

2023

HEALTH+MEDICAL RESEARCH

# Commercialisation Framework



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## Introduction

Providing Intellectual Property (IP) and commercialisation support for Local Health Districts is crucial to driving innovation in the state. NSW has excellence in basic research and clinical development underpinned by strong links to a world class health system. However, unless Public Health Organisations are able to protect their contributions to the development of IP, NSW Health will not yield the benefits.

Through better development of IP and supporting commercialisation, NSW has the potential to drive a culture of innovation in Public Health Organisations and increase collaboration between public health organisations, universities, medical research institutes and industry. Increased support for innovation and commercialisation in Public Health Organisations will ultimately lead to the better patient outcomes.

## Disclaimer

The NSW Health Commercialisation Framework (Commercialisation Framework) is designed to assist NSW Public Health Organisations and employees to effectively manage the IP they own, create or use. It does not offer, or replace, legal advice in relation to commercialisation matters. It is not a comprehensive guide to applicable law or NSW government policy, and may be incomplete, inaccurate, or out of date. The IP Framework references some key government policies and requirements current at 1 July 2021. Should such policies or requirements be updated, an agency should refer to and follow the updated version.

NSW Health accepts no responsibility or liability in relation to the use of this document.

## Framework purpose

This document is designed to provide accessible information to NSW Health employees engaged in the commercialisation of intellectual property resulting from health and medical research. This document is to be used as guidance only and does not supersede NSW Health IP policy or any other governing policies.

## Who this framework applies to

This framework applies to all employees of NSW Health, including Students, Visiting Practitioners and Clinical Academics.

### Employees of NSW Health

A member of the NSW Health Service who is employed under Part 1 of Chapter 9 of the *Health Services Act 1997* (NSW) to enable a Public Health Organisation to exercise its functions (and in respect of an affiliated health organisation, to exercise its functions in relation to its recognised establishments and recognised services).

### Visiting Practitioners, Students and Clinical Academics

#### Visiting Practitioners

A Visiting Practitioner is a medical practitioner or dentist who is appointed, otherwise than as an Employee, to practice as a medical practitioner or dentist in accordance with the conditions of appointment (including honorary medical officers, visiting medical officers and visiting dental officers). The term can be applied to visiting practitioners appointed otherwise than under a service contract (i.e. who are not visiting medical officers or honorary medical officers), and otherwise is as defined in the *Visiting Practitioner Appointments Policy* ([PD2016\\_052](#)) and any subsequent variations to that policy.

#### Students

Students are defined and covered under the *Student Placements in NSW Health Policy* ([PD2022\\_049](#)) and any subsequent variations to that policy.

## Visitors

Any person (other than a Student, Employee and Visiting Practitioner) who utilises the Resources of a Public Health Organisation at any time (for example, a visiting researcher).

