

Intellectual Property Management in the WA Health System

Intellectual Property Procedures

Research and Innovation Office
Clinical Excellence Division

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Purpose

These Intellectual Property (IP) procedures outline mechanisms and pathways whereby IP can be managed across the different entities of the WA health system.

Application

These procedures are recommended for application across the following entities of the WA health system:

- The Department of Health (the Department), as the System Manager.
- Health Service Providers:
 - Child and Adolescent Health Service
 - East Metropolitan Health Service
 - Health Support Services
 - North Metropolitan Health Service
 - o PathWest Laboratory Medicine Western Australia
 - o Quadriplegic Centre
 - South Metropolitan Health Service
 - Western Australian Country Health Service.

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

These procedures constitute supporting information to the Mandatory Requirement of the Research Policy Framework of the System Manager, titled MP 0156/21 Intellectual Property Policy.

They also complement supporting information contained in the document titled *Intellectual Property Management in the WA Health System: Intellectual Property Guidelines.*

What is Intellectual Property?

Intellectual Property (IP) refers to creations of the human intellect, the rights to which are protectable by law, and that can have financial value.

IP is recognised as an intangible asset which can potentially be exploited for economic benefit. As such it aligns with the *WA Health Financial Management Manua*l definition of an Asset as being a resource controlled by a WA health entity, from which future economic benefits are expected to flow to the health entity. Future economic benefits can be in the form of cash, cash equivalents or the potential to provide goods and services to achieve the health entities' objectives

Significant IP that is developed during innovation, discovery and research within the WA health system can be a valuable asset for both the health system and the broader community. As such it needs to be protected in order to maximise its strategic or commercial potential. The level of protection will depend on the type of IP, its intrinsic value and its commercial potential.

Types of IP Protection

IP not requiring registration

Copyright

Copyright protects the original expression of ideas (not the ideas themselves) and includes documents and reports, photographs, drawings, art, literature, music, film, broadcasts, multimedia presentations and computer software and programs.

In Australia, under the *Copyright Act 1968*, copyright protection arises automatically upon the creation of a work. It is not required, but is highly recommended, that a copyright symbol or disclaimer be attached to affirm copyright to the material.

A variation on copyright is Creative Commons licensing. This provides a standardised means for individuals and organisations to legally share their work, under conditions that are specified in the different types of licence.

The WA health system generally uses copyright, rather than Creative Commons. However, in appropriate circumstances this might be considered under the provisions of the WA Whole of Government Open Data Policy and the Australian Governments Open Access and Licensing Framework (AusGOAL).

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

Trade secrets

Trade secrets include information such as formulas, processes and methods that are only protected to the extent that they are strictly maintained within the organisation, or are only disclosed to any external party that has signed a confidentiality or non-disclosure agreement.

Trade secrets have relatively limited applicability to the WA health system because of the requirements for accountability and transparency in public sector organisations, and in particular with respect to openness of information regarding healthcare delivery.

Circuit layouts

Circuit layout protection applies to the original layout and designs for integrated circuits and computer chips. Although protection is based on legal principles similar to copyright, circuit layouts are afforded their own unique form of protection.

IP requiring registration

Patents

The *Patents Act 1990* provides an exclusive right to commercially exploit IP in a device, substance, method or process (an invention) that is new, useful, inventive or innovative.

There are three stages of patent application:

- 1. *Provisional patent*: This is filed through a patent attorney within a single geographical jurisdiction, such as Australia.
- Patent Co-operation Treaty (PCT): This is filed 12 months after the provisional
 application. This allows time to further develop the IP and assists in seeking international
 patent protection.
- 3. *National phase:* After 30 months the patent application can be filed in different countries, which incurs additional costs that are specific for each country.

Trade Marks

A trade mark is a sign used to distinguish goods or services of one trader from those of another. A trade mark can be a word, letter, name, phrase, colour, symbol, picture, scent, sound or moving image, that is registerable under the *Trade Marks Act 1995*.

Design

Design gives a product a unique appearance that can be registered under the *Designs Act* 2003. This includes shape, colour, configuration, pattern and ornamentation.

