

Interim Guidelines

**Intellectual Property Management
for
Health and Medical Research**



NHMRC

National Health &
Medical Research Council

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The strategic intent of the National Health and Medical Research Council is to provide leadership and work with other relevant organisations to improve the health of all Australians by:

- fostering and supporting a high quality and internationally recognised research base;
- providing evidence based advice;
- applying research evidence to health issues thus translating research into better health practice and outcomes; and
- promoting informed debate on health and medical research, health ethics and related issues.

NHMRC web address: <http://www.nhmrc.gov.au>

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FOREWORD

The rapid development of science and technology, especially the emergence of modern biotechnology, provides Australia with an unprecedented opportunity to use its strong position in health and medical research to build knowledge-based industries that can compete in the global knowledge economy. Commercial exploitation of research findings benefits the economy through employment growth and national wealth generation, as well as being an essential step in the delivery of new drugs or health treatments to the community. It also presents new challenges for the research community to participate in the cultural change that is needed to position Australia to capture the benefits from the generation and diffusion of knowledge and technology.

Knowledge and research findings have become the most important resources, and the key elements, in this new business paradigm of commercial development. The Government strategic policy direction to reinforce research investment and commercialisation is clearly reflected in a number of recent reports and discussion papers, including, the *Health and Medical Research Strategic Review* (the Wills Report)¹; the *Knowledge and Innovation: A policy statement on research and research training* (the White Paper)²; the Science Capability Review *Chance to Change*³; the Innovation Summit Implementation Committee's final report *Innovation: Unlocking the Future*⁴ and *Backing Australia's Ability: an innovation action plan for the future*⁵. To ensure Australia captures the benefits of publicly funded health and medical research, it is essential to have the skills and appropriate mechanisms to identify, value, protect, develop and commercialise these resources. Thus, the good management of intellectual property (IP) becomes one of the most critical steps in the translation of research into national wealth.

NHMRC is in a unique position to play a leadership role in the development of a framework for the management and exploitation of IP in the health and medical research sector in Australia, through its high profile and reputation in the research community and its leverage as the main public funding provider for the sector.

NHMRC will continue to support the best health and medical research in the national interest to achieve its goal of improving the health and wellbeing of all Australians, irrespective of the commercial potential of the research. NHMRC does not wish to hold a stake in direct ownership of IP nor does it intend to benefit directly from commercial outcomes of NHMRC funded research. Rather, the purpose of developing Guidelines for IP management is to assist NHMRC funded researchers and their administering institutions, in ensuring that they have access to best practices for the identification, protection and management of IP, and therefore, to maximise the benefits and returns of public investment in health and medical research.

The Guidelines are presented in three parts. The first is background relating to IP in the context of NHMRC's role as a major funder for health and medical research in Australia. The second is the Principles for IP Management and the third is a set of Appendices that provide additional information and guidance for the administering institutions (Appendix 1) and for researchers (Appendix 2), to assist them in

managing their own IP in the context of their institution's detailed strategies and NHMRC's requirements.

The Interim Guidelines are expected to undergo further revision following the completion of the National Principles of IP Management for Publicly Funded Research, a joint initiative of the NHMRC and other agencies⁶. It is acknowledged that, transitional arrangements will be required to assist institutions in bringing their policies and procedures into line with the Guidelines.

¹ The Health and Medical Research Strategic Review: *The Virtuous Cycle: Working together for health and medical research*. Commonwealth of Australia, 1999

² Knowledge and Innovation: A policy statement on research and research training. Commonwealth of Australia, 2000

³ Australian Science Capability Review: *The Chance to Change*. Commonwealth of Australia, 2000

⁴ Innovation: *Unlocking the Future*. Commonwealth of Australia, 2000

⁵ *Backing Australia's Ability*: an innovation action plan for the future. Commonwealth of Australia, 2001

⁶ National Principles of IP Management for Publicly Funded Research Working Group: the Australia Research Council (ARC), the National Health and Medical Research Council (NHMRC), the Australian Vice-Chancellors' Committee (AVCC), the Department of Education, Training and Youth Affairs (DETYA), the Department of Industry, Science and Resources (ISR), the Australian Tertiary Institutions Commercial Companies Association (ATICCA), and IP Australia.

