

The Aurum Project Management of Data and Information in Research

A guide supporting The Aurum Project Code for the Responsible Conduct of Research

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The Aurum Project is a not-for-profit organisation dedicated to natural medicine research and is the peak body for homeopathy research in Australia. ABN 45162173707 Registered with the ACNC.

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Terms and abbreviations used in this guide

AP - The Aurum Project

AP Code - The Aurum Project Code for the Responsible Conduct of Research

Author - An individual who has made a significant intellectual or scholarly contribution to research and its output and who has agreed to be listed as an author.

Corresponding Author - The author who is, as agreed by all co-authors, responsible for communication between the publishers, managing communication between the authors and AP, managing communication between the co-authors, and maintaining records of the authorship Page 1 APData.V2

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agreement.

Research Output - A research output communicates or makes available the findings of research that may be in hardcopy, electronic or other form. Examples of research outputs include journal articles, book chapters, books, conference papers, blog posts or other social media publications, reports, datasets, patents and patent applications, performances, videos and exhibitions.

Introduction

This guide supports the *Aurum Project Code for the Responsible Conduct of Research* (AP Code), which articulates the broad principles and responsibilities that underpin the responsible conduct of Aurum Project research.

The responsible conduct of research includes within its scope the appropriate generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information. Aurum Project (AP) policies developed to govern the conduct of research require attention to ethics guidelines, privacy legislation, relevant laws, regulations and guidelines, as well as research discipline-specific practices and standards and models for best practice. AP Code and this guide apply to all research conducted under the auspices of AP.

AP conducts its research activity using Teal Organisation principles and an AP structure called Research Pods (Pods). Please refer to the <u>Aurum Project Teal Organisational Theory Statement</u> for more details of Teal organisations and how this applies to AP.

AP Responsibilities

AP has a responsibility to develop and implement policies and provide facilities and processes for the safe and secure storage and management of research data and primary materials to:

- allow for the justification and verification of the outcomes of research
- maximise the potential for future research
- minimise waste of resources of value to researchers and the wider community.

AP culture must advocate responsible research conduct and the following of AP data management policies both during a research project and after the project has been finalised.

Ownership of data and primary materials can be difficult to determine and AP should clarify the criteria that will be used to determine this. With respect to data and information used in or generated by research involving Aboriginal and Torres Strait Islander peoples, AP or researchers may hold data or information; however, they should not make decisions about its access or reuse without proper consultation with its Indigenous owners, if any.

The most satisfactory arrangement will be that materials and data retained at the end of a project are the property of AP or the institution that hosted the project, another institution with an interest in the research, or a central repository. Institutional policies on these matters should not unnecessarily impede the normal use of research data and primary materials.

Upon the determination of ownership of research data, a relevant licence should be considered for the purpose of clarifying the status of the data for re-use by third parties.

In some instances, research may be conducted using data or materials that are owned by another party. In such cases, neither AP nor the researcher can assert ownership. Therefore, to meet the requirements outlined in this guide, both AP and the researcher should document the source of the data or materials and describe access arrangements. Such arrangements should be in place to allow justification and verification of the outcomes of research.

Retention (or disposal) of the research data is important because it may be all that remains of the research work at the end of the project and it should:

- be consistent with any copyright or licensing arrangements that are in place
- be in accord with research discipline-specific practices and standards
- comply with relevant privacy, ethical and publication requirements
- comply with other relevant laws, regulations and guidelines.

The period for which data should be retained is determined by prevailing standards for the specific type of research and any applicable state, territory or national legislation. In general, the minimum period for retention of research data is 5 years from the date of publication. However, the period for which data should be retained is determined by the specific type of research, subject to any applicable state, territory or national legislation. For example:

- for short-term research projects that are for assessment purposes only, such as research projects completed by students, retaining research data for 12 months after the completion of the project may be sufficient
- for most clinical trials, retaining research data for 15 years or more may be necessary
- if the work has community, cultural or historical value, research data should be kept permanently, preferably within a national collection
- researchers are informed of relevant confidentiality agreements and restrictions on the use of research data
- computing systems are secure
- good archival practice includes scheduled review of items in long-term storage.

AP should address options for sharing data via open access and via mediated access (i.e. access to data or information with the assistance of a data custodian or other authorised person). When considering licensing for this purpose, the least restrictive option, such as at https://creativecommons.org.au is encouraged.

Where the sharing of research data has been requested and access has been refused, the reasons for not sharing the data should be transparent and justifiable.

Research data should be stored in facilities provided by or approved by AP. These facilities, including information technology, must comply with privacy requirements and other relevant laws, regulations and guidelines, and research discipline-specific practices and standards related to safe and secure storage of data and information.