## Glossary of Terms

<b>Commercialisation</b>	means exploitation of the intellectual property in exchange for any benefit, whether monetary or otherwise, from a third party.
<b>Copyright</b>	a type of intellectual property that protects original works of authorship as soon as an author fixes the work in a tangible form of expression.
<b>Creator</b>	An Employee or Employees who make a significant contribution to the creation or invention of the subject matter (e.g. the work, product or process) in which the Intellectual Property subsists, or a Visitor, Visitors, Visiting Practitioner, Visiting Practitioners, Student or Students who make a significant contribution to the creation or invention of the subject matter (e.g. the work, product or process) in which the Intellectual Property subsists and assign their and interests in the Intellectual Property to the Public Health Organisation.
<b>Establishment costs</b>	in relation to intellectual property means any costs paid by the Public Health Organisation to establish and develop the intellectual property for protection or Commercialisation, once it has been determined by the Public Health Organisation that Commercialisation of the intellectual property should take place. Establishment costs do not include costs that the Public Health Organisation would normally have incurred in carrying out the research as its core function, for example, the costs of employing/retaining the creators in their regular capacity or providing infrastructure for medical research.
<b>Gross Commercialisation proceeds</b>	means all amounts receivable in consideration of the assignment or licensing of intellectual property rights. These amounts may be lump sum payments made up-front or periodically or may be in the nature of royalties payable on the happening of future events such as product sales.
<b>Intellectual Property (IP) Committee</b>	committee established by a Public Health Organisation to review IP created by employees. This committee can provide advice and funding along the IP journey from concept to Commercialisation.
<b>Intermediary</b>	person appointed by a Public Health Organisation for the purpose of assisting an employee with the notification process.
<b>Local Health District (LHD)</b>	<a href="#">Local Health Districts and Specialty Networks</a> are established to operate public hospitals and institutions and provide health services to communities within geographical areas or a defined patient population for Specialty Networks.
<b>Net Commercialisation proceeds</b>	Gross Commercialisation Proceeds received by the Public Health Organisation, less Establishment Costs and Protection Costs.
<b>Protection costs</b>	any costs incurred in taking any step towards obtaining registration or protection of the intellectual property including fees for preparing and filing patent applications, renewals, extensions, taxes, stamp duty, design or trade mark application and legal and patent attorney's fees expended in the course of obtaining protection.
<b>Public Health Organisation</b>	As defined in section 7 of the Health Services Act 1997 (NSW) is a local health district, a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services. For the purpose of this framework HealthShare NSW and NSW Health Pathology are considered Public Health Organisations.

<b>Research</b>	means laboratory, pre-clinical and clinical research and development in all its forms.
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## Understanding research in Public Health Organisations

Research is a core component of the NSW Health service. Research comprises laboratory, pre-clinical and clinical research and development in all its forms.

This includes, but is not limited to:

- development of treatment and diagnostic procedures and methods;
- development of equipment or other goods which may have application in a research laboratory, clinical setting or a health application;
- artificial intelligence as training and stimulation tools;
- biomedical research;
- research and development of therapeutics; and
- epidemiological and research methods,
- incidental research and discoveries, in circumstances embraced by this policy, arising other than in the course of a formal research program; and
- research and discoveries which are not health-specific but have application to treatment.

Research can result in the creation of Intellectual Property (IP), when research is undertaken by an employee of NSW Health.

### Intellectual Property (IP)

IP is the legally recognised outcome of creative effort and economic investment in creative effort. It refers to the product of intellectual activity in the industrial, scientific, literary, artistic, musical and dramatic fields. It also refers to the various statutory and common law rights the law gives to permit the protection and exploitation of intellectual efforts.

Employers will, generally speaking, own IP created by their employees or created under the employer’s direction or control (see further 2.2 [Agencies and copyright ownership]).

IP can be transferred as a form of property and can be licensed, which grants permission for another person to use the licensed IP.

IP rights are contained in a wide range of materials such as:

- agency internal documentation, policies, website materials and other publications;
- material produced by or for the agency;
- research and development materials;
- reports, text on websites and other written materials;
- photographs, drawings and other images (including artworks);
- plant varieties;
- video and audio recordings;
- branding materials such as logos and crest designs;
- training and educational materials;
- software;
- designs and plans for the manufacture of products and buildings; and
- archival collections of copyright material such as artworks, books or research papers.

Whilst copyright is the most common form of IP agencies will manage and use, an agency's IP assets may include other forms of IP.

## Types of Intellectual Property common in Public Health Organisations

Below are the main forms of IP with explanations and examples of how they may present in Public Health Organisations.

### Copyright

- There are three categories of protection under the *Copyright Act 1968* (Cth) being:
  1. literary, musical, dramatic and artistic works, including adaptations and arrangements of works. This also includes software which is protected as a type of "literary work";
  2. films, sound recordings, television broadcasts, radio broadcasts, published editions;
  3. performers' protection (not strictly copyright but included in *Copyright Act*).
- Copyright protection is automatic on the creation of a work in Australia. It gives the owner the exclusive right to do various acts in relation to the work, including reproducing the work.
- There is no copyright in an "idea". Copyright protects the author's particular way of expressing an idea.
- Copyright law only gives protection against the copying of the work and does not protect against the independent creation of a similar work.
- Moral rights also exist in relation to literary, musical, dramatic and artistic works and in relation to cinematograph films. Moral rights cannot be assigned or sold to another person and cannot be owned by a company. They seek to protect the individual creator's honour and reputation and include:
  - The right to attribution as the work's author whenever the work is published or reproduced
  - The right to prevent any other person from falsely claiming they are the author of the copyright work
  - The right to prevent their work being subjected to derogatory treatment.

