

Intellectual Property arising from Health Research

Summary The Policy Directive states obligations of Public Health Organisations and employees regarding intellectual property arising from health research. The policy provides a clear and consistent guide for Public Health Organisations to protect their intellectual property arising from research.

Document type Policy Directive

Document number PD2023_007

Publication date 16 February 2023

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Replaces PD2005_370

Review date 16 February 2028

Policy manual Not applicable

File number H21/165085

Status Active

Functional group Clinical/Patient Services - Research
Corporate Administration - Governance

Applies to Ministry of Health, Public Health Units, Local Health Districts, Board Governed Statutory Health Corporations, Chief Executive Governed Statutory Health Corporations, Specialty Network Governed Statutory Health Corporations, Affiliated Health Organisations, NSW Health Pathology, Public Health System Support Division, Cancer Institute, Government Medical Officers, Community Health Centres, NSW Ambulance Service, Dental Schools and Clinics, Public Hospitals

Distributed to Ministry of Health, Public Health System, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, Private Hospitals and Day Procedure Centres, Health Associations Unions, Tertiary Education Institutes

Audience All NSW Health employees;Local Health Districts;Public Health Organisations;Affiliated Health Organisations;Research Institutes;Public and Private Hospitals

Intellectual Property Arising from Health Research

POLICY STATEMENT

NSW Health recognises that the acquisition and dissemination of knowledge and skills in the area of research and clinical practice is of major public benefit and a primary role of Public Health Organisations.

Public Health Organisations must establish a centralised system of managing their Intellectual Property, utilising an Intellectual Property Committee or other Committees which adhere to the requirements of this Policy Directive. They must also ensure that relevant agreements are in place with Clinical Academics, Visiting Practitioners, Visitors, Students, Independent Research Institutes and other third parties which appropriately deal with Intellectual Property.

SUMMARY OF POLICY REQUIREMENTS

Occasionally, the outcome of Health Research may have a significant commercial value. The objectives of this Policy are to:

- provide a framework for the use, generation, acquisition and management of Intellectual Property in NSW Health
- ensure that Intellectual Property owned by NSW Health is used to generate public value, knowledge transfer and innovation to the fullest extent possible
- encourage health research relating to the public health system and the acquisition and dissemination of knowledge and skills
- foster an environment within which the role of Intellectual Property in enabling clinical application of health research and realising commercial value is understood and recognised
- manage Intellectual Property with a potential commercial value in a manner which benefits the public health system as a whole
- foster an environment within which Intellectual Property issues can be identified and developed, and
- recognise and reward innovation by staff of NSW Health Organisations.

NSW Health provides an environment in which NSW Public Health Organisations are rewarded for the commercial exploitation of Intellectual Property.

The Office for Health and Medical Research will establish a Central Support Service offering assistance in commercialising intellectual property, which Public Health Organisations can delegate matters of that nature to if they are unable to establish or utilise a Committee.

Employees of Public Health Organisations will be required to notify the Committee or Central Support Service (whichever is applicable within their Organisation) of Intellectual Property they develop or will imminently develop.

The Committee/ Central Support Service must examine and consider all notifications provided to it by Employees. Further, they will offer legal and commercialisation advice, and make recommendations to the Chief Executive of the relevant Public Health Organisation. They will also act as a resource for staff on Intellectual Property matters, particularly in relation to the provision of advice on prior disclosure.

REVISION HISTORY

Version	Approved By	Amendment Notes
PD2023_007 February-2023	Secretary, NSW Health	Provides a clear guide for LHDs to protect IP arising from research and establish processes for managing IP. Clarifies ownership of IP and disclosure obligations for employees when dealing with potential IP. Recommends that agreements made between Public Health Organisations and third parties set out IP and commercialisation obligations, and protect the interests of the Public Health Organisation proportionately to its contribution to the project. Establishes a support service for NSW Health entities, and particularly employees to allow them to adequately protect and commercialise intellectual property.
PD2005_370 January-2005	Director-General	New policy directive

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1. BACKGROUND

This Policy recognises the value of Intellectual Property arising from Health Research within Public Health Organisations (PHOs). It recognises that the acquisition and dissemination of knowledge and skills in the area of Health Research and clinical practice is of major public benefit and a primary role of Public Health Organisations. Occasionally, the outcomes may have a significant commercial value.

1.1. About this document

This Policy aims to encourage engagement with industry, while enabling an environment in which Public Health Organisations are rewarded for the commercial exploitation of Intellectual Property.

In some cases, Public Health Organisations are not best placed to further develop Intellectual Property. Instead, where there are opportunities for innovation, NSW Health are to allow staff or third parties to further develop and commercially benefit from Intellectual Property, provided this can be done on a fair, equitable and transparent basis and clearly generates public benefit, knowledge transfer or innovation and does not erode the Public Health Organisations' Intellectual Property.