1. INTRODUCTION

1.1 WHAT IS INTELLECTUAL PROPERTY (IP)?

IP is generally regarded as representing ‘... *the property of your mind or intellect*’⁷
Methods for the protection and exploitation of IP include, but are not limited to:

- **patent** for new or improved products or processes;
- **copyright** for original material in literary, artistic, dramatic or musical works, and in other works that include films, broadcasts, multimedia and computer programs;
- **trade mark** for words, symbols, pictures, sounds, smells or a combination of these, to distinguish the goods and services of one trader from those of another;
- **design** for the shape or appearance of manufactured goods;
- **circuit layout right** for the 3-dimensional configuration of electronic circuits in integrated circuit products or layout designs;
- **plant breeder’s right** for new plant varieties;
- **trade secret** including know-how, other confidential or proprietary information and background knowledge.

Many of the major issues concerning IP relate to the inventor’s and/or owner’s legal rights to exploit this property exclusively. Many of these issues, at least in the context of the university environment, have been canvassed in detail by the AVCC⁸.

Certain types of IP require registration with a relevant Government agency eg. patents, trademarks and designs. Other IP, such as copyright, does not, even though the rights associated with it are strongly established by legislation and legal precedent. Still other types of IP, eg. trade secrets and know-how, can be protected only under Common Law.

⁷ IP Australia (2000)

⁸ Australian Vice-Chancellors’ Committee, *Ownership of Intellectual Property in Universities* 1995 (under review).

1.2 WHICH OF THESE CATEGORIES IS RELEVANT TO NHMRC SUPPORTED RESEARCH?

In the context of NHMRC supported research, IP of most relevance would be generally related to patent, copyright and 'trade secret'. Of these, that which has the greatest potential for a positive economic outcome is patent, with some 'blockbuster' drugs and developments having multi-million dollar sales. Specific 'tools', such as antibodies, probes, cell lines etc that are generated in the course of some research programs are an area of additional importance and potential value. Patents and 'materials transfer agreements' can be used to protect these 'tools'. The value and importance of 'know how', upon which much of an individual's success in attracting future grants is based, cannot be estimated easily. It could be argued that, in the context of higher education and the research carried out in such institutions, 'know how' is an essential 'tool of trade' and there is an expectation that the benefit of its use should flow also to the community in general and to the general fund of knowledge. Any policy that interferes with its fundamental use must be fully justified and managed with great care and sensitivity.

1.3 WHY INTELLECTUAL PROPERTY IS IMPORTANT

IP *per se* is of little economic value unless it is protected and exploited; it is the rights that are attached to it that are valuable. In the case of patents this is the exclusive right to exploit the invention, or authorise others to exploit it; for a fixed term; in the case of copyright it is the exclusive right [among others] '*...to reproduce the work in a material form*', again for a fixed term. These temporary exclusive rights reward investment in research and innovation and can prevent others 'free-riding' on a creator's investment. Although there are established academic rights associated with the generation and ownership of IP in most institutions, it is the commercial exploitation of IP that has the major consequences for national, institutional and individual wealth creation.

Governments throughout the world have recognised the necessity to protect an individual's IP rights, and have implemented procedures for this protection. In some cases protection may be legislative in framework in others judicial. Many of the frameworks for these rights are set down by international treaties that form the subsequent basis for national policies and legislation.

1.4 WHY NHMRC NEEDS AN IP POLICY

Current NHMRC policy acknowledges the need to capture IP generated from publicly funded research and that IP '*... will be owned by the administering institution and must be managed in the national interest.*' However, NHMRC has no systematic mechanism to enforce this policy, and ensure that IP generated from its funded research is protected and managed effectively.

In response to the Government's strategic direction and the recommendations of the Health and Medical Research Strategic Review, and other commissioned reviews, NHMRC recognises the need to strengthen its policies relating to IP management.

As the major public funder for health and medical research in Australia, NHMRC is responsible for setting an environment that assists in the development of research findings to national advantage, and in ensuring that NHMRC supported researchers are vigilant that they do not inadvertently, or through inaction, lose potentially valuable IP.

NHMRC generally has not required grant applicants to demonstrate adequate IP management procedures nor included any assessment of opportunities relating to the exploitation of IP rights in its grant review process. It is NHMRC's intention to include the requirements outlined in the Interim Guidelines in its future grant application and approval processes. With the introduction of outcome focused performance measures, commercial development, including patent registration, will be considered along with other measures for grant report and review.