Whenever the formal protection or registration of IP developed in the WA health system is considered, this should be in consultation with the Department's Legal and Legislative Services (LLS) or the State Solicitor's Office (SSO, which, where applicable, includes General Counsels assigned to health service providers).

Legislative and Policy Directions

This section considers the overarching legislative and policy directions that relate to IP management in the WA health system.

National Legislation and Policy

Commonwealth legislation

Copyright is under the jurisdiction of the Australian Government's Department of Communications and the Arts. Patents, trademarks and designs 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.

These 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.

Under these principles public sector institutions are defined as those that are majority funded by the Australian government, and which include public hospitals. These principles have, however,

been generally adopted by other governmental jurisdictions, although specific provisions of IP ownership have also been applied.

If the health service providers are not registered as administering institutions for such Commonwealth research grants, which include those from the NHMRC and the ARC, any such grants that are awarded to staff of a health service provider must be administered by an accredited administering 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 health service provider, but in the external institution. If considered necessary, it is possible for individual health service providers to apply for consideration by the funding agencies to be registered as administering institutions, providing a number of criteria are met.

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.

WA Legislation and Policy

Industry and Technology Development Act 1998

Section 6 (g) of this Act stipulates that IP opportunities in the Western Australian Government should be identified, assessed, developed and managed in a timely and efficient manner through to commercialisation where appropriate.

Where commercialisation is not appropriate, IP should be disposed of in the least restrictive legal manner appropriate for Government assets and information in the operating context.

Health Services Act 2016

The *Health Services Act 2016* states (Section 13.2.d) 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.

With respect to health service providers the *Health Services Act 2016* refers (Section 36.3.f) to functions and powers, stating that a health service provider 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 *Health Services Act 2016* (Section 35.1) states that health service providers may earn revenue by engaging in commercial activities that are not inconsistent with, and do not have an adverse effect on, the performance of its other functions.

The *Health Services Act 2016* also states (Section 35.4) that when engaging, or proposing to engage, in a commercial activity, a health service provider 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.

In this respect it is noted that the *Health Services Act 2016* (Section 36.3.c) states that a health service provider may participate in any business arrangement and acquire, hold and dispose of, shares, units, or other interests in, or relating to, a business arrangement. 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 *Health Services Act 2016* (Section 38) refers to transactions associated with a business arrangement which require agreement by the Minister and/or the Treasurer.

The Commercial Activity Policy (MP 0018/16) of the Department, as System Manager, specifies that health service providers must seek legal advice from the Department's LLS or the SSO prior to engaging in a commercial activity pursuant to Section 35 of the *Health Services Act* 2016.

Other 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:

Public Sector Management Act 1994: This Act 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.

Section 102 of this Act could be relevant to employees of the WA health system in cases where they might be directly involved in IP commercialisation initiatives, and whereby they could have employment or remuneration relationships outside of their Government position.

Financial Management Act 2006: This Act can potentially influence the way any revenue derived from the commercialisation of IP generated in the WA health system can be received and used.

State Trading Concerns Act 1916: This Act 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 *Health Services Act 2016* (Section 35.6) states that a health service provider is taken to be expressly authorised by Parliament for the purposes of the *State Trading Concerns Act 1916* Section 4(2).

In the case of the Department, commercialisation of IP needs to be authorised under Section 4A of the Act. However, under the *State Trading Concerns (Authorisation) Regulations 1998* the Department is prescribed for the provision of goods, information or IP relating to health matters.

The LLS or SSO should be consulted regarding the applicability of any of these Acts to particular cases or situations involving IP that arise in the WA health system.

WA Government IP Policy 2015

The Western Australian Government Intellectual Property Policy 2015 (WA Government IP policy) is the responsibility of the Department of Jobs, Tourism, Science and Innovation (DJTSI), under the Industry and Technology Development Act 1998.

