

NSW Health Pathology Intellectual Property Framework

Intellectual Property Framework

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Intellectual Property Framework

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1. Introduction

NSW Health Pathology is the largest public pathology provider in Australia and operates collection services for community-based doctors and their patients. Our laboratory testing plays a crucial role in timely clinical diagnosis, monitoring therapy and preventing disease in individuals and the community.

We play a major role in teaching undergraduate medical students and in training current and future pathologists and medical scientists.

We are also committed to high quality research which drives innovation. Research and innovation lie at the heart of our efforts to create better health and justice systems. We research new and existing diseases, diagnostic tests and treatments, methods of service delivery and advance how crimes are solved.

We achieve this by collaborating closely with colleagues in universities, medical research institutes, hospitals, industry and other health services to produce translational research that has clinical and forensic applications.

Intellectual property (IP) is the legally recognised outcome of creative effort and economic investment in creative effort. NSW Health Pathology creates, owns and commercialises IP through standard operations. We target initiatives that create better value healthcare and optimise the use of health resources while maintaining the safety and quality of patient experience.

Following are some examples of IP that we produce:

- Novel treatments based on genetic knowledge or new techniques for genetic analysis which improve patient care
- Forensic research into how we can more efficiently and effectively solve crimes and determine the cause of death in some unexplained cases
- The development of innovative biobanking approaches that integrate research, diagnostics and clinical care
- The modification of current protocols to enhance testing capability range or sensitivity and
- The development of information technology systems such as smart device applications.

IP is a significant and valuable asset which needs to be managed in accordance with prudent commercial, financial and ethical practices consistent with the public interest.

2. Objective

The NSW Health Pathology Intellectual Property Framework establishes the system for effectively managing the creation, use, sharing, protection and commercialisation of IP to:

- a) Optimise the economic, social and environmental benefits to the people of NSW
- b) Support our core functions and service delivery outcomes
- c) Encourage research, innovation, invention and service improvement
- d) Identify valuable assets and revenues
- e) Consider IP assets when making strategic and operational decisions
- f) Increase awareness of the assets for which we are responsible and manage those assets in a publicly accountable way
- g) Protect our investment in creative effort
- h) Pursue commercial development of IP where appropriate
- i) Provide clear accountability for the management of significant IP assets
- j) Provide regular reporting to ensure control and accountability for significant IP assets and
- k) Dispose of assets in a transparent way, assess value and ensure probity.

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3. Background

This framework has been developed to support NSW Health Pathology's implementation of key IP legislation, policies and guidelines as follows:

- a) The [Intellectual Property Management Framework for the NSW Public Sector \(C2005-06\)](#) (NSW IP Framework) which sets out the IP principles that require mandatory compliance by NSW Health Pathology staff
- b) The [NSW Audit Office – Management of Intellectual Property Better Practice Guide](#) which provides better practice aims to manage IP efficiently and effectively
- c) The [NSW Health Intellectual Property Arising from Health Research Policy Directive PD2005_370](#) (NSW Health PD2005_370) which governs any IP that arises from health research including laboratory, pre-clinical and clinical research and
- d) Our assets management obligations as set out in the [Public Finance & Audit Act 1983](#), [Public Sector Employment and Management Act 2002](#), [Total Asset Management \(TAM\) Policy](#) and [Annual Reports legislation](#).

4. Scope

This framework is mandatory and applies to:

- a) IP created within NSW Health Pathology including copyright, moral rights, patents, trademarks, designs, circuit layout rights, trade secrets and confidential information and any other IP
- b) IP created by NSW Health Pathology's predecessors and former bodies that now comprise NSW Health Pathology
- c) All NSW Health Pathology staff, students on clinical placement and work experience, visitors, research partners, volunteers and contractors and consultants carrying out work on behalf of NSW Health Pathology.

All staff are expected to have an understanding of their IP responsibilities in respect of both NSW Health Pathology IP and the IP rights of others.

This framework is not a substitute for legal, commercial and/or financial advice if required which would be obtained through the NSW Health Pathology IP Coordinator.

Any or all of the provisions contained in this framework may be amended or revoked at any time.

5. Definition of IP

[NSW Health](#) defines IP as the legally recognised outcome of creative effort and economic investment in creative effort. IP rights are rights to:

- a) The protection of intellectual activity or the protection of ideas and information that have been created
- b) Control the distribution of such activity, ideas or information
- c) Receive benefits from such activities, ideas or information by way of exploitation and commercialisation and
- d) Recognition and acknowledgement.

