in the context of potential additional resource and cost implications?*

The responses of the HSPs to these questions are presented on pages 10 and 12 of the *Current State Review*.

These responses show that that the HSPs currently have very limited IP capability, capacity and expertise, and do not have the human or financial resources to enhance this into the near or medium-term future.

Most of the HSPs refer to the support that they have received from the Department in dealing with IP matters, which has been provided by LLS and/or the RDU. A number of the HSPs state that they will to continue to avail themselves of this assistance as they feel that, apart from their limited capacity, they also do not have sufficient volume of IP matters to justify having in-house IP expertise.

The IP support that has been provided across the WA health system by the RDU, in conjunction with LLS, is summarised on page 6 of the *Current State Review*.

It is noted that the RDU only has 0.5 FTE assigned to IP activity, and LLS does not have legal expertise specifically designated to this.

It is suggested that the Department consider increasing its IP management capacity by an additional FTE, and offer the availability to the WA health system of an enhanced IP resource which provides guidance and assistance regarding different operational procedures and pathways involved in IP management and commercialisation.

As noted previously in this document, NSW Health has made available to the RDU a final draft copy of their updated IP policy. This policy states that a Central Office will be established for the purpose of assessing opportunities, making recommendations and providing general advice on matters relevant to the management of IP.

In this respect the RDU has recently engaged an external consultant to assist with the development of Best Practice Guidelines for IP management and commercialisation, and where relevant, Standard Operating Procedures and Commercialisation Pathways. This activity will be undertaken in conjunction with the HSPs.

This suggestion was included in the document provided to the Health Executive Committee, and was not contested.

FREQUENTLY USED ACRONYMS

CAHS	Child and Adolescent Health Service
CE's	Chief Executives
Department	Department of Health Western Australia
DJTSI	Department of Jobs, Tourism, Science and Innovation
EMHS	East Metropolitan Health Service
HSA	*Health Services Act 2016*
HSP	Health Service Provider
HSS	Health Support Services
IP	Intellectual Property
LLS	Legal and Legislative Services
MRCF	Medical Research Commercialisation Fund
NHMRC	National Health and Medical Research Council
NMHS	North Metropolitan Health Service
NSW	New South Wales
PathWest	PathWest Laboratory Medicine Western Australia
QLD	Queensland
RDU	Research Development Unit
SA	South Australia
SMHS	South Metropolitan Health Service
SSO	State Solicitor's Office
UWA	University of Western Australia
VIC	Victoria
WA	Western Australia
WACHS	Western Australia Country Health Service

APPENDICES

Appendix 1: Guiding Questions for Health Service Providers

1) What is the current capacity/capability of your health service to effectively deal with IP matters?

For example:

Does your health service have persons/organisational entities with relevant IP expertise?

Do they contribute to the management of IP matters in your health service?

Does your health service either have, is developing, or has identified a need for, guidelines, pathways or standard operating procedures for the identification, notification, protection and exploitation of IP?

Does your health service have, is establishing or recognises the need for, an executive IP management group, or equivalent, with decision making responsibilities?

Does your health service have access to specialised IP advice when required, such as legal, commercial etc.?

2) What importance do you give to enhancing the capacity/capability of your health service to effectively deal with IP, in the context of potential additional resource and cost implications?

For example:

Are you in a position to fund any additional staffing resources (that could require specialised expertise)?

Would you prefer that IP matters be managed in conjunction with existing resources in the Department of Health?

Does, or could, your health service have access to funding to cover: the costs of IP protection (eg patenting); funding of business cases for commercialisation; seed funding to develop innovative ideas/inventions to the proof-of-concept stage?

3) How important to you is uniformity and consistency in IP policy, management and operating procedures across the WA health system?

For example:

Would you support either: an over-arching WA health system IP policy; standardised operational guidelines/procedures etc.?

If not, what approach would you take in dealing with IP matters that cross different HSPs?

4) What importance do you give to your health service having its own individual IP policy?

For example:

In comparison with simply abiding by the existing WA Government IP Policy, or by an overarching WA health system policy.

5) What importance do you see for the Department of Health as the System Manager being involved in, and overseeing, IP policy and management across the WA health system?

For example:

Do you feel that certain critical aspects of IP policy and management should be directed through a Mandatory Policy?