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 Key Principles of this policy are:

When developing, managing, and commercialising IP generated using Government financial, physical or human resources, Western Australian Government Agencies will:

- Lawfully use IP to improve service delivery and operational performance.
- Preserve and enhance IP asset value while achieving core strategic business objectives.
- Cooperate with the Western Australian business community to develop and commercialise IP opportunities, including open data access.
- Ensure IP related risks are known, managed and acceptable for Government.
- Ensure IP policies, processes and decisions are accountable, transparent and auditable.
- Adopt best practice for IP development, management, commercialisation and disposal.
- Recognise, and as appropriate, reward employee achievements including outstanding extraordinary outcomes.
- Clearly communicate to staff and stakeholders how the Western Australian IP Policy is applied within the agency.
- Where considered appropriate adopt Creative Commons Licensing as described in the Australian Governments Open Access and Licensing Framework (AusGOAL) and seek to minimise net costs to the Western Australian Government from copyright use.

As stated in the italicised principle above, the entities of the WA health system are required to apply this policy.

Sustainable Health Review

The 2019 Final Report to the WA Government of the Sustainable Health Review recommends (Recommendation 28) that a central unit be established in the WA health system to provide advice and guidance on innovation such as IP, legal, marketing, commercialisation, and facilitate sharing and connecting of innovative work across the health system.

Research Policy Framework

The Research Policy Framework of the Department, as System Manager, has a Mandatory Requirement titled MP 0156/21 Intellectual Property Policy.

Asset Management

Section 701 of the *WA Health Financial Management Manual* refers to intangible assets, which would include IP with commercial potential. This section requires that all WA Health officers are to ensure that the policy and its procedures relevant to this section are complied with, and will be held accountable for any non-compliance.

IP Management Procedures

The purpose of this section is to address processes for the management of IP in the WA health system.

Intellectual Property Contact Points

It is important that the staff of the WA health system are aware of pathways for the reporting and possible further consideration of any IP matters that they might be involved in.

The starting point for this will generally be through IP Contact Points established in the different entities of the WA health system (health service providers and the Department).

These IP contact points will be nominated by the Chief Executive of each entity.

The contact points will report to their Chief Executive, or a nominated representative, through the established channels of each entity.

The contact details of the IP contact points will be made widely known across the WA health system.

Each entity will require that any significant IP arising in the entity be brought to the attention of the IP contact point.

The IP contact points can be either named persons or positions. It is preferable, but not obligatory, that the contact point have a least basic knowledge of IP, or be prepared to receive an appropriate level of training in this.

The IP contact point should have contingency back-up in cases of unavailability of the primary contact.

There will be two basic roles of the IP contact points:

- Receiving, and appropriately forwarding, information regarding significant IP either arising in their entity, or from external sources. This could include:
 - Information provided by staff of their entity regarding IP matters, which will be forwarded to the WA Health System Intellectual Property Advisory Committee (IPAC, see below) by their Chief Executive, or nominated representative.

- Forwarding information from the IPAC to their Chief Executive (or representative) and/or the staff involved in the IP matter under consideration.
- Receiving and forwarding information related to IP matters that involve external parties, such as universities, medical research institutes or funding bodies.
- Referring any potential or actual IP breaches to accepted IP policy and practice within the WA health system, to relevant officers of the health service providers or the Department, and in cases of particular concern, to the IPAC.
- Represent their entity on the IPAC.

WA Health System IP Advisory Committee

The IPAC will assist in the management and further development of significant IP matters arising in the health service providers and the Department. The *Terms of Reference* of the IPAC are presented in Appendix 1.

The IPAC will align with the WA health system central unit which will be established under Recommendation 28 of the 2019 Final Report of the Sustainable Health Review, and which is currently the Department's Research and Innovation Office (RIO: formerly the Research Development Unit).

Although the IPAC represents a system-wide approach to IP matters, each health service provider is an independent statutory body, and will, within legislatively, legally and administratively prescribed activities, be responsible for the management, exploitation, commercialisation and disposition of IP developed within the entity, as well as the distribution of any benefits, whether financial, material, or otherwise, arising from such activities. Where applicable, and according to internal health service provider processes, these activities will generally be overseen by the Health Service Boards.

Early-stage funding support

The Department will, at its discretion and according to need, make available through the *Innovation Seed Fund* of the *Future Health Research and Innovation Fund* (currently being established) an annual budget for limited funding of early-stage strategies for the commercialisation of IP initiatives developed in the WA health system.