6. Types of IP

IP is divided into the following types:

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- a) **Copyright and related rights:** Legal protection for people who express ideas and information in certain forms including writing, visual images, music and film
- b) **Moral rights:** Belong to the authors or creators of a wide range of works including literary works (manuscripts, articles, software and databases*), artistic works (photographs, paintings, drawings, maps, architecture and sculpture), dramatic and musical works and film
- c) **Patents:** A right granted for a specified period in relation to a device, substance, method, or process, which is new, inventive and useful
- d) **Trade marks:** Can take the form of a letter, number, word, phrase, sound, smell, shape, logo, picture, aspect of packaging, or any combination of these. It is the right to control the use of a sign and can be registered ® or not registered ™
- e) **Designs:** Visual features of shape, configuration, pattern or ornamentation which give an article its unique appearance, for example, syringe designs
- f) **Circuit layout rights:** Rights to protect original layout designs for integrated circuits and computer chips
- g) **Plant breeder's rights:** Exclusive commercial rights to a registered variety of plant
- h) **Trade secrets:** Confidential information held within a trade or business (for example a process, method, plan or formula) the disclosure of which to a competitor would be liable to cause significant harm to the owner and
- i) **IP and Traditional Knowledge/Indigenous IP:** Agricultural, scientific, technical, ecological, medicinal (including related medicines and remedies), biodiversity-related knowledge and expressions of folklore. It may traverse many forms of IP including copyright, patents and designs.

For more detailed information on the types of IP, relevant legislation, key contacts at a Commonwealth and State level and related policies and websites, please refer to pages 27 to 34 of the [NSW IP Framework](#). * Please refer to pages 8 and 14 for useful scenarios on software and databases.

7. Significant IP

The NSW Government requires NSW Health Pathology to identify and record all “significant IP” that it owns, controls or uses. NSW Health Pathology distinguishes “significant IP” as:

- a) Involving significant investment, direct or in-kind
- b) Having substantial* value to NSW Health Pathology, or substantial value to another organisation, in the outcomes that are generated
- c) Involving significant cost to NSW Health Pathology if the IP is lost or the cost of alternatives to NSW Health Pathology is significant
- d) Resulting in reputational damage if mismanaged and
- e) Important to the operations of NSW Health Pathology for example, reports, diagnoses, research of our staff and services.

* The IP Committee, following the consideration of the utility of the IP, will determine whether the IP is of “substantial value”.

The Chief Executive will determine whether IP is “significant IP”. For further information on the process, please refer to section 10 “Identifying IP” of this framework.

“Significant IP” will be managed by the IP Coordinator. This includes the process of identifying significant IP and recording significant IP.

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8. Identifying and Disclosing IP

Staff, students, visitors, research partners, volunteers and contractors and consultants **must** inform the NSW Health Pathology IP Coordinator of any IP that is created in the course of their duties as follows:

1. Staff must complete the confidential [Intellectual Property Disclosure Form](#) and forward it to the IP Coordinator as soon as IP is created, when anticipated creation is imminent or as soon as it comes to light.

Note: A staff member must not take steps to apply for any registration of IP created in the course of their employment in his or her own name unless NSW Health Pathology has assigned IP to a staff member in accordance with this framework. Examples include lodging a patent application or registering a design.

2. The IP Coordinator will consult and seek additional information as required for example informing the manager of the portfolio area seeking any other legal, commercial or financial advice.
3. The IP Committee will consider all disclosures made in accordance with this framework and in accordance with section 5.2 of the [NSW Health PD2005 370](#).
4. After considering each IP Disclosure, the IP Committee will make a recommendation to the Chief Executive as to whether any steps towards protection and/or commercialisation of IP disclosed should be undertaken in accordance with section 5.3 of the [NSW Health PD2005 370](#).
5. On the recommendation of the IP Committee, the Chief Executive will approve the IP strategy to protect and/or commercialise.
6. If NSW Health Pathology determines that no steps be taken toward protection and/or commercialisation of the IP, the IP Committee will consider making further recommendations to the Chief Executive in accordance with section 5.3.7 and 5.3.8 in the [NSW Health PD2005 370](#) such as:
 - a) The IP be assigned to the creator(s) on appropriate terms and conditions or
 - b) The IP be retained by NSW Health Pathology but that the creator(s) be allowed to act as an agent for NSW Health Pathology.

The IP Coordinator will retain a record of all IP Disclosures.

9. Creating and Acquiring IP Rights

Key Decision Points

In all circumstances in which IP might be created or acquired, ownership of IP must be considered by staff. The key decision points include:

- a) When developing in-house test methodology and protocols
- b) During the feasibility phase or research grant/human research ethics application stage of a program or project ie prior to commencement
- c) Prior to collaborating with external organisations such as a Local Health District, university or research institute on a program or research or commercial project utilising NSW Health Pathology resources and/or staff
- d) At each stage of a project for example business case, status reports, reviews and project completion
- e) Before tenders and bids are called and before contractors or consultants are engaged
- f) Prior to entering into a business relationship with another organisation, supplier, distributor or manufacturer (for example trialing or placing instruments in our laboratories)
- g) Before finalising the employment of a new staff member, contractor or consultant and
- h) As part of a final procurement check at the time goods and services are procured.