6) What importance do you give to the potential commercialisation of IP, and possible revenue generation through this?

For example:

Do you feel that your health service has taken advantage of IP that has arisen?

Do you feel that there have been missed opportunities?

Does your health service have access to specialised commercialisation advice and expertise?

Would you consider the option of having your health service either establish or participate in spin-off companies?

Do you have experience with, or views on, the Medical Research Commercialisation Fund, of which the Department of Health is a Public Research Partner?

7) What importance do you give to issues around IP ownership and rewards for innovative/inventive staff of your health service?

For example:

Do you think that any IP generated in your health service should generally either vest in the service, or the inventor/innovator?

Is your health service aware of current legal opinion, or have access to legal advice, on IP ownership issues?

Do you think that it is feasible that employment contracts in your health service have IP clauses that specify this?

Do you think that employees should be rewarded for their inventive/innovative activities, even if these occur in the course of their employment duties?

8) How important are IP matters for your health service in the context of external organisations, such as universities or medical research institutes, through which IP can be jointly developed. This could include collaborative research and shared employment relationships.

For example:

Are you aware of any advantages or disadvantages in collaborating with external organisations in IP management, in particular with respect to commercialisation?

Does your health service have the capacity, or have access to specialised expertise, to negotiate IP agreements and revenue sharing arrangements with external organisations?

9) Are there any other critical issues that you think should be addressed in the IP review?

Appendix 2: Guiding Questions for Universities and Medical Research Institutes

Background

The WA Department of Health is undertaking a review of IP management in the WA public health system, in the context of the *Health Services Act 2016*.

Whilst under this Act the Department of Health (Department) has a System Manager role, the different Health Service Providers (HSPs) of the WA health system are now autonomous statutory bodies, which have defined powers and functions related to IP.

The most significant HSPs in this respect are: Child and Adolescent Health Service (which includes Perth Children's Hospital); East Metropolitan Health Service (which includes Royal Perth Hospital); North Metropolitan Health Service (which includes Sir Charles Gairdner Hospital and King Edward Memorial Hospital); South Metropolitan Health Service (which includes Fiona Stanley Hospital); PathWest; and the WA Country Health Service.

Because many of the WA universities and medical research institutes have relationships with the Department and the HSPs that involve IP the Department is undertaking a consultation of such stakeholders.

This is being led by Dr Neil Lynch of the Department's Research Development Unit, under the direction of the Director of Research, Dr Darren Gibson.

Guiding Questions

The following questions are proposed as a (non-prescriptive) base for obtaining the views of the university and medical research institute sectors on the interaction with the WA health system with respect to IP. This could include general IP matters, such as: IP clauses in research agreements; IP ownership; IP assignment agreements, as well as commercialisation initiatives; revenue sharing agreements, amongst others.

- In general terms, what has been the extent of interaction between your organisation and the WA health system over, for example, the past five years?
- If you have had interaction, has this been with the Department and/or the different HSPs (since 2016)?
- Has this interaction been productive, or not, and can you provide some examples of such interactions (respecting confidentiality etc.)?
- Do you have suggestions as to how these interactions might be improved?
- Does your organisation have a clear appreciation of how to access relevant parties in the WA health system, when required?
- Do you feel that members of the WA health system are aware of: persons/areas in your organisation who should be contacted regarding IP matters of mutual interest; and pathways, both within the WA health system and your organisation, for these to progress?
- Have any interactions that have occurred been primarily initiated by the WA health system (which includes individuals, rather than the system itself), or your organisation?
- If you have had interactions with the WA health system, how do these generally arise? For example, through joint or shared employment arrangements, collaborative research projects, student placements, etc.?
- How would you deal with IP ownership in cases of joint or shared employment relationships, and do you have any examples of these?

- Do you have preferred means of progressing potential commercialisation initiatives jointly with the WA health system, such as assignment or licensing of IP, and do you have any examples of these?
- Do you have access to development or commercialisation funding that WA Health itself does not, but could potentially do so on a joint basis? Do you have any examples of these?
- Are you aware that WA Health is a member of the Medical Research Commercialisation Fund, and do you have any views on how this might facilitate (or hinder) joint commercialisation initiatives?
- Do you have any other views or suggestions that pertain to IP interactions with the WA health system?

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