



Australian Government



**NATIONAL
ARCHIVES
OF AUSTRALIA**

Records Authority

2014/00527054

**National Health and Medical
Research Council**

*Human Embryo Research Licensing, Public Health and
Medical Research*

2014

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INTRODUCTION

The National Health and Medical Research Council (NHMRC) and the National Archives of Australia have developed this Records Authority to set out the requirements for keeping or destroying records for the core business areas of Human Embryo Research Licensing and Public Health and Medical Research. It represents a significant commitment on behalf of NHMRC to understand, create and manage the records of its activities.

This Authority is based on the identification and analysis of the business of NHMRC. It takes into account the agency's legal and organisational records management requirements, and the interests of stakeholders, the agency and the National Archives of Australia.

The Authority sets out those records that need to be retained as national archives and specifies the minimum length of time that temporary records need to be kept. This Authority gives NHMRC permission under the *Archives Act 1983*, for the destruction of the temporary records described after the minimum retention period has expired. Retention periods for these temporary records are based on: an assessment of business needs; broader organisational accountability requirements; and community expectations, and are approved by the National Archives of Australia on the basis of information provided by the agency.

As changes in circumstances may affect future records management requirements, the periodic review of this Authority is recommended. All amendments must be approved by the National Archives.

APPLICATION OF THIS AUTHORITY

1. This Authority is to be used to determine how long records must be kept. Records are matched to the relevant core business and records class in the Authority.
 - Where the minimum retention period has expired and the records are not needed for agency business they should be destroyed as authorised in this Authority.
 - Records that have not reached the minimum retention period must be kept until they do.
 - Records that are identified as Retain as National Archives (RNA) are to be transferred to the National Archives of Australia for preservation.
2. This Authority should be used in conjunction with general records authorities such as:
 - the Administrative Functions Disposal Authority (AFDA) and/or AFDA Express issued by the National Archives to cover business processes and records common to Australian Government agencies;
 - General Records Authority 24 – Records Relating to Data Matching Exercises; and
 - General Records Authority 31 for source (including original) records that have been copied, converted or migrated.
3. The Normal Administrative Practice (NAP) provision of the *Archives Act 1983* gives agencies permission to destroy certain records without formal authorisation. This usually occurs where records are duplicated, facilitative or for short-term use only. NAP does not replace arrangements agreed to in this Authority but can be used as a tool to assist in identifying records for destruction together with an agency's Records Authority or Authorities, and with AFDA and AFDA Express. The National Archives recommends that agencies develop and implement a Normal Administrative Practice policy. Advice and guidance on destroying records as a normal administrative practice and on how to develop an agency NAP policy is available from the National Archives' website at www.naa.gov.au.
4. Records that are reasonably likely to be needed as evidence in a current or future judicial proceeding or are subject to a request for access under the *Archives Act 1983*, the *Freedom of Information Act 1982* or any other relevant Act must not be destroyed until the action has been completed.
5. Records subject to a disposal freeze must not be destroyed until the freeze has been lifted. Further information about disposal freezes and whether they affect the application of this Authority is available from the National Archives website at www.naa.gov.au.
6. Where the method of recording information changes (for example from a manual system to an electronic system, or when information is migrated from one system to a new system) this Authority can still be applied, providing the records document the same core business. The information must be accessible for the period of time prescribed in this Authority. The agency will need to maintain continuing access to the

information, including digital information, for the periods prescribed in this records authority or until the information is transferred into the custody of the National Archives.

7. In general, retention requirements indicate a minimum period for retention. The NHMRC may extend minimum retention periods if it considers that there is an administrative need to do so, without further reference to the National Archives. Where NHMRC believes that its accountability will be substantially compromised because a retention period or periods are not adequate, it should contact the National Archives for review of the retention period.
8. Records coming within 'Retain as national archives' classes in this Authority have been determined to be part of the archival resources of the Commonwealth under Section 3C of the *Archives Act 1983*. The determination of Commonwealth records as archival resources of the Commonwealth obliges agencies to transfer the records to the National Archives when they cease to be current and, in any event, within 15 years of the records coming into existence, under Section 27 of the *Archives Act 1983*.
9. Records in the care of agencies should be appropriately stored, managed and preserved. Agencies need to meet this obligation to ensure that the records remain authentic and accessible over time. Under Section 31 of the *Archives Act 1983*, access arrangements are required for records that become available for public access including those records that remain in agency custody.
10. Appropriate arrangements should be made with the National Archives when records are to be transferred into custody. The National Archives accepts for transfer only those records designated as national archives.
11. Advice on how to use this Authority is available from NHMRC's records manager. If there are problems with the application of the Authority that cannot be resolved, please contact the National Archives.

