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1. Introduction

NHMRC supports the sharing of outputs from NHMRC funded research including publications and data. The aims of the NHMRC Open Access Policy are to mandate the open access sharing of publications and encourage innovative open access to research data. This policy also requires that patents resulting from NHMRC funding be made findable through listing in SourceIP.

Combined, these approaches will help to increase reuse of data, improve research integrity and contribute to a stronger knowledge economy. Open access will also assist with reporting, demonstration of research achievement, improve track record assessment processes for the long term and contribute to better collaborations.

All recipients of NHMRC grants must therefore comply with all elements of the NHMRC Open Access Policy.

The NHMRC Open Access Policy is consistent with the Australian Government’s commitment to open access, open data and intellectual property (IP) management. This policy is also aligned with the global open access movement where funding bodies, international organisations, governments and institutions have implemented open access policies or guidelines. In Australia, the NHMRC Open Access Policy is generally aligned with the Australian Research Council Open Access Policy 2017 and supports the overall intent of the F.A.I.R. Access to Australia’s Research Statement through which data/information are made findable, accessible, interoperable and reusable.

Researchers and administering institutions must adhere to the principles of responsible research conduct and fulfil the responsibilities as outlined in the Australian Code for the Responsible Conduct of Research (2007) in all areas of research. The guidance as outlined in the Values and Ethics - Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003) and Keeping Research on Track: A guide for Aboriginal and Torres Strait Islander peoples about health research ethics (2005) must also be adhered to in all areas of research including managing and sharing data.
2. Key changes to the NHMRC Open Access Policy

The overall intent of this updated version of the NHMRC Open Access Policy (2018) remains substantively the same as the previous version of the policy. This version has been shortened and simplified and the language and guidance clarified through extensive external consultations. The key updates are as follows:

1. Research publications are now referred to as ‘Research literature’ and include peer-reviewed journal articles and conference papers.
2. NHMRC now strongly encourages researchers to take reasonable steps to share research data and associated metadata arising from NHMRC supported research.
3. NHMRC has a new requirement for patents generated from public funding to be listed in SourceIP.
4. Greater guidance in the area of sharing data and metadata has been provided.
5. Roles and responsibilities in relation to the NHMRC Open Access Policy have been clarified.
6. Guidance for licensing of research publications and data has been provided.
7. Reference to the Australian F.A.I.R. principles (Findable, Accessible, Interoperable, Reusable) when publishing research literature and sharing data has been made.
8. The ‘NHMRC Principles for Accessing and Using Publicly Funded Data for Health Research’ have been removed from the NHMRC Open Access Policy, but are still referred to in the ‘Frequently Asked Questions for research data’ section (Appendix 2).

3. Definitions

**Administering institutions**: Organisations responsible for administering NHMRC grant applications, awards, reporting and other aspects of grant management.

**Data/information**: The terms ‘data’ and ‘information’ are often used interchangeably. Data can refer to raw data, cleaned data, transformed data, summary data and metadata (data about data). It can also refer to research outputs and outcomes. Likewise, information takes many different forms. Where information is in a form that can identify individuals, protecting their privacy becomes a consideration. ‘Data’ is intended to refer to bits of information in their raw form, whereas ‘information’ generally refers to data that have been interpreted, analysed or contextualised.

Data and information may include but not be limited to:
- what people say in interviews, focus groups, questionnaires/surveys, personal histories and biographies;
- images, audio recordings and other audio-visual materials;
- records generated for administrative purposes (e.g. billing, service provision) or as required by legislation (e.g. disease notification);
- digital information generated directly by the population through their use of mobile devices and the internet;
- physical specimens or artefacts;
- information generated by analysis of existing personal information (from clinical, organisational, social, observational or other sources);
- observations;
- results from experimental testing and investigations; and
- information derived from human biospecimens such as blood, bone, muscle and urine.
DOI: Digital Object Identifier, a unique persistent identifier for a published digital object (report, publication, article) that is issued by the DOI Foundation and its authorised agencies.

Institutional repository: An online repository (usually hosted by an institution) that is publicly accessible in which the metadata of publications/data and the publications/data themselves can be stored, managed and preserved for the long term.