2. PRINCIPLES OF INTELLECTUAL PROPERTY MANAGEMENT

2.1 BEFORE THE PROJECT STARTS

Administering institutions will have policies relating to the ownership and exploitation of IP, good scientific conduct (including best practice record keeping) and to human and animal experimentation ethics.

2.2 IDENTIFICATION OF IP

Administering institutions will have procedures that ensure that NHMRC-funded researchers are made aware of the potential value of their discoveries and the issues of confidentiality and that a review process is available to identify the generation of protectable and exploitable IP, and, if considered necessary, that IP protection will be obtained prior to any public disclosure of research results.

2.3 PROTECTION OF IP

Administering institutions will have policies that make clear and binding to staff their separate and mutual obligations and responsibilities in relation to IP management and protection. Institutions should provide, wherever possible, assistance to researchers in fulfilling these obligations and responsibilities, as well as encouraging their participation in any subsequent commercialisation process.

2.4 OWNERSHIP OF IP

The NHMRC will not claim any ownership or associated rights for IP generated from its research support.

Administering institutions will have policies, and relevant procedures which determine the ownership and/or assignment, if any, of IP rights. Particular attention is required in the case of IP relating to the cultural, spiritual or other aspects of indigenous Australians.

Administering institutions will have policies, and relevant procedures, that require employees, or grant holders using the administering institution for that purpose, to acknowledge the relevant ownership and rights associated with IP.

2.5 MANAGEMENT OF IP

Administering institutions will have procedures that require the regular review of IP holdings, including associated commercial activities and outcomes, arising from the NHMRC funded research.

Administering institutions will have procedures to provide advice to the creators of the IP on the options that are available for value adding.

2.6 ALIGNMENT OF STAKEHOLDER INTERESTS

Administering institutions will have policies that recognise the rights and needs of all stakeholders in the research supported by NHMRC research funds.

These policies will include a method by which income from the development and exploitation of the IP will be allocated to the inventors and other stakeholders.

2.7 TRANSPARENCY AND REPORTING

An Authorised Officer of each administering institution will be required to make a statement, to the NHMRC, that the institution follows the Guidelines for Intellectual Property Management for Health and Medical Research.

Institutional policies (but not individual agreements) relating to IP management and exploitation should be made publicly available.

In order for the NHMRC to fulfil the reporting requirements to the Government on the outcomes of its funded research, administering institutions will be responsible for reporting IP outcomes⁹ on a confidential basis. Such information may include:

- ***newly generated IP, and its status***
- ***the status of existing registered IP***
- ***commercialisation and income generation from the exploitation of IP.***

The NHMRC will retain the right to confirm that the policies, procedures and activities of administering institutions in relation to IP generated from NHMRC funded research observe these Guidelines.

2.8 POTENTIAL CONFLICT OF INTEREST

Administering institutions will have policies and procedures that provide guidance in relation to potential conflicts of interest concerning ownership, management and exploitation of IP.

⁹ In this context, the Principles refer to the production and status of IP that requires registration eg patents and does not refer to the generation of copyright material.

3. COMMERCIALISATION OF RESEARCH FINDINGS

Individual researchers and their administering institutions are expected to consider the most appropriate way of exploiting their IP rights. It is acknowledged that there is no single 'best approach' to developing IP, and each instance has to be developed on a case by case basis. Options for consideration may range from exclusive and non-exclusive licenses, research agreements or contracts through to joint ventures or the establishment of spin-off companies. NHMRC intends to contribute to a future document that gives guidance on commercialisation procedures for public-funded institutions.

APPENDIX 1

ADDITIONAL INFORMATION FOR ADMINISTERING INSTITUTIONS

(Refer to section 2 of the Interim Guidelines)

The information presented in this Section is intended to provide additional explanatory information to assist administering institutions in developing appropriate policies and procedures for IP management and commercialisation.

The NHMRC Interim Guidelines for Intellectual Property Management are deliberately generic and broadly based, to allow institutions to develop best-practice policies and procedures that are able to take account of local environment. They are intended to provide institutions with the framework within which to work, not the specific rules.

