

Intellectual Property Arising from Health Research - Policy - NSW Department of Health

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Summary States requirements in accounting for intellectual property related to research in the public health system.

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, Public Hospitals

Distributed to Public Health System, Health Associations Unions, Health Professional Associations and Related Organisations, NSW Department of Health, Public Hospitals, Tertiary Education Institutes

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Compliance with this policy directive is mandatory.

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NSW DEPARTMENT OF HEALTH – POLICY ON INTELLECTUAL PROPERTY ARISING FROM HEALTH RESEARCH**Mandatory Policy**

This document states the Department's policy in relation to intellectual property arising from health research. Compliance with this policy is mandatory. The Minister for Science and Medical Research supports the policy. The policy may be amended or revoked from time to time.

Application

The policy applies to all public health organisations, Area Health Services, Statutory Health Corporations and Affiliated Health Corporations in respect of their recognised establishments and recognised services. Health research means laboratory, pre-clinical and clinical research and development in all its forms.

This policy does not apply to intellectual property which arises in the course of any other endeavour. It does not apply to commissioned works, that is, work that is specifically commissioned or contracted by public health organisations for a fee.

The main points of this policy are as follows:

- It requires public health organisations to establish intellectual property (IP) committees to manage their IP interests;
- It requires employees to notify any IP they create in the course of their employment to the committee;
- It sets up structures to deal with managing IP created by visitors (including visiting practitioners and conjoint employees such as clinical academics);
- It allows for the proceeds of the commercialisation to be shared between the creator(s) of the IP, the department or section of the public health organisation which originated the IP, and the public health organisation on a 1/3, 1/3, 1/3 basis.

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Director-General

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In accordance with the provisions incorporated in the Accounts and Audit Determination, the Board of Directors, Chief Executive Officers and their equivalents, within a public health organisation, shall be held responsible for ensuring the observance of Departmental policy (including circulars and procedure manuals) as issued by the Minister and the Director-General of the Department of Health.

**NSW DEPARTMENT OF HEALTH
POLICY ON INTELLECTUAL PROPERTY
ARISING FROM HEALTH RESEARCH IN
PUBLIC HEALTH ORGANISATIONS**

July 2004

**NSW DEPARTMENT OF HEALTH
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**NSW DEPARTMENT OF HEALTH
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ARISING FROM HEALTH RESEARCH IN
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1. Introduction

1.1 This policy recognises the value of *health research* undertaken within public health organisations. It 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. Occasionally, the outcomes of *health research* may have a significant commercial value. The objectives of this policy are to:

- encourage *health research* in the public health system and the acquisition and dissemination of knowledge and skills;
- 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 public health organisations.

2. Definitions

2.1 Intellectual property as it should be understood in this policy is the legally recognised outcome of creative effort and economic investment in creative effort. IP rights are rights to:

- the protection of intellectual activity or the protection of ideas and information that have been created;
- control the distribution of such activity, ideas or information;
- receive benefits from such activities, ideas or information by way of exploitation and commercialisation;
- recognition and acknowledgement¹.

Intellectual property in a broad sense includes:

- 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 for registration of trademarks;
- get-up and trade dress associated with products and services;

¹ Performance Audit Report, Management of Intellectual Property, Audit Office of New South Wales, 2001.

- 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.

A brief description of some forms of intellectual property and the nature of intellectual property rights is to be found at Attachment A.

2.2 This policy also uses other defined terms set out below.

“Health research” means laboratory, pre-clinical and clinical research and development in all its forms. This includes:

- development of treatment procedures and methods;
- development of equipment or other goods which may have application in a clinical setting or a public health application;
- biomedical research;
- research and development of pharmaceuticals; and
- epidemiological and research methods.

“Committee” means an Intellectual Property Committee constituted in accordance with section 4 of this policy.

“Creator” in relation to any intellectual property means an employee(s) who made a significant contribution to the creation or invention of the subject matter (eg the work, product or process) in which the intellectual property subsists, or a visitor(s) or student(s) who made a significant contribution to the creation or invention of the subject matter (eg 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.