Intellectual Property: “Intellectual property is the property of your mind or proprietary knowledge. It is a productive new idea you create. This can be an invention, trade mark, design, brand or even the application of your idea”. (IP Australia, www.ipaustralia.gov.au)

Metadata: Underlying information that describes other data. It generally helps the user to understand what the data are, where they can be found and how they can be used. See Appendices 1 and 2 for further clarification.

NHMRC funded research: Research activity that is funded under a NHMRC scheme.

Open access/Openly accessible: Refers to the availability of research outputs via the internet, such that any user can find, freely access, read, download, copy, distribute, print, search, link, crawl, mine and otherwise use and reuse the research outputs both manually and using automated tools. Any use or reuse is subject to full and proper attribution, and usually will have an appropriate licence, such as any of the options available through the Creative Commons suite of licences, and should not infringe any copyrights to third-party material included in the Research Output.

ORCID: Open Researcher and Contributor ID. ORCID is a persistent digital identifier that is unique to each individual. It is issued by ORCID.

Paid open access program: Where the authors for a paper pay an ‘article processing charge’ to the publisher to make their publication openly accessible. This is sometimes referred to as ‘gold’ open access.

Patents: “A patent is a legally enforceable right for a device, substance, method or process”. (IP Australia, www.ipaustralia.gov.au)

Postprint (or Author accepted manuscript): The version of a manuscript that has been through the peer-review process of the publisher and has addressed the peer-reviewers’ comments. It is the final version of the paper before it is sent to the publisher for publication.

Preprint: The version of a manuscript as submitted to a journal or other publication. This version has not been through the publisher’s peer-review process.

Publication: Peer-reviewed journal articles and peer-reviewed conference papers.

Publisher’s version: The version of record that has been formatted by the publisher and published in its final form.
4. Research output and access

NHMRC’s Open Access Policy addresses three output types:

1. Research literature
2. Research data
3. Patents.

4.1 Research literature

The Australian Government makes a major investment in health and medical research to improve the health and wellbeing of society. To maximise the benefits of NHMRC funded research, publications resulting from such research activities must be disseminated as broadly and at the earliest possible opportunity to allow access by other researchers and the wider community.

NHMRC requires that any peer-reviewed publication arising from NHMRC supported research must be made openly accessible in an institutional repository or other acceptable location (e.g. publisher website, subject repositories) within a 12-month period from the date of publication. This policy applies to all publications from 1 July 2012 except for peer-reviewed conference papers where it applies from 15 January 2018.

‘Publications’ refers to the following:

- Peer-reviewed journal articles
- Peer-reviewed conference papers.

The metadata for the peer-reviewed publication must be made openly accessible via an institutional repository as soon as possible but no later than 3 months from the date of publication. The publication metadata requirement applies regardless of whether the publication is openly accessible upon publication, will be made openly accessible in the future, or will never be made openly accessible.

NHMRC also encourages authors of scholarly books, scholarly book chapters, edited research books, including prestigious reference works, and producers of other forms of research outputs to make them openly accessible where possible.

If authors are unable to make their publications open access within 12 months of the date of publication for any reason, this must be clearly indicated in the publication record listed in the NHMRC grants management system. Authors should endeavour to retain all necessary rights to enable the authors to publish and share their publications in any format at any time and use the Creative Commons Attribution licence, CC-BY, where possible when publishing their article. NHMRC does not require authors to make their publications openly accessible through publishers’ paid open access program.

Refer to Appendix 1 for further clarification on how to comply with this policy.
4.2 Research data

One of NHMRC’s primary roles is to fund high quality health and medical research and ensure that the Australian community receives health and economic benefits from that investment. An important part of this responsibility is enabling researchers and members of the community to access the data resulting from NHMRC funded projects for the long term and to maximise the benefits that could be derived from the data.

NHMRC acknowledges the importance of making research data publicly accessible and therefore strongly encourages researchers to consider the reuse value of their data and to take reasonable steps to share research data and associated metadata arising from NHMRC supported research.

When sharing data, researchers should ensure that appropriate metadata accompany the datasets. This will allow users of the data to fully understand the data, the curation strategies, assumptions, experimental conditions and any other details relevant to the interpretation of the data. When sharing research data, researchers must also consider the appropriate level of access that they would like to provide to users. The level of access may range from highly restricted (e.g. commercial in confidence, patient level, culturally sensitive, national security) to fully open access.