This could include (but not be limited to):

- The initial costs of IP protection.
- The development of preliminary commercialisation business cases.
- Consideration of options for commercialisation pathways.
- Identification of possible commercialisation partners, funders and investors.

Consideration of such funding will be made by the Department upon recommendation of the IPAC, and where relevant, the ad hoc IP expert group.

It is anticipated that the amount that will be made available to any one IP initiative will not exceed \$10,000, unless otherwise approved by the Assistant Director General, Clinical Excellence.

This budget will be managed by the RIO, and will not exceed \$100,000 per annum in total, unless otherwise approved by the Department.

Any costs above these will need to be met by external sources.

Ad Hoc IP Expert Group

The Department will identify a group of external IP experts, to whom specific questions regarding IP management and commercialisation can be directed by the IPAC, and who will generally be paid for their input. Such payments will be at the discretion of the Department, and will conform with generally accepted practice, and appropriate procurement processes.

The Department will issue an expression of interest to the sector with respect to participation in this group. The IPAC will nominate the members of this group to whom each particular IP matter will be directed. It is anticipated that the advice of no more than three of these experts will be requested for any one IP matter.

This group will only provide advice on the IP matters presented, and at that time will not be engaged for the actual delivery of any services that they might recommend. The latter will need to be addressed through relevant funding and procurement processes, that will take into account any prior knowledge of the matter that the members of the expert group might have obtained.

The ad hoc IP expert group could be constituted by:

- Persons with relevant expertise in IP protection, for example as provided by Patent Attorneys.
- Persons with relevant expertise in commercialisation processes, such as investment advisors in early-stage seed funding, proof-of-concept studies, access to venture capital funding, amongst other financial instruments, which, as required, could involve the development of preliminary commercialisation business cases.

Requests for advice from the ad hoc IP expert group will be made by the RIO, upon request of the IPAC.

Research and Innovation Office

The RIO, Clinical Excellence Division, through the central unit recommended by the Sustainable Health Review, will be the liaison body for IP matters across the WA health system.

The principal roles of the RIO will be to:

- Support the activities of the IP contact points across the WA health system.
- Support the IPAC.
- Liaise with the ad hoc IP expert group to obtain advice, as requested by the IPAC.
- Provide advice on IP management across the WA health system, both at the staff and Executive levels.
- Establish and maintain the WA health system IP register
- Update and maintain an IP website which will reflect the current state of IP policy and management in the WA health system.
- Establish and update IP policy documents, and maintain reference to IP in the System Manager's Research Policy Framework.
- Liaise with external organisations that interact with the WA health system in the area of IP. This includes the universities, medical research institutes, funding bodies, and the DJTSI.
- Monitor IP policy and practice in other jurisdictions, at the local, national and international levels.

- Assist with the application or development of IP clauses, for example in research collaboration and grant funding agreements, contracts for services and employment contracts. As required, this will be undertaken in conjunction with the Office of the Chief Procurement Officer, LLS and the SSO.
- Request from the Department annual funding for the limited early-stage support of IP commercialisation, which will be allocated in accordance with the recommendations of the IPAC, and where necessary, the ad hoc IP expert group.
- Manage the budget, and the relationships with approved recipients, of the above early stage funding support.
- Manage the relationship with the *Medical Research Commercialisation Fund*, of which the Department is currently a Public Research Partner.

WA Health System IP Register

The IP Register is a detailed record of significant IP developed across the WA health system.

Significant IP is considered to be that which:

- Potentially has strategic and/or commercial value.
- Risks being unlawfully copied or otherwise misappropriated or misused by external parties.

This includes IP that is automatically protected by copyright and IP that requires protection through formal registration, such as patents and trademarks.

It is noted that "significant" will necessarily be a subjective appreciation at the early stage of IP development because it is usually difficult to judge the potential value of recently generated IP, before it has gone through proof of concept, business/commercial case analysis, high-level market evaluation/testing and other value assessments.