#### Copyright example

Public Health Organisation work which may attract copyright could be a manual developed to explain a particular product or process, or diagrams and charts explaining a product or process. It is the expression of the product or process which is protected by copyright law, not the product or the process itself.

*Example: a Nurse Unit Manager (NUM) develops a training manual for staff on how to correctly wear a new piece of PPE. The NUM creates the document and includes pictures of themselves fitting and wearing the PPE. This manual proves to be useful and is shared throughout the hospital and district. The copyright of this manual is owned by the health organisation, with the NUM credited as author.*

For more information about copyright, please see the Attorney- General's Department website [here](#).

### Patents

- Patents in Australia are regulated by the *Patents Act 1990* (Cth).
- A patent is a right granted in respect of a method, process, device or substance that is new, inventive and useful.

- If it can be shown that the invention was already known publicly or that it was the subject of an earlier patent, a patent will not be granted.
- A patent gives the owner the exclusive right to commercially exploit the invention.
- Unlike copyright, a patent must be applied for with the Australian Patent Office and protection is not automatic.
- Patent rights are extremely fragile and can easily be lost if the nature of the invention is disclosed, published, sold or otherwise commercialised before a patent is applied for.
- In Australia, you can protect your device, substance, method, or process using a standard patent. The standard patent is also supported by provisional patents and international patent applications.

#### Patent example

Public Health Organisation IP which may be appropriate to patent includes new medical techniques, processes, devices or substances.

*Example: a respiratory physician develops a 3D printed device to assist neonates with optimal intubation. The device works well in practice and the physician seeks support from the LHD IP Committee to pursue a patent. Once the patent application is filed the physician can publish articles and present the device at conferences. Commercialisation arrangements can be sought as the device progresses through preclinical and clinical testing.*

For more information about patents, please see the IP Australia website [here](#).

**Note: In the vast majority of countries (e.g. Europe) Patents will not be granted if the IP has been publicly disclosed, for example the clinician has published a paper or presented on the new device, process, or drug.**

## Registered Designs

- Industrial designs can be protected by registration under the *Designs Act 2003* (Cth).
- The visual appearance of articles is protected – a distinctive shape, configuration, ornamentation or pattern.
- This protection may protect a design in relation to all sorts of items e.g. computer keyboards, furniture, toys and spare parts.
- A design must be new or original in order to be registered.
- Unlike copyright, a design must be applied for with the Australian Design Office and protection is not automatic
- It will not be possible to obtain a registration where there has been prior publication or use of the design.
- A design registration gives the exclusive right to apply the design to the article in respect of which the design is registered.

#### Registered Design example

There are overlaps between IP appropriate to patent and IP appropriate for design registration. Registered design applications increased in 2020 with many face masks and respiratory devices submitted to protect their design. The core components of face masks are similar and generally do not meet the strict criteria required to obtain a patent. However where there is variance in the style and appearance, the distinctive design appearance may be eligible for design registration. There are also circumstances in which both patent and design registrations may be appropriate to cover the same invention. For example, a design may be obtained to protect the visual appearance of a product, and a patent may be filed invention to protect the way in which it works.

*Example: A surgeon develops a nose bridge clip which more comfortably and securely holds magnifying loupes. This device does not meet patent requirements (new and inventive) as there are similar products on the market. The surgeon consults the LHD IP Committee who recommend registration of the clip design.*

For more information about designs, please see the IP Australia website [here](#).