NHMRC acknowledges that sharing certain types of data may be complex. An example would be sharing of clinical trial data due to the length of clinical trials, the types of data inherent in clinical trials and the governance of the data. NHMRC therefore encourages researchers to share clinical trial data and associated metadata as soon as possible after publication provided that all ethical, regulatory and legal obligations are fulfilled. In order for the data to be of value to other researchers and for proper analyses to be conducted, the analytical techniques, assumptions, software and other details relevant to the clinical trial should also be shared alongside the data.

A further example in which sharing of data is crucial is during public health emergencies. Public health emergencies are special cases where rapid data sharing may be necessary to facilitate an effective response to a crisis. As a member of the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R), NHMRC acknowledges the importance of sharing data and associated metadata in public health emergencies.

Researchers who use secondary data must acknowledge the original research team and provide a citation to the data source.

Refer to Appendix 2 for further clarification on data sharing.
4.3 Patents
NHMRC supports health and medical research and encourages researchers to develop best practice in identifying, managing and protecting intellectual property. This strategy will assist in encouraging commercial outcomes from publicly funded research where possible, and ensuring the return on investment is maximised.

In 2013, the National Principles of IP Management for Publicly Funded Research were released by the Australian Government to “provide guidance for the ownership, promotion, dissemination, exploitation and, where appropriate, protection of IP generated through Australian Government funded research by public sector institutions”.

SourceIP is a government database developed to facilitate innovation and commercialisation by providing a mechanism for patent holders to showcase their licensing intent and/or promote their work in an integrated format. It also facilitates more efficient and accurate access to such information, as the data are managed from a single source. The ultimate aim of SourceIP is to enhance collaborations between academia, government and industry.

NHMRC therefore:
• notes that details of patent applications (including the invention title) are published in the Australian Official Journal Of Patents 18 months after the application’s earliest priority date;

• requires publicly funded research institutions to be listed as ‘Research Organisations’ with Source IP, and to list ‘filed’ patent applications (or at the Patent Cooperation Treaty stage) generated as a result of NHMRC funding, on Source IP, with reference to the relevant NHMRC Grant ID; and

• encourages institutions to make available the IP Toolkit (including the model contract confidentiality agreement and term sheet) where collaborative research arrangements with business are involved.

This is effective from 15 January 2018. Refer to Appendix 3 for more details.
Appendix 1
Frequently asked questions for research literature

NHMRC acknowledges that researchers take into account a wide range of factors in deciding on the best outlets for publications arising from their research to maximise the impact of their work on users of research and further dissemination and production of knowledge. The decision to publish in particular formats and journal titles is therefore the decision of the authors.

1. **Who is responsible for implementing the policy?**
The [NHMRC Funding Agreement and Deeds of Agreement with the Administering Institution](https://www.nhmrc.gov.au/funding) outline the responsibilities of Administering Institutions which include complying with the NHMRC Open Access Policy. Chief Investigators A (hereafter referred to as CIA, and including Fellows) must work with the Administering Institution to ensure that the provision of publication metadata and an appropriate copy of the publication are submitted to the institutional repository.

2. **Does the NHMRC Open Access Policy apply to Fellowship holders?**
Yes. This policy applies to all Fellowship holders regardless of the start date of the relevant grant.

3. **Does the NHMRC Open Access Policy apply to Scholarship holders?**
Scholarship holders are exempt due to the unique legal status of the award. However, as a matter of good research practice, NHMRC encourages all Scholars to follow the NHMRC Open Access Policy and make all their peer-reviewed publications, theses and associated metadata openly accessible.

4. **If my publication is already openly accessible through a publisher or other repository (e.g. PubMed Central), will I need to deposit a copy in my institutional repository?**
No. However, you must deposit the publication metadata, its URL/DOI and affiliated NHMRC Grant ID in your institutional repository as soon as possible but no later than 3 months from the date of publication.

5. **Will depositing my publications in a Scholarly Communications network fulfil the requirements of the NHMRC Open Access Policy?**
Scholarly communications networks (e.g. ResearchGate, Academia.edu) are social networking platforms and are not acceptable repositories for the purposes of this policy as they may not provide the appropriate support for long-term storage, curation and/or fulfilment of publisher copyright requirements.

6. **How do I deposit my publications into an institutional repository?**
The CIA should contact their institutional repository manager, library or research office to obtain instructions on how to deposit the publication and/or the publication metadata in the institutional repository, as institutional practices may vary from one institution to the next.