Responsibilities of researchers

A requirement of endorsement by AP is that the data management plan includes, but is not be limited to, the following:

- physical, network, system security and any other technological security measures
- policies and procedures
- contractual and licensing arrangements and confidentiality agreements
- training for members of the project team and others, as appropriate
- the form in which the data or information will be stored
- the purposes for which the data or information will be used and/or disclosed
- the conditions under which access to the data or information may be granted to others, and what information from the data management plan, if any, needs to be communicated to potential participants.
- planning for the management of data, particularly for retention of research data, should include considerations of practicality and cost.

If not otherwise clarified in AP policy, researchers should:

- retain accurate, secure and complete records of all research data and primary materials
- retain and be able to produce on request all relevant approvals, authorisations and administrative document eg: ethics, financial approvals, receipts and consent forms
- where possible allow access to research data and primary materials, in particular, to facilitate sharing of data. This access should be facilitated by the use of indexes or catalogues of data and information generated, accessed and used during the research
- respect any project-specific conditions of consent or confidentiality obligations
- report any inappropriate use of or access to or loss of data, in accordance with applicable policies
- ensure that agreements are in place between institutions for managing responsibilities set out in this guide for data and information in multicentre or collaborative projects.

In order to optimise project efficiency and avoid information loss and duplication, researchers should employ good management practices:

- stable storage formats and regular backup to an external source
- version control and other relevant mechanisms for datasets, algorithms, models and software configuration management

- workflow documentation with provenance information for instruments (use and calibration) and software used
- adherence to appropriate national and international standards for scientific terminology and information encoding.

Research data can be the subject of Freedom of Information requests, and in such circumstances, there is an expectation that any information that is delivered will be provided in an understandable format and state. Such requests would need to follow AP arrangements for accessing data, and could incur fees to cover expenses.

Retention and publication

The central aims of retention of data and information are to enable the justification of outcomes of the research and the facilitation of sharing of research data.

Researchers have primary responsibility for deciding which research data and primary materials are candidates for long-term retention and wider accessibility.

In addition to legal requirements and the requirements of funders, government bodies and publishers, the following criteria should be considered in deciding which research data and primary materials should be retained:

- uniqueness and non-replicability
- reliability, integrity, and usability
- relevance to a known research initiative or collection
- community, cultural or historical value
- economic benefit.

In addition to standard publication requirements, options for researchers include publishing or making their research data available through data centres, national and international collections, or through online repositories maintained by institutions and research communities.

Researchers should adhere to national and international standards for data description and structuring to facilitate tracking of references: including using Digital Object Identifiers for datasets, ORCID IDs for researchers, and standard terminology for scientific concepts.

Published research data generally require an online description (i.e. metadata) and should be accessible, interoperable, and re-usable, both manually and with automated tools. This requires researchers to include context (descriptive, technical, methodological, access, and provenance information) in the data structure or in separate metadata records.

Researchers must exercise care with confidential or sensitive information eg:

- data or information that is commercial-in-confidence or that is inherently confidential and which has been provided in confidence (e.g. secret and sacred religious or cultural practices, or information on the location of vulnerable species)
- sensitive data or information subject to privacy legislation (e.g. identifiable human medical/ health and personal data or information)
- data or information subject to classification regimes (e.g. national security information, police records or information and primary materials subject to export controls).

Breaches of AP Code

Breaches of AP Code related to management of data and information in research:

- falsification or fabrication of research data or primary materials
- failure to notify AP and relevant authorities in a timely manner of a data breach or instance of inappropriate access to data held by the researcher
- failure to retain clear, accurate, secure and complete records of all research including research data and primary materials
- failure to adhere to the conditions of any institutional policy or project-specific approvals that relate to the retention, sharing or destruction of research data or primary materials
- selective retention of research data or primary materials so as to hinder the verifiability of a research output or access request
- failure to apply appropriate security controls to research data or primary materials
- failure to obtain necessary approvals or acting inconsistently with a condition of any approval granted in relation to the management of research data or primary materials.

Development of AP Management of data and information in research guide

(Review frequency - 3 yearly)

Policy Identifier / Version	AP Author Guide developed by AP Director	Date Review	AP Auth Guide accepted by Management Committee	Date AP Auth Guide accepted and published to AP website
APdata.V1	Linlee Jordan	1/11/2020	11/11/2020	14/11/2020
APdata.V2	Celeste Salter 29/04/2024	28/6/2024	Nyema Hermiston 18/7/2024	26/7/2024