“Establishment costs” in relation to intellectual property means any costs paid by the public health organisation to establish and develop the intellectual property for protection or commercialisation, once it has been determined by the public health organisation that commercialisation of the intellectual property should take place. Establishment costs do not include costs that the public health organisation would normally have incurred in carrying out the research as its core function, for example, the costs of employing/retaining the *creators* in their regular capacity or providing infrastructure for medical research. Examples of establishment costs would include:

- 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 joint venture agreements,

- licence agreements or assignments, or providing advice on the commercialisation of the intellectual property; and
- any taxes, or similar outgoings to third parties.

“Gross commercialisation proceeds” means all amounts receivable in consideration of the assignment or licensing of intellectual property rights. These amounts may be lump sum payments made up-front or periodically, or may be in the nature of royalties payable on the happening of future events such as product sales.

“Net commercialisation proceeds” means gross commercialisation proceeds received by the public health organisation, less establishment costs and protection costs.

“Protection costs” in relation to intellectual property 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, and legal and patent attorney's fees expended in the course of obtaining protection.

“Visitor” means:

- any person providing services at a public health organisation other than as an employee in either a remunerated or honorary position (for example, visiting practitioners, visiting medical officers, honorary medical officers);
- any person (other than a student) not employed by a public health organisation who utilises the resources of a public health organisation at any time (for example, a visiting researcher).

3. Application

- 3.1 This policy applies to all public health organisations within the meaning of the Health Services Act 1997 (Area Health Services set out in Schedule 1 of the Act, statutory health corporations set out in Schedule 2 of the Act, and affiliated health organisations in respect of their recognised establishments and recognised services set out in Schedule 3 of the Act).
- 3.2 This policy applies to intellectual property which arises, or may arise, from *health research*. It does not apply to intellectual property which arises in the course of any other endeavour.
- 3.3 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.
- 3.4 All public health organisations which are involved in *health research* must have an intellectual property policy which is consistent with this policy. A public health organisation is involved in *health research* if:
- any of its employees or *visitors* carry out *health research*; or
 - it is a party to any agreements, arrangements or collaborations with other

bodies to carry out *health research*.

3.5 A copy of the intellectual property policy of the public health organisation must be provided to:

- all current employees and *visitors* who are, or may be, engaged in *health research*;
- all new employees who will be, or may be, engaged in *health research*, at the commencement of their employment;
- all *visitors* and students who will be, or may be, engaged in *health research* at the commencement of their association with the public health organisation.

The policy which is provided to the individuals listed above, must contain a clear statement to the effect that any or all of the provisions contained in the policy, including provisions relating to the sharing of any proceeds from the commercialisation of intellectual property, may be amended or revoked at anytime.

4. Intellectual Property Committee

4.1 Establishment

Each public health organisation involved in *health research* shall have an Intellectual Property Committee. Some public health organisations which do not undertake a significant amount of *health research* may:

- agree to utilise the *Committee* of another public health organisation;
- may constitute an ad hoc committee from time to time; or
- utilise an existing committee to carry out the IP Committee's functions, such as the research committee, provided that the membership of such a committee is in accordance with this policy.

4.2 Composition

4.2.1 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 is to include:

- the Chief Executive Officer or a senior executive nominated by the Chief Executive Officer;
- the Director Finance of the organisation or senior financial employee nominated by the Director Finance;
- a senior officer in charge of research within the organisation (except that such a senior officer shall not participate in the making of recommendations in relation to research in which he or she is directly involved or has an interest); and
- a person designated by the CEO of the public health organisation.

- 4.2.2 Specialist legal advice should be available to the *Committee*, either by having a legal adviser as a member, or by seeking advice as appropriate. Public health organisations may wish to include members with expertise in commercialising intellectual property.
- 4.2.3 The *Committee* shall 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.
- 4.2.4 Public health organisations may also have staff who are responsible for intellectual property matters within the organisation, such as IP identification, education, encouragement etc. Such staff may be members of the *Committee*.

4.3 Functions

- 4.3.1 The functions of the *Committee* shall include the receipt and consideration of notifications, the provision of advice, and the making of recommendations to the CEO of the public health organisation as set out in this policy. The *Committee* shall also act as a resource for staff on intellectual property matters, particularly in relation to the provision of advice on prior disclosure (see section 13).
- 4.3.2 The *Committee* may delegate any of its functions, except the function of making recommendations to the CEO of the public health organisation regarding protection and commercialisation of intellectual property.

4.4 Records

- 4.4.1 The proceedings of the *Committee*, and any records of those proceedings, shall be treated as commercial in confidence, in so far as they relate to the organisation's intellectual property interests. See section 13 on prior disclosure.