## Trade Marks

- The relevant legislation is the *Trade Marks Act 1995* (Cth).
- A trade mark is a sign used to distinguish goods or services dealt with or provided in the course of trade by a person from goods or services so dealt with or provided by any other person.



- Trade marks include letters, words, names, signatures, numerals, devices, brands, headings, labels, tickets, aspects of packaging, shape, colour, sound, scent or any combinations, e.g. “Vegemite”.
- Registration can be applied for under the *Trade Marks Act*.
- A registered trade mark gives the exclusive right to use the trade mark for the goods or services for which it is registered.
- Trade mark registration is for a ten-year period from the date on which the application was filed, renewable upon payment of the official fee.
- A trade mark can be used before it is registered.
- For more information about trade marks, please see the IP Australia website [here](#).

#### Trade Mark example

It may be appropriate for Public Health Organisation to apply for a trade mark upon the establishment of new departments, entities or programs.

*Example: an oncology department creates a clinical trial unit, this unit has a distinctive name and a logo of interlocking leaves. A formal review is undertaken to ensure there are no similar registered trade marks, and registration of the logo and unit name is submitted to IP Australia. This trade mark registration protects the clinical trial unit if another organisation uses a substantially identical or deceptively similar mark on identical or similar goods/services (such as another hospital's clinical trial unit) .*

## Trade Secrets

- The protection of trade secrets is an aspect of the law of confidential information, and this law tends to be used when traditional areas of intellectual property provide no relief. Trade secrets include manufacturing techniques, customer lists, engineering designs, marketing procedures and some government information.
- Employees owe a duty of confidentiality to their employer. This does not mean that information cannot be transferred from one scientist or researcher to another. However, if the information is particularly sensitive or relates to potentially valuable IP, the secrecy of the information can be maintained and protected by confidentiality agreements.
- Confidentiality is an important concept and is useful in research and development. It can be used to assist the flow of scientific or medical information while maintaining legal secrecy and safeguarding patenting rights.

#### Trade Secret examples

Examples of trade secrets could include specific formulations exclusive to a company.

## Understanding the costs involved

To develop IP through from concept stage to protection and Commercialisation there are a number of costs involved. These costs would be considered ‘establishment costs’.

Examples of establishment costs would include:

- fees paid to consultants or other professionals for advice on Commercialisation or further development of the intellectual property for the purposes of Commercialisation;
- any costs incurred in setting up a commercial vehicle for the purposes of developing or Commercialising the intellectual property, or any costs paid to third parties for the purposes of Commercialising the intellectual property, or further developing the intellectual property for Commercialisation;
- legal costs incurred in relation to the intellectual property or its Commercialisation, for example, in drafting joint venture agreements
- licence agreements or assignments, or providing advice on the Commercialisation of the intellectual property; and

- any taxes, or similar outgoings to third parties.

Establishment costs do not include costs that the public health organisation would normally have incurred in carrying out the research as its core function, for example, the costs of employing/retaining the creators in their regular capacity or providing infrastructure for medical research.

Employees of NSW Health should approach their LHD's IP committee for review, this IP Committee can authorise the payment of establishment costs or suggest how costs could be supported (e.g. trust funds). The IP Committee will assess the opportunity (technical feasibility, market potential, intellectual property position) and advise whether protection or Commercialisation of the intellectual property should take place. If the IP Committee declines support and the employee still wishes to Commercialise the IP, the employee may request ownership of such IP be assigned to them, with the employee to be responsible for costs upon assignment.

## Commercialisation

### Overview

In line with the NSW Government Intellectual Property Framework, Public Health Organisations are responsible for managing their own IP. This may include commercialisation. Commercialisation is defined above in the Glossary of Terms. Examples of Commercialisation include profit making activities such as licensing of rights to market a new medical treatment, sales and licensing of branded merchandise, publication of books and prints, sale of training materials and educational resources or "train the trainer" kits, licensing of software, and other forms of IP exploitation.