CONTACT INFORMATION

For assistance with this authority or for advice on other records management matters, please contact National Archives' Agency Service Centre.

Queen Victoria Terrace
Parkes ACT 2600
PO Box 7425
Canberra Business Centre ACT 2610

Tel: (02) 6212 3610
Fax: (02) 6212 3989
Email: recordkeeping@naa.gov.au
Website: www.naa.gov.au

AUTHORISATION

RECORDS AUTHORITY 2014/00527054

**Person to whom notice of
authorisation is given:**

Professor Warwick Anderson
Chief Executive Officer
National Health and Medical Research Council
Level 1, 16 Marcus Clarke Street
Canberra ACT 2601

Purpose:

Authorises arrangements for the disposal of records in accordance with Section 24(2)(b) of the *Archives Act 1983*.

Determines records classed as 'Retain as national archives' in this Records Authority to be part of the archival resources of the Commonwealth under Section 3C of the *Archives Act 1983*.

Application:

All core business records relating to Human Embryo Research Licensing, Public Health and Medical Research.

This authority gives permission for the destruction, retention or transfer to the National Archives of Australia of the records described. This authority will apply only with the consent of the agency currently responsible for the business documented in the records described.

Authorised by

David Fricker
Director-General
National Archives of Australia

Date of issue:

21 November 2014

HUMAN EMBRYO RESEARCH LICENSING

The core business of regulating activities that involve the use of certain human embryos created by assisted reproductive technology or by other means.

The **core activities** include:

- developing, implementing and reviewing policies, strategies, plans, frameworks, standards and programs;
- receiving, processing and assessing applications from organisations or individuals to be licensed to conduct human embryo research, quality assurance or training activities;
- issuing, varying, suspending or revoking licences;
- developing, maintaining and updating the list of issued human embryo research licences;
- managing and participating in internal and external committees and meetings;
- appointing inspectors to monitor licensee compliance;
- undertaking compliance monitoring and enforcement activities, including planning, conducting and facilitating inspections, undertaking investigations and determining and applying penalties and sanctions;
- managing appeals and reviews of agency decisions;
- liaising and consulting with stakeholders;
- receiving and providing advice and other forms of information; and
- reporting.

The performance of the core business is supported by **general activities** such as:

- developing, implementing and reviewing human embryo research processes, systems and procedures;
- negotiating, establishing and implementing agreements and contracts with individuals and organisations;
- planning, conducting and facilitating audits;
- preparing and presenting speeches;
- arranging and attending conferences and seminars;
- delegating powers and authorising actions;
- evaluating and reviewing;
- identifying, assessing and managing risks; and
- managing and responding to enquiries and feedback from the public.

Cross references to AFDA Express records authority

For the preparation of budget estimates, budget proposals, cost modelling and financial transactions, including the processing of licence application fees, use FINANCIAL MANAGEMENT.

For the acquisition of goods and services, use PROCUREMENT.

For advice, briefs and submissions to the portfolio Minister, cabinet submissions and the organisation's participation in formal inquiries, use GOVERNMENT RELATIONS.

For development of new legislation and amendments to existing legislation, use GOVERNMENT RELATIONS and/or STRATEGIC MANAGEMENT.

For media releases, use COMMUNITY RELATIONS and/or GOVERNMENT RELATIONS.

For developing and executing contracts under seal or deeds, use CONTRACTS UNDER SEAL/DEEDS.

Cross references to other records authorities

For statutory and non-statutory advisory bodies, including the Council of NHMRC, use ADVISORY BODIES.

HUMAN EMBRYO RESEARCH LICENSING

Class no	Description of records	Disposal action
61682	<p>The following significant records documenting:</p> <ul style="list-style-type: none"> • developing, implementing and reviewing national and high-level human embryo research licensing policies, standards, strategies, plans, frameworks and programs. Includes final versions, major drafts, results of stakeholder consultations and related research; • high-level advice given to, or received from, major stakeholders. Includes final versions of formal advice, submissions, briefs, opinions, position papers and supporting research; • high-level internal and external committees, working groups, sub working groups and other bodies (such as the Embryo Research Licensing Committee) where the agency provides the secretariat, is the Australian Government's main representative, or plays a prominent or central role. Includes establishment records, agenda, final versions of minutes, reports, briefing notes and tabled papers; • development of national and high-level reports relating to the licensing of human embryo research. Includes final versions, stakeholder consultation and supporting research; • summary records created to support the core business, such as the database of human embryo licences issued; • master set of human embryo research licences issued to successful applicants; • human embryo research licence case files relating to applications that are precedent setting, controversial or attract significant public interest (eg licences permitting somatic cell nuclear transfer also known as therapeutic cloning). Includes receipt, assessment and processing of applications and final decisions; • appeals or reviews of decisions made by the agency that are precedent setting, controversial or of significant public interest; • final versions of significant agreements and contracts and supporting documents, that: relate to the establishment of partnerships or cooperative arrangements with other governments, agencies and organisations; are controversial, of public interest or ground-breaking in nature; or have a substantial impact upon the licensing of human embryo research in Australia. Includes high-level inter-governmental agreements and Memorandums of Understanding; • high-level liaison or consultation with major stakeholders in support of the core business, including with State and Territory Governments and agencies. • master versions of agency publications produced to support human embryo research licensing. Includes information sheets and published audit reports; • final versions of speeches presented by the Minister, the agency head, or senior agency staff, including speeches presented at conferences; • national and high-level reviews, including sector-wide and major internal reviews. Includes final review, reports, major drafts, recommendations, stakeholder consultations, submissions and supporting research; • final versions of reports, papers and proceedings from conferences, 	Retain as national archives