IP that should be placed on the IP register can be already existing or newly generated in the WA health system. It only includes IP that is wholly, or in part, owned by any of the entities of the WA health system (health service providers and Department). It does not include IP that has been in-licensed from external parties for use in the WA health system, or provided as Background IP for contracted services or collaborative activities.

The IP Register will be maintained by the RIO, on behalf of the IPAC. It will be constituted by information received through the IP contact points for the different entities of the WA health system, or other sources as appropriate.

IP Notification

Staff of the WA health system will advise their respective employing entity of any significant IP that they have developed, or which they have been involved in developing. This will generally be through the provision of a formal written notification.

This notification which in some sectors, enables employees of the WA health system to:

- Comply with the reporting requirements of the WA health system.
- Provide relevant information for the WA health system IPAC to assess the potential benefits (e.g. operational and commercial) and risks (e.g. legal, administrative and financial) that this IP might signify.

• Potentially support a request for the limited contribution by the Department to costs of early-stage commercialisation.

The information provided will be collated into the WA health system IP Register.

Although the notification has a focus on IP that has commercial potential, it also aims to identify IP that is not necessarily commercialisable, but that has significant strategic and/or operational value.

The notification should be directed to the designated IP contact point in the entity of employment, who will then provide this to the Chief Executive of the entity, and the WA health system IPAC. The notification should be marked Commercial-in-Confidence.

Important note: If the IP is potentially patentable, information should not be provided without considering confidentiality and non-disclosure requirements.

The *IP Notification Details* table (Appendix 2) provides a general description of the information that should be provided in IP notification. The points listed will not necessarily be applicable to all IP initiatives, but should be addressed as completely as possible. If the points request a "yes" or "no" answer, relevant details should also be provided.

Further Documentation

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

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

Frequently Used Acronyms

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

Appendix 1:

WA Health System Intellectual Property Advisory Committee: Terms of Reference

Membership

The IPAC will be composed of:

- A Chair, which will be the Director of Research of the Department.
- The IP contact point of each health service provider and the Department.
- A single representative of, and nominated by, the Research Directors (or equivalent) of the health service providers.
- A single representative of, and nominated by, the Innovation Leads (or equivalent) of the health service providers.
- A representative of the RIO (if different from point 2).
- A member of the WA health system with appropriate experience in, or understanding of, IP commercialisation. This person will be nominated by the Chair, in consultation with the other members of the IPAC.
- Other temporary member(s) as required.

Reporting

 The Chair of the IPAC will report to the Assistant Director General, Clinical Excellence, who will, as required, liaise with the Chief Executives of the health service providers. The Assistant Director General will oversee the function and activities of the IPAC, as well as any budget allocation by the Department to the activities of this committee (see below).

Functions and responsibilities

The functions and responsibilities of the IPAC will include:

- Facilitating the application of, and communication regarding, the requirements of the 2015 WA Government IP policy in the WA health system.
- Consideration of significant IP matters submitted by the different entities of the WA health system (health service providers and Department).
- Oversight of the WA health system IP Register.
- As required, the submission through the RIO of relevant IP matters for further consideration by an Ad Hoc IP Expert Group.
- Make recommendations to the relevant Executives of the entities of the WA health system regarding potential IP commercialisation initiatives, which could include anticipated costs, benefits and risks.
- Make recommendations to the Department, through the Assistant Director General, Clinical Excellence, on the allocation of any funding that the Department may make available for the early-stage support of specific IP initiatives.
- These funding recommendations will be made after internal discussion within the IPAC, and after consideration of advice from the ad hoc IP expert group, if required. If consensus is not reached within the IPAC on the funding of a particular IP initiative, the recommendation will be made on the basis of a majority vote. The Chair will have the right to a casting vote if required. The final decision on the allocation of such funding will be made by the Assistant Director General, Clinical Excellence.

General considerations

- The proceedings of the IPAC will be treated as commercial-in-confidence.
- Any actual, potential or perceived conflicts of interest that IPAC members might have with regard to IP matters presented will be appropriately declared.
- The IPAC will meet at a frequency determined by need, but will not be less than quarterly.
- The RIO will provide Secretariat support for the IPAC, and will be the point of liaison between the different entities of the WA health system and the IPAC.