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Ownership

Collaborative IP applications through networking with our government, university and industry partners will assist in achieving our strategic objective of encouraging and supporting innovation.

Prior written agreement of the Chief Executive is required in order to use NSW Health Pathology resources outside the course of his or her employment to perform work in the course of creating IP. For further information on how proceeds of commercialisation can be shared between creators, please refer to [NSW Health PD2005 370](#).

In the absence of any written agreement indicating otherwise, all IP created by NSW Health Pathology staff in the course of their employment is owned by NSW Health Pathology. This includes IP that is created by staff through any significant use of the resources of NSW Health Pathology for example funding, other staff, laboratory facilities, equipment and our existing IP. Please refer to [NSW Health PD2005 370](#).

Nothing in this framework detracts from the moral rights conferred on creators under the *Copyright Act 1986*. Moral rights automatically belong to the creator in the absence of an agreement to the contrary.

NSW Health Pathology does not assert ownership of any IP in scholarly books, articles, audiovisuals, lectures or other such scholarly works unless commissioned by NSW Health Pathology. However, NSW Health Pathology may reserve the right to use such works or subject matter generated by our staff.

NSW Health Pathology will take reasonable steps to ensure that the people of NSW have the best opportunity to benefit from IP, whether the ownership of, or rights to, the IP are vested in NSW Health Pathology, a contracted developer, a collaborative developer, a grant recipient or another party.

NSW Health Pathology reserves its right to determine whether IP should be pursued and developed or whether protection such as patents should be obtained. NSW Health Pathology will assist and provide advice to staff in progressing IP protection where required.

Registered and Unregistered IP Rights

IP rights are created in different ways depending on the type of IP. Some examples of registered and unregistered IP are provided below:

- a) Copyright, trade secrets and circuit layout rights are automatic and do not require registration
- b) Patents and designs (including those that are pending) must be registered for the legal rights of ownership to apply
- c) Trade marks do not need to be registered but it is advisable and
- d) Common law provides protection against infringement of trade secrets and for breach of confidentiality agreements.

Acquiring Rights

A considered approach needs to be taken in relation to managing risk and opportunity in determining what IP rights to acquire. Please refer to section 13 Managing Risk.

The IP Coordinator must be contacted about potential or actual commercially exploitable IP.

All decisions in relation to acquiring IP will be made by the Chief Executive on the recommendation of the IP Committee.

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Protecting and Enforcing Rights

Protecting IP normally refers to the registration of particular types of IP. The potential cost of protecting IP is a major consideration when determining whether to protect IP.

Where NSW Health Pathology decides to commercially exploit IP, all necessary and reasonable steps must be taken to ensure the protection of IP.

Enforcing rights means responding to breaches of IP by third parties. The reputational and/or financial cost will assist in determining whether or not to respond to a breach of NSW Health Pathology's rights.

If a breach is suspected, please contact the IP Coordinator. Please refer to section 18 "Resolving IP Issues" in this framework for further information.

Third Party Rights

NSW Health Pathology must take steps to avoid infringing third party IP rights.

Where NSW Health Pathology is unsure whether IP under development may lead to an infringement of third party rights, appropriate searches for trademarks, business and domain names, patents and designs must be conducted. Please refer to the search databases on the [IP Australia](#) website or contact the IP Coordinator for further assistance.

Where NSW Health Pathology is aware that the IP it wishes to use belongs to a third party, the IP Coordinator will obtain written consent. The written consent will be retained on file in the NSW Health Pathology Corporate Office.

10. Confidentiality

All IP is confidential. Unauthorised disclosure may, in some circumstances, breach NSW Health Pathology's statutory confidentiality provisions or privacy obligations, and/or it may destroy the commercial value of the IP asset particularly where disclosure is made prior to publication or commercialisation.

The creators of IP are required to uphold confidentiality. Creators of significant IP may be required to enter into confidentiality agreements to maintain the confidentiality of secret information both during and after employment with NSW Health Pathology. The IP Coordinator will facilitate this process.

Where a creator wishes to make a disclosure relating to a health research innovation which has potential commercial value (for example, a publication or a presentation at a scientific conference), the creator must first seek the permission of the IP Committee. The IP Committee may seek legal advice in relation to whether the nature of the publication will jeopardise patent or other IP rights and advise the creator appropriately regarding what disclosures may and, may not, be made.

All confidential information must return to NSW Health Pathology on termination of the creator's engagement or their agreement for use of NSW Health Pathology resources, unless otherwise agreed.

Please refer to section 13 of the [NSW Health PD2005_370](#) for confidentiality provisions related to the disclosure, registration and commercialisation of health research.

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11. Agreements

NSW Health Pathology may enter into agreements concerning IP rights and ownership. This includes agreements with staff and agreements with external parties.