HUMAN EMBRYO RESEARCH LICENSING

Class no	Description of records	Disposal action
	<p>symposiums, forums, seminars or workshops hosted by the agency; and</p> <ul style="list-style-type: none"> • investigation or compliance cases that are of widespread public interest, precedent setting or relate to offences not previously known to Commonwealth law, or result in revocation of licences or policy change. Includes joint investigations involving collaboration with other Commonwealth agencies, treaty partners or international authorities and organisations. <p><i>[For records supporting litigation activities, use LEGAL SERVICES.]</i></p>	
61683	<p>Records documenting:</p> <ul style="list-style-type: none"> • receipt and processing of applications to conduct research, quality assurance and training activities involving human embryos, other than those covered in class 61682; • monitoring of and reporting on compliance with governing legislation; • investigations into breaches of compliance with relevant legislation by licensed institutions and other individuals or organisations, other than those covered in class 61682. Includes the obtaining of warrants, the carrying out of inspections and investigations, the seizure of relevant evidence including embryos, sanctions or penalties applied, and suspending or revoking licences; • appointing inspectors and issuing identity cards; • variation of licences; and • appeals and reviews of decisions made under the relevant legislation, other than those covered in class 61682. 	Destroy 20 years after action completed
61684	<p>Records documenting:</p> <ul style="list-style-type: none"> • routine operational administrative tasks supporting the core business; and • human embryo research licensing activities, other than those covered in classes 61682 and 61683. 	Destroy 10 years after action completed

PUBLIC HEALTH AND MEDICAL RESEARCH

The core business of ensuring consistent health standards across Australia by fostering public health and medical research and providing related guidance and other forms of information to the public and health professionals. Includes advocating high ethical standards in health research.

The **core activities** include:

- developing, implementing, and reviewing public health and medical research policies, strategies, plans, frameworks, schemes, programs and projects;
- developing, implementing and reviewing public health and medical research standards, rules and codes of practice, including setting standards for the development of high-quality, implementable clinical guidelines;
- receiving and providing advice and other information;
- developing and submitting proposals and submissions;
- managing and participating in internal and external committees, working groups and other bodies;
- supporting and contributing to the development of guidelines created by other organisations;
- research translation, including making recommendations, developing, issuing and promoting clinical practice and public health guidelines for particular fields, and assessing and approving externally developed guidelines;
- receiving, processing and assessing applications, and registering and certifying health research ethics committees;
- monitoring research institutions and registered or certified health research ethics committees for compliance with standards or requirements;
- receiving, managing and investigating complaints and identified ethical breaches or instances of research misconduct and imposing sanctions or penalties;
- referral of matters under investigation to other agencies;
- managing appeals and reviewing agency decisions;
- liaising and consulting with key stakeholders, including public consultation processes;
- negotiating, establishing, managing and reviewing agreements and contracts;
- conferring awards for excellence in public health and medical research; and
- developing training materials and conducting training courses.

The performance of the core business is supported by **general activities** such as:

- developing, implementing and reviewing public health and medical research processes, systems and procedures;
- receiving and responding to enquiries;
- preparing and presenting speeches;
- arranging and attending conferences and seminars;
- delegating powers and authorising actions;
- reporting and reviewing;
- arranging trips and visits;
- planning, conducting and facilitating audits; and
- identifying, assessing and managing risks.

Cross references to other areas of this records authority

For the control of human embryo research, use HUMAN EMBRYO RESEARCH LICENSING.

PUBLIC HEALTH AND MEDICAL RESEARCH

Cross references to AFDA Express records authority

For the preparation of budget estimates, budget proposals, cost modelling and financial transactions, use FINANCIAL MANAGEMENT.

For the acquisition of goods and services, use PROCUREMENT.