This Policy does not apply to commissioned works, that is, any Intellectual Property arising from work specifically commissioned or contracted by the Public Health Organisation for a fee. The Intellectual Property in such work is governed by the terms of the commissioning agreement.

In accordance with this Policy, the default position for Intellectual Property ownership, dependant on the Creator, is summarised as follows:

Creator	Who owns Intellectual Property?	Section
Employee	PHO unless inequitable or pursuant to a contract.	4.1
Affiliated University/ Clinical Academic	Jointly owned unless it is inequitable.	5.1
Visitor or Visiting Practitioner	Depends on the relevant agreement. If there is no written agreement, the default position is that the Visitor, Visiting Practitioner or the entity who employs or engages them owns the Intellectual Property unless it is inequitable.	6.1
Students	Students except in limited circumstances. It also depends on whether the Student attends an Affiliated University.	7
Members of an Independent Research Institute (IRI)	No default position on Intellectual Property ownership. Where a PHO provides Resources to the Independent Research Institute. There must be an agreement in place between the parties determining Intellectual Property rights.	9

1.2. Key definitions

In relation to defined terms in this Policy, a word importing the singular includes the plural and vice versa.

Intellectual Property arising from Health Research

Affiliated University	Any entity supervised or controlled in controlled with the university, and that exists or is organised for the benefit of the university.
Benefits	<p>Monetary or non-monetary goods or results that are produced as a result of exploiting Intellectual Property. It includes but is not limited to:</p> <ul style="list-style-type: none"> • Royalties • Licence fees • Milestone payments • Dividends, and/or • Proceeds from the sale of shares.
Central Support Service	The service established by the Office for Health and Medical Research within the NSW Ministry of Health for the purpose of assessing opportunities, making recommendations and providing general advice on matters relevant to the management of Intellectual Property created in Public Health Organisations.
Clinical Academic	<p>A person who:</p> <p>(a) is a medical practitioner (as defined in the <i>Health Practitioner Regulation National Law (NSW) 2009</i>) holding general or conditional specialist registration who is employed or engaged as a member of staff of a NSW university's school of medicine, and</p> <p>(b) accepts an offer of employment with NSW Health in accordance with the NSW Health Policy Directive <i>Clinical Academics Employed in the NSW Health Service</i> (PD2019_055), and any subsequent variations to that policy directive.</p>
Commercialisation	The exploitation of an entity's Intellectual Property in exchange for any benefit, whether monetary or otherwise, from a third party.
Committee	An Intellectual Property Committee constituted in accordance with section 3 <i>Intellectual Property Committee, Intermediary and Central Support Service</i> .
Creator	<p>In relation to any Intellectual Property means:</p> <ul style="list-style-type: none"> • an Employee(s) who made 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

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	<ul style="list-style-type: none"> • a Visitor(s), Visiting Practitioner(s) or Student(s) who made 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 assigned his or her rights and interests in the Intellectual Property to the Public Health Organisation.
Employee	<p>A member of the NSW Health Service who is employed under Part 1 of Chapter 9 of the <i>Health Services Act 1997</i> (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).</p>
Establishment Costs	<p>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 is to take place.</p> <p>Establishment Costs do not include costs that the Public Health Organisation would normally have incurred in carrying out the Health Research as its core function, for example, the costs of employing/retaining the Creators in their regular capacity or providing infrastructure for medical research. Examples of Establishment Costs include:</p> <ul style="list-style-type: none"> • any costs 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 collaborative agreements • licence agreements or assignments, or providing advice on the Commercialisation of the Intellectual Property, and/or • any taxes, or similar outgoings to third parties.

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<p>Gross Commercialisation Proceeds</p>	<p>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.</p>
<p>Health Research</p>	<p>Laboratory, pre-clinical and clinical research and development in all its forms. This includes, but is not limited to:</p> <ul style="list-style-type: none"> • development of treatment and diagnostic procedures and methods • development of care delivery practices and models • development of equipment or other goods which may have application in a research laboratory, clinical setting or a health application • biomedical research • research and development of therapeutics and • epidemiological and research methods, <p>together with:</p> <ul style="list-style-type: none"> • incidental research and discoveries, in circumstances embraced by this Policy, arising other than during a formal research program and • research and discoveries which are not health-specific but have application to treatment.
<p>Independent Research Institute</p>	<p>A not-for-profit institute established primarily for the conduct of health and medical research.</p>
<p>Intellectual Property</p>	<p>Intellectual Property in this Policy is the legally recognised outcome of creative effort and economic investment in creative effort. Intellectual Property includes:</p> <ul style="list-style-type: none"> • inventions, and patents granted in respect of such inventions and applications for such patents • unpatented know-how, which comprise an invention or a way of doing something which is not public knowledge • confidential information and trade secrets • registered and unregistered designs and applications for registered designs • copyright • circuit layout rights • registered and unregistered trademarks and applications