5. Intellectual property created by employees

5.1 Ownership of intellectual property created by employees.

- 5.1.1 As is the case under the general law, this policy mandates that all intellectual property created by employees of a public health organisation in the course of their employment, is owned by the public health organisation.
- 5.1.2 For the purposes of this policy, intellectual property which is created by an employee through any significant utilisation of the resources of the organisation (eg, funding, other employees, laboratory facilities, equipment, existing intellectual property of the organisation) is taken to be intellectual property created in the course of the employee's employment. This shall be the case unless the employee has the prior written agreement of the Chief Executive Officer to utilise the organisation's resources outside the course of his or her employment to perform the work in the course of which the intellectual property was created.

5.1.3 Public health organisations are not to assert ownership of any intellectual property in scholarly books, articles, audiovisuals, lectures or other such scholarly works (unless commissioned by the public health organisation). However, public health organisations may reserve the right to use such works or subject matter generated by employees.

5.1.4 Nothing in this policy shall be taken to detract from the moral rights conferred on creators under Part X of the Copyright Act 1968.

5.2 Notification by employees of intellectual property

5.2.1 An employee of a public health organisation is to notify the *Committee* as early as possible of the creation, or anticipated imminent creation, of any work, product or process as a result of, or in the course of, *health research* undertaken in the course of the employee's employment which may have, or which the employee believes may have, commercial application.

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

- the work, product or process in detail;
- each person 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 in the course of which the work, product or process was created; and
- any known details as to the likely commercial significance of the work, product or process.

5.2.3 Notifications are to occur whether the employee is carrying out the research alone or with other employees, or as part of a collaborative research project with *visitors* or persons from other organisations.

5.2.4 Only one notification need be made where the research is being carried out by more than one employee, or by employees from different areas of the organisation, provided the notification covers the whole of the research and identifies all employees and other persons involved in the research.

5.2.5 In no case is an employee to take steps to apply for any registration of intellectual property created in the course of their employment in his or her own name (eg file a patent application, or lodge an application for registration of a design etc), unless the intellectual property has been assigned to him or her by the public health organisation in accordance with this policy (see paragraph 5.3.7).

5.3 Role of the Committee on notification

5.3.1 The *Committee* shall examine and consider all notifications under paragraph 5.2. If a notification does not contain sufficient information about the work, product or process for the *Committee* to properly consider the notification, the notifying employee shall provide to the *Committee* such further information as the *Committee* requests.

- 5.3.2 After consideration of each notification, the *Committee* shall make a recommendation to the CEO of the public health organisation as to whether any steps toward protection and/or commercialisation of intellectual property notified to it should be undertaken. Such recommendation should be made in a timely manner without undue delay. Recommendations as to protection and commercialisation may not be made at the same time, or be decided upon at the same time. A recommendation may be made to take steps to protect the intellectual property, pending a later consideration and recommendation as to commercialisation.
- 5.3.3 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 engaged by them for that purpose).
- 5.3.4 Where protection and/or commercialisation is to proceed, the *Committee* shall consult the *creators* in relation to appropriate protection and commercialisation strategies.
- 5.3.5 Prior to taking any step toward protection or commercialisation, the *Committee* is to ensure that all relevant *creators* have been identified.
- 5.3.6 Where there is more than one *creator* the *Committee* shall elicit as soon as possible a written agreement from each *creator* as to the relative contribution of each of them to the creation of the intellectual property.
- 5.3.7 If the public health organisation determines that no steps be taken toward protection and/or commercialisation of the intellectual property, the *Committee* is to consider making a further recommendation to the public health organisation that:
- the intellectual property 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 proceeds of commercialisation* 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.
- 5.3.8 The appropriate recommendation will depend upon the circumstances of the case and the *creator* should be consulted in this regard.

5.4 *Distribution of proceeds of commercialisation*

- 5.4.1 Where intellectual property developed by an employee 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 5.5.