For advice, briefs and submissions to the portfolio Minister, cabinet submissions and the organisation's participation in formal inquiries, use GOVERNMENT RELATIONS.

For development of new legislation and amendments to existing legislation, use GOVERNMENT RELATIONS and/or STRATEGIC MANAGEMENT.

For media releases, use COMMUNITY RELATIONS and/or GOVERNMENT RELATIONS.

For developing and executing contracts under seal or deeds, use CONTRACTS UNDER SEAL/DEEDS.

Cross references to other records authorities

For the receipt, evaluation, processing and management of applications from organisations or institutions for funding to carry out research, use GRANT MANAGEMENT.

For receipt, assessment, awarding and administration of agency funded public health and medical research fellowships and scholarships, use GRANT MANAGEMENT.

For records documenting statutory and non-statutory advisory bodies, including the Council of NHMRC, use ADVISORY BODIES.

Class no	Description of records	Disposal action
61685	<p>The following significant records documenting:</p> <ul style="list-style-type: none"> developing, implementing and reviewing national and high-level policies, strategies, plans, frameworks, assessment criteria, schemes (eg Centres of Research Excellence Scheme) and programs for public health and medical research, including programs for the former National Institute of Clinical Studies. Includes final versions, major drafts, proposals, submissions, records of consultation and supporting research; providing and receiving high-level advice. Includes final version, major drafts, stakeholder consultation and supporting research and briefs; high-level internal and external committees, working groups and other bodies, where the agency provides secretariat support, is the Australian Government's main representative, or plays a prominent or central role (eg Research Committee). Includes establishment documentation, agenda, final versions of minutes, reports, briefing notes and tabled papers; developing implementing and reviewing public health and medical research standards, rules and codes of conduct (eg <i>National Statement in Ethical Conduct in Human Research (2007)</i>). Includes final versions, stakeholder consultation and supporting research; outcomes of research including guidelines, research advice, codes of practice, public statements, literature reviews, issues papers and submissions relating to current and emerging health issues. Includes final version, major drafts, stakeholder consultation and supporting research and briefs; assessing and approving externally developed standards and guidelines; summary records created to support the core business, such as those consolidating information on research project outcomes and registers of review panel members (eg <i>Clinical Practice Guidelines Portal</i> and the 	Retain as national archives

PUBLIC HEALTH AND MEDICAL RESEARCH

Class no	Description of records	Disposal action
	<p><i>Guidelines in Development Register</i>);</p> <ul style="list-style-type: none"> • investigations into complaints about institutions carrying out public health and medical research that are controversial or of significant public interest, precedent setting, or result in significant changes to agency policy and programs (eg serious ethical breaches or research misconduct or scientific fraud). Includes related monitoring records; • final versions of high-level internal and external reports on agency funded projects relating to public health and medical research issues. Includes final research reports, stakeholder consultation, statistical and trend analysis, data models, and supporting research; • high-level liaison and consultation with major stakeholders in support of the core business, including the design and implementation of centres of collaboration (eg liaison with Partnership Centres); • final versions of significant agreements and contracts and supporting documents, that: relate to major funding arrangements or the establishment of partnerships and cooperative arrangements with other governments, agencies and organisations; are controversial, of public interest or ground-breaking in nature; or substantially impact upon the provision of public health and medical research in Australia (or have substantial implications for the conduct of agency business). Includes high-level inter-governmental and international agreements, joint ventures and Memorandums of Understanding; • appeals or reviews of decisions made by the agency that are precedent setting, controversial or of significant public interest; • master set of training materials developed for external stakeholders; • master versions of agency publications. Includes reports, guidelines, handbooks, standards, and information sheets; • final versions of speeches presented by the Minister, the agency head, or senior agency staff, including speeches presented at conferences; • national and high-level reviews, including sector-wide and major internal reviews. Includes final review reports, major drafts, recommendations, stakeholder consultations, submissions and supporting research; • ceremonies for conferring national or international awards for excellence in public health and medical research. Includes programs, photographs and award recipient nomination and assessment; and • final versions of reports, papers and proceedings from public health and medical research conferences, symposiums, forums, seminars or workshops hosted by the agency. 	
61686	<p>Records documenting:</p> <ul style="list-style-type: none"> • enquiries relating to advocating high ethical standards in health research; and • assessment, registration, certification and compliance case records of human research ethics committees, other than those covered in class 61685. Includes annual institutional compliance report. 	<p>Destroy 20 years after action completed</p>

PUBLIC HEALTH AND MEDICAL RESEARCH

Class no	Description of records	Disposal action
61687	Records documenting: <ul style="list-style-type: none">• routine operational administrative tasks supporting the core business; and• public health and medical research activities, other than those covered in classes 61685 and 61686.	Destroy 10 years after action completed