It is expected that at the time of the introduction of the interim Guidelines, the majority of administering institutions will have policies and procedures in place that are generally consistent with the principles of the interim Guidelines. However, some institutions may wish to review or may need to amend their current policies and procedures in order to meet the requirements of the Guidelines. The NHMRC will take any such requirements into consideration during the transitional period.

2.1 PRE-COMMENCEMENT

- The NHMRC will require all administering institutions to ensure that NHMRC supported researchers are aware of the interim Guidelines, and to work towards appropriate policies and procedures for IP management that are consistent with the interim Guidelines.

2.2 IDENTIFICATION OF IP

- Specific procedures for the identification of potentially valuable IP will be developed by individual institutions, and would be expected to reflect the available resources and skill base that may depend in turn on the size of the institution. The diversity in knowledge, skills and interest in the area of IP management on the part of researchers should be acknowledged by administering institutions and procedures to provide support may be necessary. Possible options that could be considered by institutions to assist researchers in the identification and management of IP include:
 - education programs in IP awareness and management for researchers and research managers;
 - monitor and review of material by senior staff with skills in the area;
 - appointment of intellectual property officers; or,
 - utilisation of institutional (or faculty or departmental) committees.

- Confidentiality

Because any disclosure of information prior to filing a patent application may threaten the subsequent granting or validity of that patent, researchers and their institutions need to be alert to the possibility and consequences of premature disclosure. It is necessary to safeguard material that is to enter the public domain, including conference abstracts and proceedings, manuscripts, student theses and presentations such as slides or PowerPoint or similar media presentations. Researchers should be made aware of necessary procedures available to protect their discoveries including confidentiality agreements and Materials Transfer Agreements, prior to discussing confidential results with a potential collaborator or commercial partner.

2.3 PROTECTION OF IP

- Institutional IP policies should state clearly the rights and responsibilities of both the creators of the IP and the institution in relation to the protection and management of the IP. Some institutions may allow or require the creators to play a major role in the protection and exploitation of IP, others may themselves choose to play a more significant role.
- Administering institutions should, wherever possible, assist researchers in the protection of IP. It is acknowledged that the administering institutions themselves may not have the resources available to pay the costs of preparing applications and the relevant registration fees. However, it is expected that they will have procedures that assist researchers in determining what IP is worth protecting, which IP experts to seek assistance from, and the funding options available to support the preparation and registration of patents. In the case of 'trade secrets', administering institutions should provide advice on the best procedures for its protection, if such a course of action is warranted.
- The competing requirements of researchers in publishing their results as quickly as possible (including for the purposes of appointment and promotion) and of the owners of the IP in holding it for sufficient time to allow optimal development must be recognised. In addition, it is acknowledged that there may be competing requirements between the publication requirements of researchers and the need for any commercial partner in withholding the information for the purpose of value adding and/or patent protection. Institutions should take these needs into consideration in any policy of non-disclosure and registration of IP. Institutions may wish to include in their policies time limits beyond which publication cannot be withheld, and within which patent protection should be sought. It is recommended that institutions take account of these competing needs in the development and implementation of criteria used for appointment and promotion.

2.4 OWNERSHIP OF IP

- NHMRC makes NO claim to any ownership of IP nor associated rights for IP generated from its funded research.
- Institutional IP policies should include clear statements regarding the ownership of IP and IP rights. Some institutions may choose to hold the ownership of all IP rights themselves, as the employer of the IP creators, while maintaining some focus on the moral and financial reward rights of the creators of the IP. In others full ownership of IP may be assigned to its creators.
- In general, it would be expected that such agreement concerning the ownership of IP between institutions and employees would be included in the institution's Conditions of Employment. If not, it would be expected that employees should sign an appropriate document stating agreement with conditions relating to ownership of IP and assignment of any rights.
- Ownership of indigenous peoples' IP. The ownership of IP relating to the cultural, spiritual or other aspects of indigenous people is an issue that some researchers and their administering institutions will need to be aware of. Any institution in which researchers are undertaking such research would be expected to have policies that are sensitive to, and deal appropriately with, the issues of ownership of indigenous peoples' IP.