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	<p>for registration of trademarks</p> <ul style="list-style-type: none"> • get-up and trade dress associated with products and services • plant variety rights • all other rights resulting from intellectual activity in the scientific, industrial, literary, or artistic fields, and • any contractual rights to use or exploit any of these rights. <p>A brief description of some forms of Intellectual Property and the nature of Intellectual Property rights is available in appendix 12.2.</p>
Intermediary	A person appointed by a Public Health Organisation pursuant to section 3.2 of this Policy for the purpose of assisting an Employee with the notification process required under this Policy.
Net Commercialisation Proceeds	Gross Commercialisation Proceeds received by the Public Health Organisation, less Establishment Costs and Protection Costs.
NSW Health	Public Health Organisation, the NSW Ministry of Health, the Ambulance Service of NSW, and all other organisations under the control and direction of the NSW Minister for Health or the Secretary of NSW Health.
Protection Costs	In relation to Intellectual Property, this means 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 trademark application and legal and patent attorney's fees expended while obtaining protection.
Public Health Organisation (PHO)	<p>As defined in section 7 of the <i>Health Services Act 1997</i> (NSW) is a local health district, a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services.</p> <p>For the purpose of this Policy, all business units of the Health Administration Corporation including HealthShare NSW, NSW Health Pathology, NSW Ambulance, eHealth NSW and Health Infrastructure are considered Public Health Organisations.</p>

Resources	Any funds, Employees, laboratory facilities, equipment, existing Intellectual Property of the Public Health Organisation, products, materials, equipment, hardware, software, documents (whether stored in hard copy or electronically), any article or material from which images or writing are capable of being reproduced, and any electronically stored text or graphics capable of being manipulated by document processing software.
Student	A Student as defined and covered under the NSW Health Policy Directive <i>Student Placements in NSW Health</i> (PD2022_049) and any subsequent variations to that policy.
Visiting Practitioner	<p>A medical practitioner or dentist who is appointed under Chapter 8 of the <i>Health Services Act 1997</i> (NSW), otherwise than as an Employee, to practise as a medical practitioner or dentist in accordance with the conditions of appointment (including honorary medical officers, visiting medical officers and visiting dental officers).</p> <p>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).</p>
Visitor	Any person (other than a Student, Employee and Visiting Practitioner) who utilises the Resources of NSW Health at any time (for example, a visiting researcher).

2. INTELLECTUAL PROPERTY COMMITTEE, INTERMEDIARY AND CENTRAL SUPPORT SERVICE

Each Public Health Organisation must determine their method of managing their Intellectual Property and decide to do one or more of the following:

- establish a Committee
- agree to access the Central Support Service
- agree to utilise the Committee of another Public Health Organisation
- constitute an ad hoc committee from time to time
- utilise an existing committee to carry out the Committee's functions, such as a research committee, provided that the membership of such a committee is in accordance with this Policy.

2.1. Intellectual Property Committees

2.1.1. Composition of a Committee

The composition of a Committee is a matter for the Public Health Organisation and may include co-opted members appropriate to the matter under consideration. However, the standing membership must include:

- the Chief Executive (CE) of the Public Health Organisation or a senior executive nominated by the Chief Executive
- the Director of Finance of the Public Health Organisation or senior financial Employee nominated by the Director of Finance
- a senior officer in charge of research within the Public Health Organisation (except that such a senior officer must not participate in the making of recommendations in relation to Health Research in which he or she is directly involved or has an interest), and
- a person with experience in the commercialisation of Intellectual Property.

It is recommended that specialist legal advice be available to the Committee, either by having a legal adviser as a member of the Committee, or by seeking legal advice as appropriate.

The Committee must have a secretariat or responsible officer who is available to coordinate the business of the Committee when it is not sitting, and to receive notifications.

If Public Health Organisations have staff who are responsible for Intellectual Property matters (such as Intellectual Property identification, education, encouragement etc.) those staff members can be members of the Committee.

A Public Health Organisation may seek a recommendation by the Central Support Service for the appointment of suitable Committee members.

2.1.2. Functions of a Committee

The functions of the Committee include the receipt and consideration of notifications, the provision of advice, and the making of recommendations to the Chief Executive of the Public Health Organisation as set out in this Policy. The Committee will also act as a resource for staff on Intellectual Property matters, particularly in relation to the provision of advice on prior disclosure (see section 10).