Appendix 2:

IP Notification Details

Person reporting (either the primary developer of the IP, or the designated representative of a group of developers)
Name:
Position:
Employer:
Workplace:
Head of Department or Director of work area:
Telephone:
E-mail:
Date of submission

Project description

Short title and description of the IP.

IP ownership considerations

Describe the employment relationship of the primary developer with the WA health system. List any other employees of the WA health system who have been directly involved in the development of the IP (i.e. those who are co-developers).

Is the IP directly or indirectly related to the employment duties within the WA health system of the developer(s) (i.e. would the IP have been generated if you/they were not employees of the WA health system)?

Has the IP been developed using any resources (e.g. financial, physical, support systems and personnel) or patients or patient-derived material, of the WA health system?

Does the developer(s) have any additional formal employment relationships with organisations external to the WA health system (e.g. universities and medical research institutes)? Note that this excludes Adjunct titles.

Have any persons or organisations external to the WA health system been directly involved in the development of the IP (i.e. are they co-developers)?

Has any legal advice from LLS, SSO or other sources, been received regarding ownership of the IP?

Did the IP result from a specific funding arrangement (e.g. contract for services, research grant or industry collaboration) that had an IP clause?

Has any pre-existing (Background) IP, either of the WA health system or external organisations, been used in developing the new IP?

Funding considerations

Please provide as best an estimate as possible of the total development costs of the IP to the present (e.g. include salaries, materials, consultant fees, infrastructure costs and inkind support).

Have pilot or proof-of-concept studies been undertaken on the IP? If not, can you estimate the costs involved in these, if required?

Does the IP require further development before it is a marketable commodity? If 'yes', can you inform as to the next steps that might be required, and an estimate of additional costs that might be required for this?

Have you identified potential sources of funds for the further development of the IP (if required)?

Demand

What was the reason for developing the IP (e.g. did it fill an unmet need, or is it more cost-effective than other current sources)?

Could the product be used outside the WA health system or in businesses outside of healthcare?

Do you have an estimate of the potential market size for this product?

Are you aware of anyone else having developed a similar or related product?

Could such products be considered potential competitors in the current marketplace?

If there are possible equivalents already on the market, what advantage does this new IP offer over these?

Do you have evidence of potential external demand for the IP (e.g. existing market, enquiries from interested parties or other agencies with similar requirements)?

Can you estimate the projected life of the product?

Risks/benefits

Can you identify any potential risks associated with the further development of the IP (e.g. financial, legal, administrative or political)?

How will commercialisation of the IP benefit the State of WA (e.g. positively impact health, create revenue, enhance the product, improve service delivery)?

Commercialisation

Is the IP protected/protectable by copyright, patent, design, trade mark, or is it a trade secret?

Do you have any view on how this IP might be commercialised (e.g. licenced, assigned or other)?

Has a business plan, commercialisation plan or costing model been developed for the product?

Have any potential commercial partners, backers, funders, developers been identified?

The Department is a Public Research Partner in the Medical Research Commercialisation Fund, which can be approached for consideration of early stage seed funding for commercialisation. Would you consider exploring this option?

For patentable inventions

Have strict recording and reporting procedures been used in the course of the development of the IP (e.g. certified laboratory notebooks)?

Can you demonstrate the time period in which the IP was developed (e.g. through laboratory notebooks, confidentiality and non-disclosure agreements or other appropriate documentation)? Note that in some cases it may be required to establish first-to-invent status.

Has the IP been disclosed in any form that is not subject to confidentiality/non-disclosure agreements (e.g. publications, conference presentations, general discussions)?

Have patent searches been conducted on the IP? Potentially relevant databases include:

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

Has a provisional patent/PCT been applied for? If 'yes', please provide details, including fees already paid or due to be paid.

Have any patents been granted?

An *IP Notification Form* template is available through: the IP contact point for each entity of the WA health system (health service provider or Department); the RIO; and the WA health system IP web page.

This document can be made available in alternative formats on request for a person with disability.
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