2.5 MANAGEMENT OF IP

- Institutions would be expected to have policies and procedures that require the regular review of the status of its IP portfolio. As with the other policies and procedures that are required to comply with these Guidelines specific institutional procedures could take account of the available resources and skill base, along with the size and complexity of the IP portfolio.
- The most appropriate developmental pathway for a specific item of IP will vary considerably, depending on the nature of the invention/creation, the size of the potential market, activity of competitors and availability of finance/support etc. Options that could be considered would be to develop partnerships with commercial organisations, to license the property for development by another organisation, to sell the property outright or to establish an appropriate joint venture or spin-off company. Each situation should be judged on its merits given the opportunities available.
- Protection of IP will involve ongoing maintenance also, by, for example, putting in place confidentiality agreements to protect institution or third party IP in commercial negotiations and Materials Transfer Agreements to protect the use to which vital research materials can be put by third parties. Maintenance issues to be considered may also include the regular payment of fees for continued patent protection.

2.6 ALIGNMENT OF STAKEHOLDER INTERESTS

- In this context stakeholders are seen to include the following groups:
 - The creators of the IP;
 - Collaborating institutions and their researchers;
 - Others associated directly with the research, but who would not necessarily be classified as inventors or creators of the IP, eg. support staff;
 - Researchers not directly involved with the research who may require access to it in order to develop their own research further;
 - The administering institution;
 - NHMRC, as the instrument of Government that is responsible for the delivery of health and medical research in Australia and as a major funder of the research;
 - Other funding bodies;
 - Commercial partners who have supported the research, and/or who are potential partners in its subsequent development; and
 - The Australian public, through their need for better health and improved health care and the economic development of Australian discoveries and developments.
- As with other specific aspects of these Guidelines, it is acknowledged that administering institutions will develop their own specific procedures and formula for the allocation of license fees, royalties and other commercial income. Of importance in any distribution are the interests of the creators of the IP in order to encourage them and, through example, others in the value of nurturing and exploiting their future discoveries and inventions. Other issues that may need consideration in the development of an institutional policy include; any distribution of income to the creator's laboratory, department, faculty etc and whether costs associated with developing the IP are to be 'repaid' prior to distribution of any income.

2.7 TRANSPARENCY AND REPORTING

- It is not the purpose of the NHMRC to be prescriptive in the development and management of institutional IP policies. However, each administering institution should have policies and procedures which ensure that the principles of good management of IP are followed, while bearing in mind local conditions, resources and skills. Only administering institutions that follow the interim Guidelines, and for whom such a statement has been provided, will be eligible for funding support from NHMRC. Following the introduction of the Guidelines it is proposed that there will be a reasonable transition period to allow administering institutions to review their policies and procedures to comply with the interim Guidelines.

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- The exploitation of the IP portfolio generated from NHMRC funding will be one of the outcomes against which NHMRC evaluates its activity as required by the Government. To inform this requirement administering institutions will be required to report annually to the NHMRC any newly generated registrable IP and its status; the status of existing patents; and any commercial development and income associated with the exploitation of IP, that has arisen as a result of NHMRC funding. The reporting procedures will be developed during the implementation phase in consultation with administering institutions, taking into consideration the potential resource implications of reporting.
 - The NHMRC may confirm that the policies, procedures and activities of your administering institutions observe these interim Guidelines. The NHMRC will consider an incentive-based, rather than punitive based policy and methodology to encourage administering institutions to comply with the interim Guidelines.

2.8 POTENTIAL CONFLICT OF INTEREST

- Administering institutions will be required to have policies relating to the declaration and management of conflict of interest. As with other aspects of these Guidelines, it is acknowledged that the development of these policies will take regard of local institutional conditions.
- Examples of potential conflicts of interest in the context of management of IP would include, but are not limited to:
 - Excessive external time commitments that prevent researchers efficiently discharging their institutional duties.
 - External commitments (eg. consultancies) that may create personal or institutional legal liabilities or lead to the misuse of the institutional name.
 - Financial interests in external companies that do business with administering institutions, especially where these entail research contracts and exchange of rights to IP.
 - The nature and terms of institutional support for start-up companies and the equity holdings of the institution and its staff.
- It is impossible to be prescriptive about when such potential conflicts become real conflicts, but full and prompt disclosure of all potential conflicts to a responsible institutional officer is essential to protect all parties and to allow for a rational evaluation of the net benefits of an external relationship to all involved.