The Committee may, at its discretion, refer in writing any of its functions to the Central Support Service to be discharged by the Central Support Service in part or in full, except the function of making recommendations to the Chief Executive of the Public Health Organisation regarding protection and Commercialisation of Intellectual Property which must be completed by the Committee.

All decisions of the Committee must be made in a timely fashion. The Committee must respond promptly to any enquiry from a Creator or their representative as to the status of any matter under consideration by the Committee, provide an estimate of time contemplated for the conclusion of the Committee's deliberations and give reasons for any actual or anticipated delay of significance.

2.1.3. Records to be retained by a Committee

The proceedings of the Committee, and any records of those proceedings, must be treated as commercial in confidence, in so far as they relate to the organisation's Intellectual Property interests.

2.2. Intermediary

2.2.1. Appointment and Function of Intermediary

Each Public Health Organisation can, at its own election, appoint an Intermediary to discharge the function of:

- (a) assisting Employees with the process of notifying a Committee of new Intellectual Property for the purposes of section 3.2 and/or
- (b) facilitating notification direct to the Central Support Service if requested by the individual or if otherwise considered by the Intermediary to be an appropriate course of action.

2.3. Central Support Service

2.3.1. Establishment of the Central Support Service

The Office for Health and Medical Research must establish and maintain the Central Support Service.

2.3.2. Composition of the Central Support Service

The composition of the Central Support Service is a matter for the Office for Health and Medical Research and may include members appropriate to the matter under consideration. However, the standing membership is to include:

- A senior NSW Health Executive nominated by the Secretary, NSW Health
- A senior financial Employee nominated by the Secretary, NSW Health and
- A person with Commercialisation experience nominated by NSW Health.

The Central Support Service must have a secretariat or responsible officer who is available to coordinate the business of the Central Support Service when it is not sitting, and to receive notifications.

2.3.3. Functions of the Central Support Service

The functions of the Central Support Service will include:

- providing support and assistance in relation to the Commercialisation of Intellectual Property as may be requested by a Public Health Organisation
- maintaining such panels of suitably qualified external experts as it considers appropriate
- recommending appropriate expertise upon request by the Committee

- making recommendations regarding the technical enhancement or improvement of inventions (other than in circumstances where a Committee demonstrably has the expertise to discharge such a function)
- overseeing the composition and functioning of Committees to ensure that they reflect the appropriate skills and resources as described in section 2.3.2 and
- maintaining a central register of NSW Health's registered Intellectual Property assets.

3. INTELLECTUAL PROPERTY CREATED BY EMPLOYEES

3.1. Ownership of Intellectual Property created by Employees

All Intellectual Property created by an Employee in the course of their employment with the NSW Health Service is owned by the Public Health Organisation unless inequitable or pursuant to a contract.

Intellectual Property which is created by an Employee through any utilisation of the Resources of the Public Health Organisation is taken to be Intellectual Property created during the Employee's employment with the NSW Health Service. This must be the case unless the Employee has the prior written agreement from the Chief Executive of the Public Health Organisation to utilise the Public Health Organisation's Resources outside the course of their employment to perform the work during which the Intellectual Property was created.

Public Health Organisations are not to assert ownership of any Intellectual Property in an Employee's scholarly books, articles, audio-visuals, lectures or other such scholarly works that are not created in the course of the Employee's employment with NSW Health. This does not apply where those works are commissioned by the Public Health Organisation, in which case the Intellectual Property rights in the work will be governed by the agreement pursuant to which the work was commissioned.

Nothing in this Policy must be taken to detract from the moral rights conferred on Creators under Part 10 of the *Copyright Act 1968* (Commonwealth).

3.2. Notification of Intellectual Property

An Employee is to provide complete and accurate notification as early as possible of the creation, or anticipated imminent creation, of any work, product or process created in the course of their employment with a NSW Health Service which may have, or which the Employee believes may result in, the creation of Intellectual Property.

For the purposes of section 3.2 written notification must be given to:

- a Committee
- an Intermediary, or
- the Central Support Service,

whichever is specified by the relevant Public Health Organisation.

Each notification must be in writing marked "confidential" and must identify:

- the work, product or process in detail

- each person and their affiliations involved in the creation of the work, product or process
- the period in which the work, product or process was created
- the research project or program during which the work, product or process was created, and
- any known details as to the likely commercial significance of the work, product or process.

Notifications are to occur whether the Employee is carrying out the Health Research alone, with other Employees, or as part of a collaborative research project with Visitors, Visiting Practitioners and/or persons from other organisations.

Only one notification need be made where the Health Research is being carried out by more than one Employee or by Employees from different areas of the Public Health Organisation, provided the notification covers the whole of the Health Research and identifies all persons involved in the Health Research. If there is disagreement amongst Employees as to whether notification is to be provided, any individual may provide notification so long as the nature of the disagreement is adequately recorded in the notification.