5.5 Formula for distributing proceeds of commercialisation

- 5.5.1 The public health organisation shall deduct all *establishment costs* and *protection costs* expended by the public health organisation as a first call on all gross commercialisation proceeds.
- 5.5.2 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 which originated the intellectual property; and
 - one third to the public health organisation.
- 5.5.3 The public health organisation shall divide the one third share of *net commercialisation proceeds* payable to the *creators* amongst the individual *creators* in accordance with the contributions identified by them in the agreement referred to in paragraph 5.3.6. If no such agreement has been made, the public health organisation shall 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 should be given to the role of any *creators* who have left the employ of the public health organisation. The estimate of the *Committee* shall be final and binding on the *creators* until such time as an agreement has been reached between them. This must be noted in the deed of release which is required by paragraph 9.1.
- 5.5.4 Monies paid to employees under this policy shall be paid as income.
- 5.5.5 The eligibility of an employee under section 6 is conditional upon the employee having acted in good faith in accordance with the requirements of the intellectual property policy of the public health organisation.

6. Clinical academics and joint teaching hospital/University facilities

- 6.1 Significant issues arise in relation to intellectual property created by clinical academics, who work in both the University sector and the public hospital sector. Both the relevant university and the public health organisation are likely to have contributed significantly to the remuneration of the clinical academic, as well as providing the clinical academic with resources, support and infrastructure. It will not always be possible to determine which resources were utilised in the creation of intellectual property by clinical academics.
- 6.2 Similar issues arise in relation to joint teaching hospital/University facilities, where health research may be undertaken jointly by a mixture of University and hospital staff.

- 6.3 It is in the interests of both universities and public health organisations that issues regarding intellectual property created by clinical academics and at joint facilities be clarified as early as possible in the identification/protection/commercialisation process.
- 6.4 Public health organisations which have affiliations with universities are encouraged to negotiate fair and equitable agreements as to the rights of respective parties to the intellectual property created in joint facilities or by clinical academics. Such agreements should take into account the rights of *creators* as set out in both this policy and the university policy, and the equitable contributions of all parties to the creation of the intellectual property.

7. Intellectual property created by visitors

7.1 Ownership of intellectual property created by visitors

- 7.1.1 The ownership of intellectual property created by *visitors* will depend upon the terms of any agreements between the *visitor* (or the *visitor's* employer) and the public health organisation. In general, however, intellectual property created by *visitors* is owned by the *visitor* or his or her employer (subject to any applicable agreements).

7.2 Agreements with visitors regarding intellectual property

- 7.2.1 Where a *visitor* is to use the resources of a public health organisation to carry out research which may result in the creation of commercially valuable intellectual property, it is appropriate for a prior written agreement to be reached regarding the basis upon which those resources are used. Where the *visitor* is an employee of another body (for example, an independent research institute or a practice company) the agreement will need to be between the public health organisation and that body. Heads of clinical and research departments of public health organisations should ensure that, where *visitors* are utilising the resources of their department to create potentially valuable intellectual property, the issue of an appropriate agreement is raised with the *visitor* and referred to the *Committee* at the earliest opportunity.
- 7.2.2 The *Committee* shall provide advice to the CEO of the public health organisation on appropriate agreements between the public health organisation and *visitors* who utilise the resources of the public health organisation to conduct *health research*.
- 7.2.3 Appropriate agreements may include an assignment of intellectual property by the *visitor* to the public health organisation on certain terms and conditions, or may include terms under which the public health organisation receives a share of the income of commercialisation of the intellectual property. Whether such terms are appropriate will depend upon a number of factors, including:
- the extent and nature of the research;
 - the use of the resources of the public health organisation;
 - the source of funding of the research;
 - the involvement of other public health organisation staff; and
 - any other relevant factors.
- 7.2.4 The *visitor* (and his or her employer, if any) is to be fully informed and

consulted by the *Committee* when it considers these issues. Before entering into any agreements with a public health organisation regarding intellectual property, *visitors* should be given an opportunity to seek their own legal advice.

8. Intellectual property created by students

8.1 Students may be involved in health research utilising a range of resources of the public health organisation. Generally, public health organisations should not claim ownership over intellectual property created by students. However, it may be appropriate for public health organisations to assert rights over intellectual property created by students in the following circumstances:

- the intellectual property has been created utilising substantial resources of the public health organisation;
- 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 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.

8.2 Heads of research departments should be cognisant of any students undertaking health research within their department that may lead to the creation of valuable intellectual property. Appropriate agreements as to ownership should be concluded at that time, considering the same matters as set out in paragraph 7.2.3.

8.3 Where the student is a student of a University with which the public health organisation has an arrangement under paragraph 6.4, the public health organisation and the 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 University.