7. **What if my institution does not have an institutional repository?**
If your administering institution does not have an institutional repository, one of the other CIs may lodge in their institution’s repository or your institution may negotiate with an affiliated institution for access on behalf of their researchers.

8. **What manuscript versions are acceptable under the NHMRC Open Access Policy?**
- The author’s accepted manuscript version which is also referred to as ‘postprint’ that has been peer reviewed and accepted for publication is acceptable.
- The publisher’s version or ‘version of record’ (VoR) with final pagination and formatting is only acceptable if it meets all legal copyright and licensing requirements relating to open access.
- ‘Preprints’ are not acceptable versions under this policy.
9. What is the definition of the date of publication?
The date of publication is the official date as supplied by the publisher/journal, not the ‘Epub ahead of print’ date.

10. What should be included in the publication metadata?
“Metadata is information about an object or resource that describes characteristics such as content, quality, format, location and contact information” (http://www.ands.org.au). They may include (but are not limited to) NHMRC grant IDs, other funding sources, Digital Object Identifiers (DOI), author(s), publisher(s), titles, volume numbers, issue, date of publication, page numbers, type of research output, ISBN/ISSN/other standard number, licence type and other relevant details. The publication metadata must also include the ORCID identifier of the author submitting the metadata. A checkbox is available in NHMRC’s grant management system to indicate if the research output is a publication that is openly accessible.

11. When do I deposit my publication metadata into an institutional repository?
The publication metadata must be deposited into an institutional repository as soon as possible but no later than 3 months from the date of publication.

12. When do I deposit my publication into an institutional repository?
The publication must be deposited into an institutional repository as soon as possible and made openly accessible within 12 months of publication.

13. My publication has an embargo beyond 12 months, or will never be made open access. How do I comply with the NHMRC Open Access Policy?
The CIA must provide a reason for non compliance with the NHMRC Open Access Policy in the NHMRC’s grant management system. The publication metadata must still be deposited into an institutional repository as soon as possible but no later than 3 months from the date of publication.

14. What kinds of licensing should I use for my publications?
NHMRC prefers that all publications resulting from NHMRC funded research be allocated a Creative Commons Attribution licence (CC-BY). If this is not possible, it must be indicated in NHMRC’s grant management system. However, other licences from the Creative Commons suite of licences may also be used.

15. What do I need to consider when entering into a contract with a publisher?
Authors should compare the terms of the publisher with the F.A.I.R. principles (Findable, Accessible, Interoperable, Reusable) and consider publishing their research with publishers that have policies that are aligned with these principles.

16. If an article is not able to be made openly accessible, will it affect the applicant’s peer-review score or eligibility?
Current NHMRC peer-review scoring and eligibility criteria do not take open access levels into account.

17. How does the NHMRC Open Access Policy compare with the Australian Research Council’s Policy?
NHMRC and ARC Open Access policies are substantially comparable. While the ARC Open Access Policy says it applies to all Research Outputs arising from ARC funded research and their metadata, it does not include research data and research data outputs. The NHMRC Open Access Policy applies to publications, research data and patents. However, for NHMRC, the open access mandate only applies to publications while open access to data is strongly encouraged.
18. Which Open Access Policy should be used for multi-funder projects?
The NHMRC Open Access Policy must be complied with by the Australian investigators. If the other funding bodies have stronger mandates, they must also be complied with.

19. Does the NHMRC Open Access Policy apply to NHMRC Fellows undertaking non-NHMRC funded projects?
Yes. If a project is not funded by NHMRC but the researcher is supported by a NHMRC Fellowship, the work of the Fellow must comply with the NHMRC Open Access Policy.

Appendix 2
Frequently asked questions for research data

1. What is research data in the context of the NHMRC Open Access Policy?
Research data refers to all data produced (partially or in its entirety) by NHMRC funded researchers and/or as a result of NHMRC funded projects.

2. Does NHMRC require a data management plan to be submitted with a grant application?
NHMRC does not currently require a data management plan. However, NHMRC encourages researchers to conduct data management planning activities as a matter of best practice. A data management plan will ensure that the data generated from the research are well managed and able to be reused efficiently. Figure 1 provides an overview of data management and guides researchers in planning for collection, curation, quality assurance, storage, preservation and dissemination in an appropriate manner. Planning for well managed data collections prior to the project commencing will facilitate the data being findable, accessible, interoperable and reusable.