In no case is an Employee to take steps to apply for any registration of Intellectual Property created in the course of their employment with the NSW Health Service in their own name unless the Intellectual Property has been assigned to them by the Public Health Organisation (see section 3.3).

3.3. Role of the Committee/ Central Support Service on Notification

The Committee/ Central Support Service (as the case may be) must examine and consider all notifications. Where the notification is made directly to the Central Support Service, this notification must be authorised in writing by the Chief Executive of the Public Health Organisation or their delegate.

If a notification does not contain sufficient information about the work, product or process for the Committee/ Central Support Service to properly consider the notification, the Committee/ Central Support Service will inform the notifying Employee or the Intermediary (as applicable) in writing and the Committee/ Central Support Service must provide the notifying Employee or the Intermediary (as applicable) with the opportunity to provide further information to the Committee/ Central Support Service as the Committee/ Central Support Service requests. For the avoidance of doubt:

- an Intermediary may advise the notifying Employee that additional information is likely to be required by the Committee/ Central Support Service and recommend that further steps be taken to rectify the deficiency prior to submission, and
- if the Committee/ Central Support Service concludes that it has insufficient information, and that the notifying Employee is unable, unlikely or unwilling to provide such information, the Committee/ Central Support Service may at its discretion make such enquiries and collate such additional information from other sources but will not be obliged to make a recommendation.

After consideration of each notification, the Committee/ Central Support Service must make a recommendation to the Chief Executive of the Public Health Organisation for their approval as to whether any steps toward protection and/or Commercialisation of Intellectual Property notified to it is to be undertaken.

In deciding whether to make a recommendation as to whether steps are taken towards Commercialisation or protection of Intellectual Property, the Committee/ Central Support Service must refer to and consider the *NSW Health Commercialisation Framework*, as updated from time to time.

The Public Health Organisation's approval is not required for every step of the Commercialisation process. The Public Health Organisation may approve a general Commercialisation strategy, with details of the strategy to be implemented by the Public Health Organisation (or persons employed or engaged by them for that purpose).

Where protection of the Intellectual Property and/or Commercialisation is to proceed, the Committee/ Central Support Service must consult the Creators in relation to appropriate protection, Commercialisation strategies and recommendations.

Prior to taking any step toward protection or Commercialisation, the Committee/ Central Support Service is to ensure that all relevant Creators have been identified. If patent related, this inventorship determination must be completed by a patent attorney if recommended by the Committee/ Central Support Service or in the event of a dispute about inventorship.

Where there is more than one Creator, the Committee/ Central Support Service must obtain as soon as reasonably practicable written confirmation from each Creator, as to each Creator's relative contributions. If there is a dispute as to who is/is not a Creator, the Committee or Central Support Service must engage an external expert to determine the contribution of each party to the creation of the Intellectual Property if the dispute cannot be resolved by the Committee/ Central Support Service in a reasonable timeframe.

If the Public Health Organisation determines that no steps be taken toward protection and/or Commercialisation, including but not limited to the assignment or licencing of the Intellectual Property, the Committee/ Central Support Service are to consider making a further recommendation to the Chief Executive of the Public Health Organisation that:

- the Intellectual Property owned by the Public Health Organisation be assigned to the Creator(s) on appropriate terms and conditions (including any retention by the Public Health Organisation of a share of the Net Commercialisation Proceeds appropriately reflecting the effort and risk taken by the Creator in such Commercialisation), or
- the Intellectual Property be retained by the Public Health Organisation, but that the Creator(s) be allowed to act as agent for the Public Health Organisation solely for the purpose of seeking commercial partners, with the Public Health Organisation agreeing to participate in negotiations with such commercial partners (if found) regarding Commercialisation.

3.4. Formula for distributing proceeds of Commercialisation

Where Intellectual Property developed by an Employee in the course of their employment with NSW Health is commercialised by, or on behalf of, a Public Health Organisation, and such Commercialisation gives rise to income or other Benefits to the Public Health Organisation, the Benefits to the Public Health Organisation shall be dealt with as outlined in

section 4.5 of this Policy. The Public Health Organisation are to deduct all Establishment Costs and Protection Costs expended by the Public Health Organisation as a first call on all Gross Commercialisation Proceeds.

Following deduction by the Public Health Organisation of Establishment Costs and Protection Costs any Net Commercialisation Proceeds will be distributed as follows:

- one third to the Creator(s) of the Intellectual Property
- one third to the department or section of the Public Health Organisation from which the Intellectual Property originated, and
- one third to the Public Health Organisation.