9. Payment of monies under this policy.

9.1 Where a share in the proceeds of commercialisation of intellectual property is to be paid to *creators* under this policy, no monies shall be paid 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;
- his or her responsibility for any taxation obligations which may flow from the receipt of those monies; and
- that he or she has had the opportunity to seek his or her own advice in relation to the agreement.

9.2 Such agreements should not be signed or accepted by the public health organisation unless it appears to the public health organisation that the *creator* has been given an opportunity to seek his or her own advice in relation to the agreement.

10. Independent research institutes funded by public health organisations

10.1 *Ownership of intellectual property created by independent research organisations.*

10.1.1 Public health organisations may house, or be associated with, independent research institutes which carry out *health research*. Public health organisations may support or resource the development of *health research* by such institutes in a number of ways, including through the provision of research and administrative staff, infrastructure and equipment, or direct funding. Where such institutes are independent legal entities, they will, generally speaking, be the owners of any intellectual property created by their employees (subject to the terms of the Institute's constitution and any applicable agreements).

10.2 *Agreements with independent research institutes*

10.2.1 Public health organisations which provide substantial resources to independent research institutes should have in place agreements with the institute which make appropriate arrangements regarding the rights of the public health organisation in relation to intellectual property created by the institute, utilising the resources of the public health organisation.

10.2.2 Such agreements should ensure that the benefits of research undertaken by such institutes and funded or resourced by the public health organisation are preserved for the public health system. This may be achieved in a variety of ways including (but not limited to):

- provisions whereby the public health organisation is the owner of intellectual property generated by the institute utilising the resources provided by the public health organisation; or
- obtaining for the public health organisation a share of the proceeds flowing from the commercialisation of any intellectual property created by the institute utilising resources provided by the public health organisation; or
- ensuring that all proceeds flowing to the institute from the commercialisation of intellectual property are preserved for the continuing research of the institute.

10.2.3 The advice of the *Committee* may be sought in relation to such agreements.

11. Collaborative research, joint ventures, arrangements with third parties

11.1 Public health organisations may create intellectual property in conjunction with other organisations in the public or private sector, for example, under collaborative research projects or joint venture arrangements for specific research and development projects. The ownership of intellectual property

which arises from such ventures will depend upon the contractual arrangements between the parties.

- 11.2 Where public health organisations enter into collaborative research activities, joint ventures, or similar arrangements with third parties, the public health organisation should 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;
 - the benefits flowing back to each of the parties with respect to any proceeds of commercialisation.
- 11.3 Any such agreement should protect the interests of the public health organisation proportionately to its contribution to the research project.
- 11.4 The public health organisation should obtain legal advice regarding proposed agreements on joint ventures and collaborative research projects.
- 11.5 The requirements of the Public Authorities (Financial Arrangements) Act 1987 in relation to joint ventures must be complied with (including the requirement that joint venture arrangements have the Treasurer's approval).

12. Commercialisation by outside bodies

- 12.1 It is recognised that public health organisations may not have the expertise to undertake commercialisation of their intellectual property, and will contract with a third party to do so on their behalf.
- 12.2 Arrangements of this kind will vary in their terms and conditions, and may or may not involve the following aspects:
- Assignment of the intellectual property to the commercialising entity;
 - Provisions for profit sharing with *creators* (rather than relying on the intellectual property policy of the public health organisation).
- 12.3 Where such arrangements are entered into, the public health organisation should ensure that the return to the organisation is equitable, and that any profit sharing arrangements with employees do not disadvantage employees by providing a lesser entitlement than that envisaged by this policy. The advice of the *Committee* may be sought in relation to such arrangements.

13. Need for confidentiality – prior disclosure

- 13.1 Much *health research* does not, and is not intended to, lead to commercial application. Researchers, however, should be cognisant of the possibility of research leading to a commercial application. Where a researcher is in doubt

as to whether research may lead to a commercial application or have any possible commercial value, the advice of the *Committee* should be sought at the earliest opportunity.