3. What is metadata and how do I ensure the metadata is useful?
"Metadata is information about an object or resource that describes characteristics such as content, quality, format, location and contact information" (http://www.ands.org.au). The metadata should include (but not be limited to) the NHMRC grant ID, access and rights information, the Digital Object Identifier (DOI), funding sources, author(s) and their contact details and ORCID identifiers, publication details, licence type and other details such as experimental conditions or project descriptions that will help the user.

4. What is a Digital Object Identifier (DOI)?
A Digital Object Identifier is a unique code that identifies the content and provides a persistent link to its location on the Internet. More information on how to obtain a DOI and how a DOI works can be found in the Australian National Data Service website.

5. When is data sharing appropriate?
NHMRC strongly encourages researchers to consider the reuse value of their data and take reasonable steps to share research data and associated metadata arising from NHMRC supported research. This approach helps to ensure research investment by NHMRC is fully realised through the data potentially being reused for new purposes. This requires an overall strategy for managing data from the conception and planning stages of all projects. It is important to take into account ethical and legal aspects of the data before making a decision to share data. Administering institutions should have policies to guide research teams through this process.
6. NHMRC has a set of principles that are a guide for sharing and accessing data
The ‘NHMRC Principles for Accessing and Using Publicly Funded Data for Health Research’ provide a framework for researchers and data custodians to consider when requests or applications are made for access to existing publicly funded datasets for the purposes of research. A summarised Principles document is also available, along with a Consumer’s Guide to the Principles. The Principles aim to:
- Ensure that all parties have a common set of priorities for the use of data.
- Encourage communication between researchers and data custodians so they can better understand each other’s roles and responsibilities.
- Ensure the use of data is optimised for the benefit of all Australians.

7. Can I share data that are yet to be published?
Yes. However, the decision to share unpublished data can only be determined on a case-by-case basis by the researcher.

8. How do I share sensitive data?
Sensitive data can be shared if they are treated in the appropriate manner through de identification, licensing or gaining the necessary consent. In the event that these data treatments are not possible, most metadata of data can still be shared and made findable. The Australian National Data Service provides detailed guidance for sharing sensitive data.

9. My data may be the subject of the Defence Trade Controls Act (2012). What do I do?
Researchers must adhere to the requirements relating to the sharing of data in the Defence Trade Controls Act (2012). Detailed requirements can be obtained from the Defence Export Control Office and checked online using the Defence and Strategic Goods List online tool.

10. What kinds of data infrastructure and support can I use?
The data and metadata should be deposited in a well curated, openly accessible data repository. The repositories should facilitate access to the data holdings and manage any necessary approval processes that take into account any sensitivities associated with the data or metadata. The infrastructure and mechanisms for data sharing may be available through individual institutions (e.g. universities, medical research institutes), government repositories (e.g. www.data.gov.au), international repositories (e.g. Dryad), established networks (e.g. Population Health Research Network) or nationwide registry and data organisations which offer varying levels of support (e.g. Australian National Data Service).

8. Who is responsible for the cost of data sharing?
The cost of data sharing should be supported by the researchers’ institutions. They may include training, technical support and/or infrastructure.

11. What level of consent should I aim to obtain for my research?
In order to maximise the usefulness of data and biospecimens collected for NHMRC funded research, NHMRC encourages researchers to use the broadest consent that appropriately considers the codes, laws, ethics and cultural sensitivities of the community in which the research is to be conducted. More information is available in the National Statement on Ethical Conduct in Human Research (2007, updated May 2015).

12. Where can I find out more about data management?
More information about data management can be found on the Australian National Data Service website, a collaborating organisation with NHMRC.
13. **What do I include in data citations?**

Citations should include the full set of metadata to ensure that the data source is fully acknowledged and accessible.

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**Appendix 3**

**Frequently asked questions for patents**

1. **At what stage of the patent application process should patents be listed in SourceIP?**

Patents can be listed in SourceIP when a full application has been filed. If international protection is sought, this would refer to the Patent Cooperation Treaty (PCT) application stage.

2. **Should provisional patent applications be submitted to SourceIP?**

SourceIP does not accept provisional patent applications.

3. **When should the submission to SourceIP be made?**

Submissions can be made any time after the full application for the patent has been filed.