The Public Health Organisation must divide the one third share of Net Commercialisation Proceeds payable to the Creators amongst the individual Creators (if there are more than one) in accordance with the contributions identified by them in the written confirmation. If no such confirmation has been given, the Public Health Organisation must distribute the one third share in accordance with its own reasonable estimate of the relative contributions of each Creator. In making such an estimate, consideration must be given to the role of any Creators who have left the employ or engagement of the Public Health Organisation. The estimate of the Committee/ Central Support Service is to be final and binding on the Creators until such time as an agreement has been reached between them. This must be noted in the written agreement required by section 7.

Monies paid to an Employee by the Public Health Organisation under this Policy must be paid as income.

The eligibility of an Employee is conditional upon the Employee having acted in good faith in accordance with the requirements of this Policy.

4. INTELLECTUAL PROPERTY CREATED BY CLINICAL ACADEMICS AND AFFILIATED UNIVERSITIES

Public Health Organisations and Affiliated Universities are to negotiate fair and equitable agreements as to the rights of the respective parties to the Intellectual Property created in joint facilities or by Clinical Academics or Students, or created using the Resources of the Public Health Organisation. Such agreements must consider:

- the rights of Creators as set out in this Policy
- the rights of Creators as set out in the Affiliated University's policy, and
- the equitable contributions of all parties to the creation of the Intellectual Property.

The default position is that Intellectual Property in such circumstances is to be jointly owned by the Public Health Organisation and Affiliated University on an equal basis unless it can be demonstrated that this would be inequitable.

If the Public Health Organisation and Affiliated University are unable to reach an agreement, the matter can be referred to a Committee/ Central Support Service for determination.

5. INTELLECTUAL PROPERTY CREATED BY VISITORS AND VISITING PRACTITIONERS

5.1. Ownership of Intellectual Property created by Visitors and Visiting Practitioners

The ownership of Intellectual Property created by Visitors or Visiting Practitioners will depend upon the terms of any applicable agreements between the Visitor (or the entity which employs or engages the Visitor), the Visiting Practitioner (or the entity which employs or engages the Visiting Practitioner), whichever the case may be, and the Public Health Organisation.

Where there is no written agreement between the Visitor, the Visiting Practitioner, or his or her respective employer or entity which engages him or her and the Public Health Organisation, Intellectual Property created by Visitors or Visiting Practitioners is owned by the Visitor, the Visiting Practitioner, or his or her employer or entity which engages him or her as the case may be, unless it can be demonstrated that this would be inequitable.

5.2. Agreements with Visitors and Visiting Practitioners regarding Intellectual Property

Where a Visitor or Visiting Practitioner is to use the Resources of a Public Health Organisation to carry out Health Research which may result in the creation of commercially valuable Intellectual Property, it is appropriate for a prior written agreement between the Public Health Organisation and the Visitor or Visiting Practitioner to be entered into prior to the Visitor and/or Visiting Practitioner using the Resources regarding the basis upon which those Resources are used.

Where the Visitor or Visiting Practitioner is an employee of another body (for example, an Independent Research Institute) the agreement will need to be between the Public Health Organisation and that body. Heads of clinical and research departments of Public Health Organisations must ensure that, where Visitors or Visiting Practitioners are utilising the Resources of their department to create potentially valuable Intellectual Property, the issue of an appropriate agreement is raised with the Visitor or Visiting Practitioner and referred to the Committee/ Central Support Service at the earliest opportunity.

The Committee/ Central Support Service must provide advice to the Chief Executive of the Public Health Organisation on appropriate agreements between the Public Health Organisation and Visitors or Visiting Practitioners who utilise the Resources of the Public Health Organisation to conduct work that may result in Intellectual Property. Such advice will include consideration of the NSW Health Research Commercialisation Framework.

The Visitor or Visiting Practitioner (and his or her employer or entity who engaged them, if any) is to be fully informed and consulted by the Committee. Before entering into any agreements with a Public Health Organisation regarding Intellectual Property, Visitors and Visiting Practitioners must be given an opportunity to seek their own legal advice.

6. INTELLECTUAL PROPERTY CREATED BY STUDENTS

The default position is that Students of a Public Health Organisation own the Intellectual Property they create except as otherwise provided in this Policy.

It is only in the following circumstances that the Public Health Organisation must notify the relevant Committee or Central Support Service to determine whether the Public Health Organisation ought to assert ownership over Student-created Intellectual Property:

- the Intellectual Property is created as a result of pre-existing Intellectual Property owned by the Public Health Organisation
- the Intellectual Property has been created by a team within the Public Health Organisation of which the Student is a member
- the Intellectual Property has been created as a result of funding provided by or obtained by, the Public Health Organisation, or
- the Public Health Organisation has an affiliation with the Student's university and the terms of that affiliation directly or indirectly impact the default position on the ownership of Intellectual Property created by the Student.