NSW Health Pathology may also enter into agreements with an external party concerning funding, cost/risk sharing or other arrangements.

Staff must not enter into their own agreements.

Agreements will only be entered on the advice of the IP Committee and with the approval of the Chief Executive.

Should an agreement be required, please contact the IP Coordinator who will facilitate the process.

[NSW Health PD2005_370](#) provides further information on obligations in developing agreements concerning health research IP with:

- Staff (section 5)
- Clinical academics and joint teaching/University facilities (section 6)
- Visitors (section 7)
- Students (section 8)
- Independent research institutes funded by public health organisations (section 10)
- Collaborative research ventures, arrangements with third parties (section 11) and
- Outside bodies (section 12).

12. Commercialisation

IP is commercialised when it is licensed or sold to the public or third parties on a commercial or cost recovery basis. Commercialisation may include:

- a) Licensing or selling compilations of information
- b) Charging a fee for access to an information website
- c) Licensing or selling an IT system and
- d) Developing IP in commercial partnership.

Commercialisation should not dominate or jeopardise NSW Health Pathology's core business.

Decision Criteria

When making decisions about commercialising IP, the following decision criteria must be applied including whether:

- a) The people of NSW will obtain the maximum benefit
- b) It is in the best interest of NSW for the IP to be transferred to another government agency, or private industry, either for a fee, a non-commercial fee or free of charge
- c) The level of government investment warrants ownership or commercialisation
- d) Ownership would fulfill NSW Health Pathology's core functions and [strategic objectives](#)
- e) In the case of IP developed in conjunction with a vendor, if NSW Health Pathology does not claim ownership of IP, the vendor may charge NSW Health Pathology in future for updates or changes to the product and
- f) It will minimise risk to NSW Health Pathology.

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The IP Coordinator will assist in ensuring that commercialisation decisions are based on appropriate legal, financial and commercial IP advice such as:

- [Crown Solicitor's Office](#)
- [NSW Treasury](#)
- [NSW Department of Industry](#)
- [Australian Institute for Commercialisation](#)
- [Ministry of Health](#) and/or
- Advice from IP professionals and other experts.

On the recommendation of the IP Committee, the Chief Executive will approve the commercialisation of IP by NSW Health Pathology.

Distributing Proceeds of Commercialisation of IP

Health Research IP

Where health research IP developed by a staff member is commercialised by or on behalf of NSW Health Pathology, and such commercialisation gives rise to income or other benefits to NSW Health Pathology, the benefits to NSW Health Pathology shall be managed in accordance with section 5.5 of the [NSW Health PD2005_370](#). Any arrangements which depart from [NSW Health PD2005_370](#) must be approved by the NSW Health Secretary.

Other IP

The Chief Executive must approve any agreement in relation to the distribution of the proceeds for IP that is developed by a staff member which arises in the course of any other endeavor. For example, commissioned works - work that is specifically commissioned or contracted by NSW Health Pathology for a fee.

Where a share of proceeds of commercialisation of IP is to be paid to creators, no monies shall be paid unless the creator first signs a written agreement with NSW Health Pathology in accordance with the provisions in section 9 of [NSW Health PD2005_370](#).

13. Managing Risk

In accordance with section 14.3 of [NSW Health PD2005_370](#), the Executive Director, Finance must approve incurring any risks as part of the commercialisation process prior to the commercialisation being commenced.

No monies shall be paid by NSW Health Pathology to creators of IP where there are any extant risks outstanding to NSW Health Pathology unless the Executive Director, Finance has given approval in writing. Such approval shall only be given on the basis that the risks have been appropriately managed.

NSW Health Pathology uses a [risk management approach](#) in considering the risks and opportunities associated IP. The following table identifies some risks and provides guidance on how to manage each risk.

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| Risk | Potential Outcome | How to Manage |
|---|--|---|
| Failure to identify and notify of IP | IP is not protected | Complete NSWHP Disclosure Form |
| Failure to protect confidential IP | Other parties use it inappropriately; Liability for breach of copyright | Actively manage significant IP |
| Failure to protect the integrity and accuracy of copyright material | False, unclear or misleading information being disseminated to the public | Actively manage significant copyright material |
| Rights granted to NSWHP under inappropriate broad license | May result in breach of privacy, public safety, etc | Consider NSWHP IP Framework; Seek legal advice |
| Procurement contract fails to address IP | Dispute regarding ownership and use of pre-existing or resultant IP | Ensure that procurement complies with NSWHP IP Framework |
| Fund research without obtaining access to the resultant IP | Cannot use IP for the purpose of the project; Incur unnecessary costs; Waste of public funding | Ensure that the funding agreement provides for the transfer of resultant IP to NSWHP or includes an appropriate license |
| Contracts do not address pre-existing IP | Other party may be reluctant to utilise pre-existing IP | Contracts should address pre-existing IP |
| Employees moral rights not managed appropriately | Claim for breach of moral rights; Workforce dissatisfaction | Seek moral rights consent in appropriate circumstances |
| Infringement of third party IP by NSWHP | Claim for damages and reputational damage to NSWHP | Monitor and pay for use of third party IP |

These, and other risks, should be considered when assessing IP risks and mitigation plans.