APPENDIX 2

ADDITIONAL INFORMATION FOR RESEARCHERS

(refer to section 2 of the Interim Guidelines)

The information presented in this section is intended to assist researchers in understanding IP and applying best practice to the management of the IP that they create within their NHMRC grants. As a guide, it is not intended to be fully authoritative, and researchers are advised to seek additional information from their institutional Research Office or equivalent. Further information is also available from IP Australia¹⁰ and many law firms provide specific information about patents and other IP issues on their websites.

The interim Guidelines provide a framework for the policies and procedures relating to IP that all institutions administering NHMRC grants will be required to follow. They are not prescriptive other than requiring that institutions must follow the principles of the interim Guidelines. The management of IP and its associated rights should be agreed between researchers, as employees of the institution, and the institutions themselves. Special arrangements may need to be made for IP created by researchers who are not employees of the institution that administers their grants. Researchers should make themselves totally familiar with their administering institution's IP policies.

2.1 PRE-COMMENCEMENT

- Before commencing any research program, make sure that you have read and understood your administering institution's relevant policies regarding IP ownership and management, research ethics and sound scientific practice. All of these policies should be available from the institution's Research Office. In particular, it is recommended that you understand your institutional policy concerning ownership of IP and assignment of IP rights.
- The NHMRC will require all administering institutions to ensure that the NHMRC supported researchers are aware of the interim Guidelines, and to work towards appropriate policies and procedures for IP management that are consistent with the interim Guidelines.
- Make sure that you understand and follow best practice record keeping. For determining priority dates, the US Patent Office allows the use of laboratory books as evidence, although the conditions relating to keeping of records for such use are extremely stringent. Many commercial partners may have their own record keeping requirements that may need to be followed.
- As part of the development of any research proposal, in addition to the process of literature searching, it is suggested that applicants review the

¹⁰ <http://www.ipaustralia.gov.au>

relevant patent databases to understand better any potential that their research proposal may have for commercial exploitation.

- You need to understand what sort of intellectual property you are likely to generate, and the different ways in which it may be handled. Copyright, which does not require any registration, tends to be handled in a different way to patents, which require registration and have different criteria than copyright. For further details refer to the IP Australia homepage.

2.2 IDENTIFICATION OF IP

- Although researchers or creators of IP have been relied upon historically to identify potential IP arising from their research activities, your administering institution may also have specific procedures to assist you in identifying IP and in its subsequent protection and management. You should be aware that it is considered important to assess all NHMRC supported research for IP content prior to its release into the public domain.
- Specific institutional procedures will depend to a large degree on the size of the institution and on the skill base available to it and could include mentoring, the appointment of intellectual property officers, or the utilisation of appropriate institutional (or faculty or departmental) committees. Institutional Research Offices will be able to advise you on any specific procedures that need to be followed.
- Researchers, especially those leading research teams, will need to be aware of best practice of IP management and ensure that they fully understand their institutions' procedures, and apply them.
- Confidentiality. Because any disclosure of information prior to filing a patent application may threaten the subsequent granting of that patent, researchers and their institutions need to be alert to the possibility and consequences of premature disclosure. Disclosure could include a statement in a conference abstract, a statement in an institutional annual report or even a verbal statement made during a seminar or conference presentation. Consideration should be given to material that is to enter the public domain, including conference abstracts and proceedings, manuscripts, student theses, and presentation material such as slides or PowerPoint, or similar media presentations, as well as disclosure to any other person even if it is not in a public arena.

You should consider entering into a confidentiality agreement before any discussion of your research results with a potential collaborator or commercial partner.

- Many researchers perceive that there is a significant conflict between the rapid dissemination of findings and any requirement to take appropriate steps to protect the IP that has been generated. In general your reporting of findings should only be held up by a few months while appropriate

protection is sought, although in some circumstances longer delays may be encountered. The NHMRC will take account of such delays in the grant review process and will include IP management and patent registrations as indicators of “track record”.