Heads of research departments and supervisors must be cognisant of any Students undertaking Health Research within their department that may lead to the creation of Intellectual Property and take steps to ensure compliance with this Policy.

The Public Health Organisation must enter into appropriate agreements as to Intellectual Property ownership with the Student as soon as practicable.

Where the Student is a student of an Affiliated University, the Public Health Organisation and the Affiliated University may come to an agreement on how to equitably deal with the Intellectual Property of Students, bearing in mind any claims the Students may have under this Policy and the Intellectual Property policy of the Affiliated University.

7. PAYMENTS

Where a share in the proceeds of Commercialisation of Intellectual Property is to be paid to Creators under this Policy, no monies must be paid by the Public Health Organisation unless the Creator first signs a written agreement with the Public Health Organisation acknowledging:

- that the Creators' rights to receive monies under the agreement is in full and final satisfaction of any rights or entitlement that the Creator has in respect of the Commercialisation of the Intellectual Property
- the Creator is solely responsible and liable for any taxation obligations which may flow from the receipt of those monies, and
- that the Creator has had the opportunity to seek his or her own legal advice in relation to the agreement.

8. INDEPENDENT RESEARCH INSTITUTES RECEIVING RESOURCES FROM PUBLIC HEALTH ORGANISATIONS

Public Health Organisations which provide Resources to Independent Research Institutes must have a written agreement in place with the Independent Research Institutes which makes appropriate arrangements regarding the rights of the Public Health Organisation in relation to Intellectual Property created by the Independent Research Institute when the Independent Research Institute utilises the Resources of the Public Health Organisation.

Such agreements must ensure that the Benefits of Health Research undertaken by such institutes and funded or resourced by the Public Health Organisation are preserved for the public health system.

The Public Health Organisation may seek the advice of a Committee or the Central Support Service in relation to such agreements.

9. COLLABORATIVE RESEARCH AND ARRANGEMENTS WITH THIRD PARTIES

Where Public Health Organisation enter into collaborative Health Research activities or other arrangements with third parties, they must ensure that there is a written agreement between the parties which sets out:

- the rights (if any) of each party to use the Intellectual Property which the other party brings to the project
- the ownership of any Intellectual Property created by the research partners, both individually and jointly
- where valuable Intellectual Property may arise, the rights and obligations of the parties regarding the protection and Commercialisation of the Intellectual Property, and
- the Benefits flowing back to each of the parties with respect to any proceeds of Commercialisation.

Any such agreement must protect the interests of the Public Health Organisation proportionately to its contribution to the research project.

10. CONFIDENTIALITY – PRIOR DISCLOSURE

Where an Employee is in doubt as to whether Health Research may lead to a commercial application or have any possible commercial value, the advice of the Committee or Central Support Service must be sought at the earliest opportunity.

When potential commercially valuable Intellectual Property has been created, no disclosure or publication of such innovation may be made to any third party outside the Public Health Organisation, until appropriate steps have been taken to secure statutory protection.

All conversations within the Public Health Organisation must be conducted on a confidential basis and only with those that are bound by the obligations of confidentiality. Disclosure within the Public Health Organisation must be kept on a “need to know” basis, and all

Committees must have procedures in place to ensure that the confidentiality of information presented to them is preserved.

Where a Creator wishes to make a disclosure relating to an innovation which has potential commercial value (e.g., a publication or a presentation at a scientific conference), the Creator must first seek the written permission of the Committee or Central Support Service. The Committee/Central Support Service must obtain professional advice as to whether the nature of the disclosure will jeopardise Intellectual Property rights and advise the Creator appropriately in writing regarding what disclosures may and may not be made. This advice may include appropriate amendments to the proposed disclosure. Researchers must ensure that the advice of the Committee/ Central Support Service is sought a reasonable time prior to the planned publication or presentation date.

Students must not be prevented from publishing a thesis under this Policy for a period greater than 18 months.

Researchers are not to be prevented from publishing scientific publications for a period of greater than 18 months.

11. TAXATION AND RISK MANAGEMENT

11.1. Taxation matters

Public Health Organisations must comply with any relevant taxation obligations which may flow from the Commercialisation of Intellectual Property and ownership by the Public Health Organisation. Relevant taxation advice may be required to be obtained in this respect.

Employees, Visitors and Visiting Practitioners who receive a share in the proceeds of Commercialisation of Intellectual Property under this Policy are solely responsible for taxation obligations which flow as a result of the receipt of such money and they must obtain their own taxation advice.

11.2. Audit matters

The audit treatment of any monies received as a result of the Commercialisation of Intellectual Property (either by the Public Health Organisation alone, or as a result of collaborative arrangements) must be undertaken in accordance with the [NSW Health *Accounts and audit determination for public health entities in NSW*](#).