14. IP Register

NSW Health Pathology will record “significant IP” on the NSW Health Pathology IP Register.

The NSW Health Pathology IP Register will also record, in accordance with the Audit Office of NSW recommendations, the following:

- a) Computer programs developed for NSW Health Pathology where the development cost (or replacement cost) exceeds \$10,000
- b) Publications or promotional materials sold or provided free of charge
- c) Databases (that contain IP) maintained by NSW Health Pathology including our Laboratory Information Systems, our online resources (for example test lists) and our reports
- d) Television and radio advertising material developed by or for NSW Health Pathology
- e) Artworks and photographs commissioned by NSW Health Pathology and used in promotional material
- f) Computer programs licensed by NSW Health Pathology
- g) Training materials developed by NSW Health Pathology where the development cost (or replacement cost) exceeds \$10,000
- h) Trademarks or logos used by NSW Health Pathology whether or not they are registered as trademarks or business names and
- i) Patented inventions, registered designs and integrated circuit boards that are created, designed or purchased by or for NSW Health Pathology or for which NSW Health Pathology buys a license.

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The IP Coordinator will compile and maintain the following information on the NSW Health Pathology IP Register:

- Creator
- Name
- Details of IP
- Registration No of IP
- License Details
- Start Date of IP Protection
- End Date of IP Protection
- Funding Agreement
- Comments and Implications.
- Costs Revenue
- Valuations/Assessments
- Details of IP Ownership
- Results
- Technological Medium
- Provisions of Use of IP and
- Other Significant

Executive staff and senior managers will be requested annually to consider and advise the IP Coordinator of any IP which has been created within their area over the previous year that has not already been considered for inclusion on the NSW Health Pathology IP Register.

15. Retaining and Storing IP Records

The IP Coordinator will retain, update and capture on NSW Health Pathology corporate information systems copies of all relevant IP documentation in accordance with the *State Records Act 1998*. This includes, for example, license agreements.

16. Reporting

The IP Register will be reported annually via the IP Committee to the Strategic Leadership Team and Board.

Executive staff and senior managers will be requested annually to consider and advise the IP Coordinator of any IP which has been created within their area over the previous year that has not already been considered for inclusion on the NSW Health Pathology IP Register.

NSW Health Pathology's obligations in relation to accounting for IP assets and reporting will be managed by the Executive Director, Finance.

The IP Coordinator will coordinate all other external IP reporting requirements, for example, to the National Health and Medical Research Council and Therapeutic Goods Administration.

17. Managing Conflicts of Interest

The IP Coordinator will manage potential conflicts of interest concerning ownership, management and exploitation of IP in accordance with:

- a) [NSW Health Conflicts of Interest and Gifts and Benefits Policy Directive PD2015_045](#) and
- b) [NSW Health Pathology Conflicts of Interest and Gifts and Benefits Procedure](#).

The IP Coordinator may carry a higher risk of conflict of interest given the at-risk functions that it fulfills. It may warrant special consideration or require additional advice to manage these risks.

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External Sources

NSW Health Pathology supports staff, students and visitors participation in activities that involve a relationship with the private sector or other organisations.

Staff are not prohibited from receiving financial or in-kind compensation from external sources.

Staff may receive a fee-for-service for presenting seminars, lectures or other teaching forums or receive an honorarium for sitting on committees for example.

Staff must seek prior approval for secondary employment including business interests and undertakings in accordance with the [NSW Health Pathology Conflicts of Interest and Gifts and Benefits Procedure](#).

Disclosure of Affiliations

Staff, students on clinical placement and work experience, visitors, research partners, volunteers and contractors and consultants must disclose any affiliation or financial involvement with any organisation or entity with a direct interest in the subject matter or material of the research or study being undertaken by them, as soon as this affiliation or financial involvement exists.

Conflicts of interest must be declared immediately in accordance with the [NSW Health Pathology Conflicts of Interest and Gifts and Benefits Procedure](#).

18. Resolving IP Issues

Any issues arising in relation to IP should be reported to the IP Coordinator including:

- a) A breach of NSW Health Pathology's IP
- b) A breach by NSW Health Pathology of others' IP
- c) The proposed sale or disposal of IP and
- d) Conflicts of interest.

The IP Coordinator may seek advice including specialist IP legal advice in dealing with the matter.

Where NSW Health Pathology enters into individual agreements, appropriate dispute resolution procedures should be included in the agreement.