2.3 PROTECTION OF IP

- Your institution’s IP policy should include clear statements about the separate and mutual obligations of the institution and the creator of the IP in relation to the protection of that IP.
- Many administering institutions will have procedures available to assist researchers in registering or protecting IP, as is required. Applying for a patent can be both expensive and time consuming – up to \$3000 to register a provisional patent and up to \$100,000 or more to obtain full patent protection in all countries. In addition, applying for a patent can be a complex process and it is recommended that you consult an IP professional for assistance in developing your IP strategies, in accordance with institutional policies and procedures.
- It is acknowledged that administering institutions may not themselves have the resources available to pay the cost of preparing patent applications and the relevant registration fees. However, it is expected that they will have procedures to assist you in deciding whether any particular item of IP is worth protecting and they may have resources to assist researchers to find appropriate sources of funding to support its registration and development. Once you have identified something worth protecting, the key is to seek advice from your Research Office immediately.
- In the case of know how, administering institutions would be expected to provide advice on the best procedures for its protection, if such a course of action is warranted.
- In the case of copyright, which can include computer programs, no registration is required. Although not necessary, it is often useful to establish ownership unequivocally by including a statement such as ‘© Institute X 200Y. All rights reserved. Not to be reproduced in whole or in part without the permission of the copyright owner.’

2.4 OWNERSHIP OF IP

- NHMRC makes NO claim to any ownership of IP nor associated rights for IP generated from its research funds.
- Your institutional IP policy should include a clear statement regarding the ownership of IP and IP rights. Some administering institutions will hold the ownership of all IP rights themselves, while maintaining some focus on the generally accepted academic and financial reward rights of its creators. Others may assign full ownership of IP to its creators. The policies relating to

the level of diligence that must be applied to the exploitation of the IP similarly vary widely.

- In general, the conditions of your employment, or the conditions relating to non-employees using a particular institution as their administering institution, will dictate the ownership of IP that is generated during the course of your employment or of the life of the grant. It is crucial that all the parties involved in the research understand who owns the IP and who can exploit it. For commercialisation it is essential that IP ownership is clear and simple, preferably with unconditional ownership vested in a single party.
- You need to ensure that you understand your rights and responsibilities in relation to IP that you create, and ensure that they are based on a sound legal footing.
- Ownership of IP created by individuals who are not employees of the institution administering the NHMRC grant may need specific agreement by the parties if the institution has no relevant policy, as it would be considered that the administering institution continues to have a responsibility to ensure that any IP arising from the research is managed in the national interest.
- The ownership of intellectual property relating to the cultural, spiritual or other aspects of indigenous people is an issue that some researchers and their administering institutions will need to address. Any researcher undertaking such research would be expected to be sensitive to the issues of ownership of indigenous intellectual property. It would be expected that institutions where such research is undertaken would be able to provide appropriate advice and support to assist researchers and would have appropriate policies in place.

2.5 MANAGEMENT OF IP

- Protection of IP is only the first stage in its exploitation. Your administering institution should have procedures that require the regular review of IP holdings arising from NHMRC supported research. If it does not, it is in your own interest to manage your IP in a proactive way.
- The Research Office of your administering institution, or its commercial arm, will be able to provide advice on the most appropriate way to add value to the IP. Specific items of IP should be developed in a way that is most appropriate for that invention/discovery. Options that could be considered would be to develop partnerships with commercial organisations, to license the property for development by another organisation, to sell the property outright or to establish an appropriate joint venture or spin-off company. Each situation must be judged on its merits given the opportunities available and the desired outcome by you the researcher, your administering institution and any other stakeholders in the research.

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- Protection of IP will involve ongoing maintenance by, for example, putting in place confidentiality agreements to protect institution or third party IP in commercial negotiations and Materials Transfer Agreements to restrict the use to which vital research materials can be put by third parties.