- 13.2 The confidentiality provisions set out below do not apply to research which does not have a potential commercial application or commercial value. This policy is not intended to unnecessarily restrict the flow of information in the course of collaboration and communication between researchers and practitioners which this policy recognises is essential in *health research*.
- 13.3 Where it is considered that commercially valuable intellectual property has been created (in particular, patentable innovations, know-how or other secret information) it is critical that no disclosure, or publication of such innovation be made to any third party outside the public health organisation, until appropriate steps have been taken to secure statutory protection. Disclosure within the public health organisation should 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.
- 13.4 Prior publication of an innovation can be fatal to the ability to obtain a patent, as it may lead to the loss of “novelty” of an invention, a prerequisite for the granting of a patent. Prior publication can be fatal to a patent, whether the publication is made in Australia or overseas. Prior publication may include verbal and written disclosures made in any forum. The presentation of papers at scientific conferences, the publications of papers in peer journals, and the discussion of the innovation or aspects of it with colleagues who are not under obligations of confidentiality will generally constitute prior publication.
- 13.5 Where a *creator* wishes to make disclosure relating to an innovation which has potential commercial value (eg, a publication or a presentation at a scientific conference), the *creator* must first seek the permission of the *Committee*. The *Committee* can obtain legal advice as to whether the nature of the publication will jeopardise patent or other intellectual property rights, and advise the *creator* appropriately regarding what disclosures may and may not be made. This advice may include appropriate amendments to the proposed publication or presentation. Researchers should ensure that the advice of the *Committee* is sought a reasonable time prior to the planned publication or presentation date.
- 13.6 Public health organisations must ensure that advice on prior disclosure is provided in a timely manner, so as not to unnecessarily prejudice appropriate publication of research results. Students should not be prevented from publishing a thesis under this policy for a period greater than two years.

14. Miscellaneous

14.1 Taxation matters

- 14.1.1 Public health organisations should ensure that they comply with any relevant taxation obligations which may flow from the commercialisation of intellectual property. Relevant taxation advice may be required in this respect.

14.1.2 Public health organisations should inform employees or *visitors* who receive a share in the proceeds of commercialisation of intellectual property under this policy that taxation obligations which flow as a result of the receipt of such money are a matter for them and that they should obtain their own taxation advice.

14.2 Audit matters

14.2.1 The audit treatment of any monies received as a result of the commercialisation of intellectual property (either by the Area alone, or as a result of a joint venture or similar arrangement) must be undertaken in accordance with the Department's Accounts and Audit Determination for Area Health Services and Public Hospitals.

14.3 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 risks as part of the commercialisation process must be obtained from the Department's Chief Financial Officer prior to the commercialisation being commenced. No monies shall be paid by a public health organisation to *creators* of intellectual property where there are any extant risks outstanding to the public health organisation, unless the Chief Financial Officer has given approval in writing. Such approval shall only be given on the basis that the risks have been appropriately managed.

14.4 Variations from this policy

- Any arrangements in relation to intellectual property which depart from this policy must be approved in writing by the Director-General (or delegate). Such variations include:
- Any profit sharing arrangement which involves employees sharing in commercialisation other than by payment of monies (eg through equity in a start-up company);
- Any profit sharing arrangement that involves creators sharing the proceeds of commercialisation in greater share than envisaged in Para 5.5.2.

14.5 DISPUTE RESOLUTION

Public health organisations should 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.

15. Review of this policy

- 15.1 It is proposed that this policy be reviewed within a reasonable period after its implementation by the Department of Health. Comments on the operation of this policy by public health organisations are encouraged.

ATTACHMENT A: DESCRIPTIONS OF INTELLECTUAL PROPERTY

This guide is designed to provide a simple outline of some types of intellectual property. It is not intended to be a comprehensive legal guide. The advice of the Committee should be sought for a more detailed understanding.

1. Copyright

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

- a) literary, musical, dramatic and artistic works, including adaptations and arrangements of works;
- b) films, sound recordings, television broadcasts, radio broadcasts, published editions;
- c) 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 through health research which may attract copyright would 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.

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 Commonwealth Patents Act 1990. 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.

3. Registered Designs

Industrial designs can be protected by registration under the Commonwealth Designs Act 1906. The visual appearance of articles is protected – a distinctive shape, configuration, ornamentation or pattern. This protection may protect a design in relation to all sorts of items eg 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.

4. Trade Marks

The relevant legislation is the Commonwealth Trade Marks Act 1995. A trade mark is a sign used to distinguish goods or services dealt with or provided in the course of trade by a person from goods or services so dealt with or provided by any other person. Trade marks include letters, words, names, signatures, numerals, devices, brands, headings, labels, tickets, aspects of packaging, shape, colour, sound, scent or any combinations, eg "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.

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.

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.