19. Roles and Responsibilities

To facilitate the governance of IP management within NSW Health Pathology, this framework establishes key responsibilities for staff as follows:

19.1 Chief Executive

It is the responsibility of the Chief Executive to:

1. Approve protection and/or commercialisation of IP and the appropriate terms and conditions to be retained by NSW Health Pathology
2. Approve “significant IP” to be recorded on the NSW Health Pathology IP Register and
3. Approve agreements regarding IP for visitors who use NSW Health Pathology resources to conduct health research.

19.2 Intellectual Property Committee

It is the responsibility of the Intellectual Property Committee to:

1. Provide strategic advice to the Strategic Leadership Team in relation to developing and supporting IP activity and resourcing of commercialisation in NSW Health Pathology
2. Oversee the implementation of *NSW Health Intellectual Property Arising from Health Research Policy Directive PD2005_370* throughout NSW Health Pathology
3. Receive and assess IP disclosures
4. Make recommendations to the Chief Executive on whether IP is “significant IP”
5. Identify the steps required to protect and/or commercialise IP and make a recommendation to the Chief Executive
6. Identify all relevant creator(s), consult with the creator(s) and approve a protection and/or commercialisation strategy where IP is to be protected and/or commercialised
7. Arrange a written agreement as to the relative contribution of each creator where there is more than one creator
8. Identify, monitor and report potential risks of commercialisation with regard to particular cases
9. Consider agreements regarding IP for visitors who use NSW Health Pathology resources to conduct health research and making a recommendation to the Chief Executive, where appropriate
10. Make a reasonable estimate of the relative contributions of each creator where no NSW Health Pathology agreement has been made to commercialise IP but commercialisation gives rise to income or other benefits
11. Make recommendations to the Chief Executive that the IP be assigned to the creator(s) on appropriate terms and conditions or be retained by NSW Health Pathology
12. Develop processes to ensure that staff are aware and understand the commercial value of IP and know the processes in place for protecting its value
13. Make decisions and conduct the business of the IP Committee in accordance with the provisions of *PD2005_370* and the NSW Health Pathology Intellectual Property Framework
14. Seek expert legal and risk management advice to ensure that all IP is considered in a fair and equitable manner and that undue risk of liabilities is not incurred by NSW Health Pathology
15. Delegate any of its functions, except the function of making recommendations to the Chief Executive regarding protection and commercialisation of IP as it sees fit and
16. Provide advice on any other IP matters.

Note: Another NSW Health Pathology Committee may carry out the IP Committee responsibilities provided that the membership of such a Committee is in accordance with [PD2005_370](#).

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19.3 IP Coordinator

It is the responsibility of the IP Coordinator to:

1. Implement the NSW Health Pathology Intellectual Property Framework and IP management system
2. Act as a point of contact for persons seeking advice on IP matters
3. Establish and protect NSW Health Pathology's IP rights including developing contracts and confidentiality agreements on advice from the IP Committee and other appropriate advice
4. Seek advice from IP specialists on IP protection and commercialisation matters where appropriate
5. Record "significant IP" in the NSW Health Pathology IP Register and report the register to the IP Committee, Strategic Leadership Team and the NSW Health Pathology Board
6. Retain and store all NSW Health Pathology IP documentation within the NSW Health Pathology Corporate Office
7. Resolve IP issues in relation such as infringements and conflicts of interest with appropriate advice
8. Inform relevant staff of developments in IP law that may affect operations and exposure to risk
9. Seek internal or external expert advice in dealing with the matter and
10. Refer all relevant matters to the IP Committee for consideration.

19.4 Executive Director, Finance

It is the responsibility of the Executive Director, Finance to:

1. Provide advice on determining whether IP is "significant"
2. Ensure that obligations in relation to accounting for IP assets and reporting are met.

19.5 Directors and Senior Management

It is the responsibility of directors and senior managers to:

1. Ensure their staff are aware of and comply with this framework
2. Advise the IP Coordinator of any IP created within their areas as it arises
3. Ensure all "significant IP" is recorded in the IP register when prompted and
4. Include advice about IP during the local induction of all new staff.