2.6 ALIGNMENT OF STAKEHOLDER INTERESTS

- You and your administering institutions should recognise the needs of all the stakeholders in the research that has been supported by NHMRC funds. Not all of the stakeholders will be eligible to receive income from the development, and may have a stake in other outcomes, or may require that their interests are considered in the management of the IP or its exploitation.
- In this context stakeholders are seen to include the following groups:
 - You as the creator(s) of the IP;
 - Collaborating institutions and their researchers;
 - Others associated directly with the research, but who would not necessarily be classified as inventors or creators of the IP, eg. support staff;
 - Researchers not directly involved with the research who may require access to it in order to develop their own research further;
 - The administering institution;
 - NHMRC, as the instrument of Government that is responsible for the delivery of health and medical research in Australia and as a major funder of the research;
 - Other funding bodies;
 - Commercial partners who have supported the research, and/or who are potential partners in its subsequent development; and
 - The Australian public, through their need for better health and improved health care and the economic development of Australian discoveries and developments.
- Most administering institutions will have an IP policy that includes the distribution of income from the development and exploitation of the IP. Each institution will have its own formula. Examples of distribution include
 - payment of a straight proportion to the inventors eg. one third, with the institution retaining the remainder of the income, either centrally or with a distribution to the faculty or department that hosted the research;
 - payment on a sliding scale with inventors receiving the majority of the first \$50-100,000 of income (up to 50% or more), a lesser amount over the next range (eg. 20-30% of income in the \$100 – 500,000 range) and a lesser proportion above that (eg. 10-15% of income over \$500,000); and

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- Some institutions do not distribute any royalty income to staff who have created commercially-developed IP.

These numbers are included as examples only and should not be taken as any indication of what your own institution might use. Some institutions take account of direct and indirect research costs prior to distribution. Some institutions also acknowledge the role of staff other than inventors in their distribution formula.

- Commercial developments, including patent registration, will be recognised along with other measures, such as publications during the NHMRC grant application and review process.

2.7 TRANSPARENCY AND REPORTING

- Either at the time of registering as an administering institution, or at the time of grant submission, an authorised officer of each administering institution will be required to make a statement that the institution follows the NHMRC interim Guidelines. Only administering institutions that follow the Guidelines, and for whom such a statement has been provided, will be eligible for funding support from NHMRC.
- The exploitation of the IP portfolio generated from the NHMRC funding will be one of the outcomes against which the NHMRC evaluates its activity as required by the Government. To inform this requirement your administering institution will be required to report to the NHMRC any newly generated registrable IP ; the status of existing registered IP; and commercial development and income associated with the exploitation of IP that has arisen as a result of NHMRC funding. It will be your responsibility as a recipient of the NHMRC funds to assist your administering institution to provide this information as required under their policy.
- The NHMRC may confirm that the policies, procedures and activities of your administering institution observe these Guidelines. The NHMRC will consider an incentive-based, rather than punitive-based policy and methodology to encourage administering institutions to comply with the Guidelines. It is in your interest as a researcher to ensure that you follow the policies and procedures of your administering institution with regard to IP management.

2.8 POTENTIAL CONFLICT OF INTEREST

- Your administering institution will have policies and procedures that provide guidance in relation to potential conflicts of interest concerning ownership, management and exploitation of IP. In general, such policies will require timely disclosure of all activities that may create an actual or potential conflict of interest in discharging your obligations to your institution. You should become familiar with these policies to ensure that all those involved in the research are treated fairly at all times and that the interests of the institution are not disadvantaged by your external relationships.

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- Examples of potential conflicts of interest include, but are not limited to;
 - Excessive external time commitments that prevent you efficiently discharging your institutional duties.
 - External commitments (eg. consultancies) that may create personal or institutional legal liabilities or lead to the misuse of the institutional name.
 - Financial interests in external companies that do business with your institution, especially where these entail research contracts and exchange of rights to IP.
 - The nature and terms of institutional support for start-up companies and the equity holdings of the institution and its staff.
 - It is impossible to be prescriptive about when such potential conflicts become real conflicts but full and prompt disclosure of all potential conflicts to a responsible institutional officer is essential to protect all parties and to allow for a rational evaluation of the net benefits of an external relationship to all involved.

The National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) is a statutory body within the portfolio of the Commonwealth Minister for Health and Aged Care, established by the *National Health and Medical Research Council Act 1992*. The NHMRC advises the Australian community and Commonwealth; State and Territory Governments on standards of individual and public health, and supports research to improve those standards.

The NHMRC advises the Commonwealth Government on the funding of medical and public health research and training in Australia and supports many of the medical advances made by Australians.

The NHMRC also develops guidelines and standards for the ethical conduct of health and medical research.

The Council comprises nominees of Commonwealth, State and Territory health authorities, professional and scientific colleges and associations, unions, universities, business, consumer groups, welfare organisations, conservation groups and the Aboriginal and Torres Strait Islander Commission.

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