11.3. Risk management

In commercialising Intellectual Property, Public Health Organisations are not to incur undue risk of liabilities to the public health system. Legal and risk management advice must be obtained as part of the Commercialisation process.

Approval for incurring any significant risks as part of the Commercialisation process must be obtained from the NSW Ministry of Health's Chief Financial Officer prior to the Commercialisation being commenced.

No monies must be paid by a Public Health Organisation to Creators of Intellectual Property where there are any significant risks outstanding to the Public Health Organisation unless the NSW Ministry of Health's Chief

Financial Officer has given approval in writing. Such approval must only be given on the basis that the risks have been appropriately managed.

11.4. Intellectual Property Arrangements

Any arrangements in relation to Intellectual Property which depart from this Policy must be approved in writing by the Central Support Service.

11.5. Dispute Resolution

Where Public Health Organisations enter into individual agreements for the Commercialisation of Intellectual Property, appropriate dispute resolution procedures must be included in the agreements.

11.6. Dispute resolution under this Policy

Public Health Organisations are to agree on an appropriate dispute resolution process for disputes arising under this Policy. Where Public Health Organisations enter into individual agreements for the Commercialisation of Health Research it is recommended that appropriate dispute resolution procedures are included in the agreement.

12. APPENDICES

1. Implementation checklist and compliance self-assessment
2. Description of Intellectual Property
3. Invention Disclosure Form
4. NSW Health Commercialisation Framework

12.1. Implementation checklist and compliance self-assessment

Organisation / Facility:			
Assessed by:	Date of Assessment:		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Notes:		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Notes:		
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Notes:		
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Notes:		

12.2. Descriptions of Intellectual Property

12.2.1. Copyright

There are three categories of protection under the *Copyright Act 1968* (Commonwealth) being:

- literary, musical, dramatic and artistic works, including adaptations and arrangements of works,
- films, sound recordings, television broadcasts, radio broadcasts, published editions,
- performers' protection (not strictly copyright but included in Copyright Act).

Copyright protection is automatic on the creation of a work. 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. An example of a work created by a Public Health Organisation which may attract copyright may be a manual developed explaining 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. 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 seek to protect the individual Creator's honour and reputation.

12.2.2. Patents

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

12.2.3. Registered Designs

Industrial designs can be protected by registration under the *Designs Act 2003* (Commonwealth). The visual appearance of articles is protected, such as 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. 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.

12.2.4. Trade Marks/ Confidential Information

The relevant legislation is the *Trade Marks Act 1995* (Commonwealth). A trade mark is a sign used to distinguish goods or services dealt with or provided during 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.

12.2.5. 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 Intellectual Property, 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.

12.2.6. Circuit Layout Rights

Circuit layout rights protect original layout designs for computer chips and integrated circuits. The owner of an original circuit layout has the exclusive right to copy and commercially exploit the layout in Australia. Protection is automatic.

12.3. Invention Disclosure Form

CONFIDENTIAL

All information submitted within this disclosure will be treated as confidential. Nothing in this form is to be interpreted as a public disclosure.

Inventor(s)	
Invention conception date	<i>[date that invention was conceived]</i>
Has invention been shown to work in practice?	<i>[Yes/No]</i>
At invention conception date, were all inventors employed by the same organisation?	<i>[Yes/No]</i> <i>[If "No", separate invention disclosure forms must be completed by the other inventors]</i>
Invention Title	
Invention Disclosure	<p>The attached document provides full details of the invention, including:</p> <ul style="list-style-type: none"> (a) Relevant prior art <i>[include description of any current practices that relate most closely to the field of the invention]</i> (b) Problems <i>[indicate what the prior art fails to achieve, where the prior art falls short, and how this is relevant to the invention]</i> (c) Novel features <i>[describe the novel features of the invention, in other words, those features (or combination of features) that are not known in the prior art]</i> (d) Advantages <i>[describe how the invention achieves a technical advantage over the prior art]</i> (e) Proof of principle <i>[describe in detail any technical or experimental details that demonstrate the invention working in practice or the feasibility of its so doing. Include any diagrams, figures, graphs, or tables that illustrate the invention]</i>
Commercial prospects	<i>[How can the invention be exploited by the organisation, generate revenue or provide a competitive advantage?]</i>

DECLARATION

I have read the contents of this Invention Disclosure Record and the attached document(s) and request that it be submitted to and considered by the relevant management of *[name of employer]*

..... (signature)

..... (date)

CONFIDENTIAL

12.4. NSW Health Commercialisation Framework

For the NSW Health Commercialisation Framework, refer to the Office for Health and Medical Research *Intellectual Property and Commercialisation* website.