19.6 All Staff

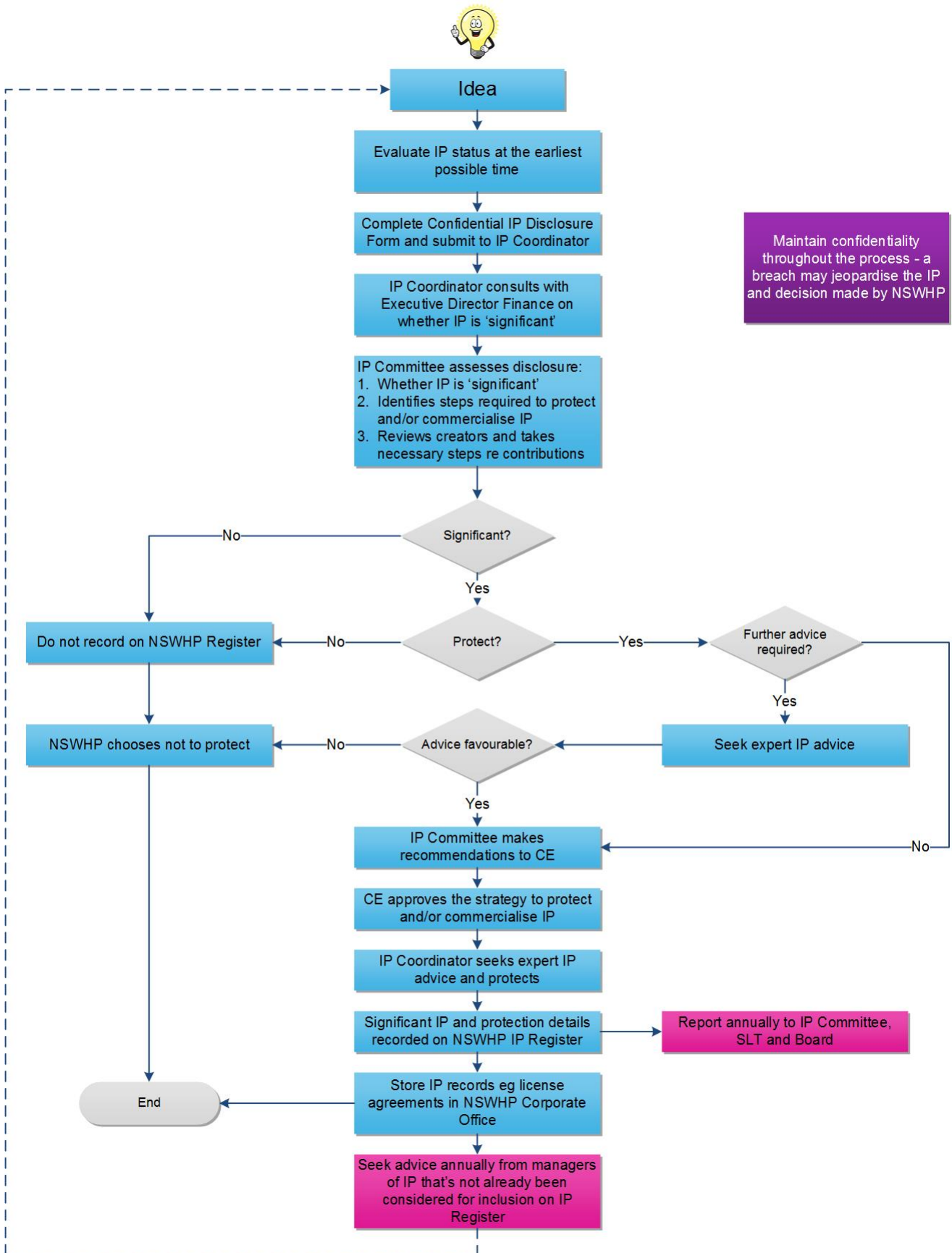
It is the responsibility of all staff to:

1. Comply with the requirements of this framework
2. Evaluate IP status before commencing all programs or projects including for commercial potential
3. Take appropriate steps to avoid the infringement of third party IP including obtaining permission for use when required and moral rights of creators of IP for example by acknowledging correct authorship
4. Maintain confidentiality of unprotected IP
5. Notify the IP Coordinator of work that may lead to the creation of IP
6. Report any IP issues to the IP Coordinator and
7. Retain and store full and accurate records of all activities associated with the development of IP arising from research (including bound laboratory notebooks, prototypes, formulae, data, software code, theses, grant applications, and reports) and commercialisation activities (such as agreements), in accordance with the [State Records Act 1998](#) and other relevant policies.

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20. IP Flowchart



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21. Further Information

Further information in relation to managing IP is available from a range of sources as detailed below:

Consulting

The [Premier's Circular 2004-17 Guidelines for the Engagement and Use of Consultants](#) makes recommendations in relation to the conditions of engagement of contractors including the consideration of ownership of IP.

Information and Communications Technology (ICT)

The [Procure IT Framework](#) includes standard clauses that address IP. NSW Health Pathology can elect on the General Order Form within the Procure IT Framework to vest IP with the agency, on the basis of public interest, exceptional circumstances, or where the agency has undertaken substantial research and development of an ICT product or service and where retention of IP benefits the agency.

In-House Tests

Any in-house test methodology and protocols developed for the purpose of human diagnostics and approved for commercial sale must be accredited by the National Association of Testing Authorities. Additionally, the accredited test must be listed on the Australian Register of Therapeutic Goods in accordance with the [Therapeutic Goods Act 1989](#) and the [Therapeutic Goods \(Medical Devices\) Regulations 2002](#).