Agencies should only Commercialise their IP where this is consistent with their powers, purposes and strategic priorities, and having regard to the general policy position set out in the NSW Government Intellectual Property Framework 2020, Principle 1 (Efficient management). Agencies should seek advice if they have any questions about their powers to commercialise IP and refer to general policies regarding the Commercialisation of state assets.

Agencies should determine whether they have the necessary expertise and resources to undertake any Commercialisation project. There are different contractual and business models that could be used including funding grants, joint ventures and licensing of Commercialisation rights to third parties. Seek legal advice on the most suitable model for the project. Some models, such as joint ventures, may also require additional approvals (e.g. pursuant to the *Government Sector Finance Act 2018*).

Agencies may wish to establish their own policy on IP arising in certain contexts, so that third parties will be aware of applicable IP arrangements.

## IP Principles for LHDs

Topic	Principles
Management and Compliance	<p>An agency's IP assets should be managed efficiently, effectively and transparently to ensure the maximum benefit and usage of these assets for the benefit of the people of New South Wales.</p> <p>Agencies should have in place internal procedures to ensure that all relevant agency personnel are made aware of and comply with IP laws, and respect the legal rights of IP creators, owners and licensors and all other people who have legal interests in IP, including moral rights under the Copyright Act.</p> <p>Before using IP material, agencies should check if they own IP, and if not, check whether their proposed use of the IP is permitted under an existing licence with a supplier, IP owner/licensor or collecting society.</p> <p>Before procuring or acquiring a licence to use IP, agencies should check if whole of government IP licences or other arrangements are in place for that class of IP.</p>
Ownership and Rights	<p>Agencies should ensure that IP ownership and rights are clearly addressed where relevant in their agreements and other commercial arrangements.</p> <p>Where an agency procures, commissions or funds the creation of new IP, the agency should consider whether the agency should own the IP, or alternatively, obtain sufficient licences for that IP to enable the agency to achieve its objectives, having regard to all relevant factors.</p>
Sharing, Licensing, Assignment and Commercialisation	<p>Agencies are encouraged to share and publicly disseminate IP material which they own where it is appropriate to do so.</p> <p>Agencies wishing to share or publicly disseminate IP material should first consider whether any third party IP rights, personal information, confidentiality, security or sensitive classification or other restrictions apply.</p> <p>Agencies may commercialise their IP material on terms which are consistent with the agency's legal powers, purpose and strategic priorities and in accordance with all relevant policies on dealing with State assets.</p>
Identification and Recording	<p>Agencies should maintain appropriate internal processes and systems to identify, record and manage any business-critical or strategically valuable IP (including any IP that has high public value) that they own, control, or use.</p>
Protection and Branding	<p>Agencies should take appropriate steps to protect the agency's business critical or strategically valuable IP (including any IP that has high public value) where there is a net benefit in doing so.</p> <p>Agency branding and marketing materials must comply with New South Wales Government policies on use of State insignia, government owned logos, publication style guides and business and domain names.</p>

## **Commercialisation Steps**

### **Research & Clinical Practice**

In the NSW Health context, the Commercialisation process begins when a discovery emerges or technology is developed from research, or insights are derived from clinical practice, that have commercial potential, where the Commercialisation pathway would be beneficial for enabling adoption in practice, such as for improving health outcomes or delivery of care. Commercialisation support is available to NSW health employees as outlined in this Commercialisation Framework.

### **Invention Disclosure**

Submitting an Invention Disclosure is the first step to formally document your invention with NSW Health. This is a confidential document which fully details your invention so that we can work with you to evaluate options for Commercialisation. You are required to complete an Invention Disclosure form and submit it to NSW Health through your Local IP Committee (or the Central Support Service on behalf of an LHD).

### **Assessment**

A Local IP Committee (or the Central Support Service at the request of an LHD) will assess your invention for its commercial potential and legal due diligence. Commercial potential is assessed by evaluating the technology for its technical feasibility, market potential, and patentability or other suitable form of IP protection. Where appropriate, advice from external experts, such as a Patent Attorney, should be sought. Legal due diligence is done to confirm who has ownership rights and where they may be joint ownership establish commercialisation lead, etc. Legal due diligence will also cover whether the IP is encumbered e.g. an existing contract where it may already be optioned to a company.