Patent Databases

When developing a new product or method, it is important to consider protection of any IP at an early stage of development. To see what already exists, search a patent database:

- [US Patent and Trademark Office](#)
- [European Patent Office](#)
- [World Intellectual Property Organisation](#)
- [Google Patents](#)

Private Sector Proposals

In the case of unsolicited private proposals, the onus is on the private sector parties to identify and detail the IP implications of their proposals. For further information, refer to the [Intellectual Property Guidelines for Unsolicited Private Sector Proposals submitted under Working with Government](#).

Publications

All NSW Health Pathology publications, including internet and intranet sites, should display the NSW Health Pathology [Copyright Statement](#), disclaimers and an acknowledgement of contributors and third party copyright owners. Staff must ensure that publications do not breach: relevant [policies, procedures and guidelines](#) including [confidentiality](#), [privacy](#), other third party IP rights, [freedom of information obligations](#) and [standard labelling and formatting of publications](#).

Tenders and Bids

In relation to managing IP as part of industry engagement in relation to goods and services, please refer to [ProcurePoint](#).

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22. Legislation and Policy

Legislation

[Copyright Act 1968 \(Cth\)](#)

[Copyright Regulations 1969 \(Cth\)](#)

[Designs Act 2003 \(Cth\)](#)

[Designs Regulations 2004 \(Cth\)](#)

[Government Information \(Public Access\) Act 2009 \(NSW\)](#)

[Government Sector Employment Act 2013 \(NSW\)](#)

[Patents Act 1990 \(Cth\)](#)

[Patents Regulations 1991 \(Cth\)](#)

[Public Finance and Audit Act 1983 \(NSW\)](#)

[Public Finance and Audit Regulation 2015 \(NSW\)](#)

[Trade Marks Act 1995 \(Cth\)](#)

[Trade Marks Regulations 1995 \(Cth\)](#)

[Therapeutic Goods Act 1989 \(Cth\)](#)

[Therapeutic Goods \(Medical Devices\) Regulations 2002 \(Cth\)](#)

Policies and Other Relevant Documents

[Australian Government Intellectual Property Principles for Commonwealth Entities](#)

[Intellectual Property Management Framework for the NSW Public Sector \(C2005-06\)](#)

[Intellectual Property Guidelines for Unsolicited Private Sector Proposals submitted under Working with Government](#)

[NSW Audit Office – Management of Intellectual Property Better Practice Guide](#)

[NSW Health Code of Conduct PD2015_049](#)

[NSW Health Intellectual Property Arising from Health Research Policy Directive PD2005_370](#)

[NSW Health Conflicts of Interest and Gifts and Benefits Policy Directive PD2015_045](#)

[NSW Health Pathology Conflicts of Interest and Gifts and Benefits Procedure NSWHP_PCP_001](#)

[Total Asset Management \(TAM\) Policy](#)

[Working with Government Guidelines for Privately Financed Projects, NSW Treasury](#)

[Research Governance in NSW Public Health Organisations GL2011_001](#)

[NSW Health Pathology Intellectual Property Disclosure Form NSWHP-F-00013](#)

23. Review

This framework will be reviewed by 30 June 2019.

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24. Risk

| | |
|-----------------------|---|
| Risk Statement | The NSW Health Pathology Intellectual Property Framework addresses the following risks: <ul style="list-style-type: none">• Failure to optimising the economic, social and environmental benefits to the people of NSW• Not fulfilling our service delivery and service improvement objectives• Non-compliance with relevant legislation with respect to both our own and third party IP rights• Failure to preserve the quality and value of our IP thereby leading to reputational and financial loss and• Minimising legal, reputational and financial risk. |
| Risk Category | Leadership and Management |

25. Contact

For further information, please contact:

| | |
|-------------------------------|---|
| Policy Contact Officer | Position: Executive Director, Strategy and Reform |
| | Name: Vanessa Janissen |
| | Telephone: 02 4920 4039 |
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For further information, please contact:

| | |
|--|---|
| Intellectual Property Coordinator | Position: Intellectual Property Coordinator |
| | Name: Amanda Koegelenberg |
| | Telephone: 02 4920 4033 |
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26. Version History

The approval and amendment history for this document must be listed in the following table.

| Version No | Effective Date | Approved By | Approval Date | Policy Author | Risk Rating | Sections Modified |
|------------|----------------|---|---------------|---|-------------|--|
| V1.0 | 20/07/17 | Transformation Governance Committee | 20/07/17 | Samantha Brookes, Senior Policy Officer | Medium | New Framework. |
| V2.0 | 11/10/17 | Chair Transformation Governance Committee | 11/10/17 | Samantha Brookes, Senior Policy Officer | Medium | Minor update to step 3 wording in the flowchart. |