### **IP Strategy and Protection**

Based on a thorough assessment, it will be determined if protection is possible and appropriate. The IP Committee (or the Central Support Service in behalf of an LHD) will manage IP protection activities, including patenting if suitable, in consultation with you.

### **Commercialisation Strategy**

A Local IP Committee (or the Central Support Service at the request of an LHD) will work with you to determine the appropriate commercialisation pathway, which could be to license the invention to and/or collaborate with an existing company, or develop a plan to create a new company (start-up) to commercialise the technology. Advice on development and funding pathways will also be provided to support progressing the technology to a point where it becomes ready for commercial investment (e.g. licensee, investor, industry partner).

### **Licensing**

The licensee(s) is chosen by the LHD based on its ability to commercialise the technology for the benefit of the general public. The nature of the technology will typically dictate whether the technology is licensed to an existing company, or licensed in order to create a start-up. Sometimes an established company with experience in similar

technologies and markets is the best choice (typically where the technology is more of an incremental improvement). In other cases, the focus and intensity of a start-up company is a better option (typically where the technology is disruptive or to align with expectations of the industry sector).

### **Commercialisation**

The licensee drives the advancement of the technology to market and often makes business investments to further develop the product or service. This could include further development, obtaining regulatory approvals, additional sales and marketing support, training, or other activities.

### **Reinvestment**

Licensing revenues received are distributed to creators and NSW Health as per the NSW Health IP Policy.

### **Questions?**

Contact your LHD who can refer you to the Local IP Committee contact or Central Support Services.

## The Central Support Service for Intellectual Property and Commercialisation

The Office for Health and Medical Research conducted a review of the NSW Health Intellectual Property Policy. This review was completed in a consultative manner including meetings with key opinion leaders, desktop scans of current practices in both Australia and abroad and through workshop consultation. The review identified:

- That there is an inconsistent approach to dealing with intellectual property arising from research in the NSW public health system
- There is no clear pathway for the progression of ideas and that can lead to the following outcomes:
- Early disclosure meaning the innovation can no longer be protected
- The innovation being commercialised outside of NSW Health
- NSW Health not being properly compensated for its role in the development of intellectual property.

It is proposed that the support unit sits within the Office for Health and Medical Research and acts as a 'one-stop-shop' for all Intellectual Property and commercialisation issues.

The proposed Central Support Service will include three key elements:

- Assessment of intellectual property: LHD will be able to submit an application to have their innovation assessed. It will be assessed both the pedigree of the intellectual property and the opportunity for Commercialisation.
- Intellectual property and Commercialisation support services: A network of experts will be engaged throughout the state and LHD's will be able to utilise their services as required.
- Intellectual property education: Education will be provided to LHD's to ensure proper treatment of intellectual property.

This initiative will not override the current local processes for reviewing intellectual property rather Local Health Districts will be able to opt in to use the service

This will address inconsistencies and duplication throughout the state and ensure all Local Health Districts have equal access to intellectual property support and Commercialisation advice regardless of geographical location.

## External support

The Central Support Service will connect LHDs with the expert advice they require. The services engaged through the network will include:

- Regulatory guidance
- Business advice
- Legal advice
- Capital raising advice
- Clinical trial protocol design
- Contract negotiation
- Advice on all types of intellectual property
- Grant writing guidance

## Templates Available

- Non-Disclosure Agreements
- IP Assignment Forms
- Invention disclosure and notification forms template
- Research Collaboration Agreements
- Pre-Disclosure Forms
- Sample IP Ownership Clauses
- Sample ADR Clauses
- Business Pitch Deck Template

To access these templates please contact [moh-ipandcommercialisationsupport@health.nsw.gov.au](mailto:moh-ipandcommercialisationsupport@health.nsw.gov.au)

## Links

- [IP Policy](#)
- [IP Australia website](#)