

# Annexure to The Responsible Conduct of Research

Schedule of Retention Periods for Research Data and Primary Materials

[Purpose] [Definitions] ['Research data' vs 'primary materials'] [Primary materials retention] [Data retention] [Research records other than research data] [Table of Minimum Retention Periods for Research Data] [Retaining data beyond the minimum period]

## 1. PURPOSE

This schedule is intended to guide researchers, both students and staff, in deciding on retention periods for research data and primary materials. It also alerts researchers to management of research records other than research data. It is consistent with the University Sector Retention and Disposal Schedule approved by Queensland State Archives, which covers research records including, amongst other matters, ethical clearances, research data, and records relating to the management of research material.

Under the The Responsible Conduct of Research, and in compliance with the Australian Code for the Responsible Conduct of Research, the University has undertaken to

- maintain a Schedule of Retention Periods for Research Data and Primary Materials to specify minimum retention periods for various types of research.
- provide information to guide researchers in identifying data and primary materials for retention and deciding on retention periods and conditions
- provide safe and secure University facilities sufficient to enable researchers to store research data and primary materials for the length of time determined by the researcher as necessary to comply with University policy as specified in this Schedule.

With regard to the third point, this Schedule should inform the planning and management of physical and digital facilities for the storage of primary materials, data and other research-related records.

## 2. DEFINITIONS

In the context of this schedule, research data are defined as:

factual records, which may take the form of numbers, symbols, text, images or sounds, used as primary sources for research, and that are commonly accepted in the research community as necessary to validate research findings.

This definition aims to be technology-neutral, in that it omits any reference to the media in which the records are made. The research community would be particular to the field of research. This allows for conventions in particular disciplines, as manifest in journal editorial policies for example, on what is regarded as data that need to be kept.

This schedule does not give a definition of 'primary materials'. Depending on the field of research, 'primary materials' could be physical objects, such as chemical samples, biological materials, human tissue, specimens; or they could take the form of records such as historical documents in archives. The

possibilities are immense and researchers will have to identify the 'primary materials' of their research for themselves, taking into account the practices within the field of research.

### 3. 'RESEARCH DATA' VS 'PRIMARY MATERIALS'

The dividing line between 'research data' and 'primary materials' will not be clear in many cases. For example, the Australian Code for the Responsible Conduct of Research implies that completed questionnaires and recordings are 'primary materials' while transcripts derived from them are 'research data' and that different standards for retention may apply. However, it could be argued that the completed questionnaires and recordings are research data in terms of the definition adopted in this schedule. They qualify as 'factual records...used as primary sources for research', so if the research community regards them as necessary to validate research findings, then they qualify as research data and should be retained for the recommended period.

If a researcher is unsure as to whether something used in a research project as a primary source should be treated as 'research data' or 'primary materials', a simple rule to follow is to treat the materials as research data if they fit the definition of research data. The first question to ask is "Are these materials factual records?" If the answer is no, then the researcher does not need to treat them as research data. They can consider them as 'primary materials'.

If the answer is yes, then the researcher needs to decide if they qualify as research data by asking a follow-up question "are they commonly accepted in the discipline's research community as necessary to validate research findings?"

### 4. PRIMARY MATERIALS RETENTION

The Australian Code for the Responsible Conduct of Research gives some general examples of minimum retention periods for research data, but gives no guidance for primary materials.

Many factors will affect whether it is feasible or legal to retain 'primary materials' used in research. Factors include the nature and durability of the materials, ownership, agreements with sponsors, practices in the discipline, and legislation on matters such as hazardous materials, animal protection, use of human tissue, health and safety. It is not possible to enumerate the types of primary materials that might be used in research and prescribe retention periods.

In cases where it is feasible and legal to retain the 'primary materials', the guiding principle is to retain sufficient materials and data to justify the published or reported outcomes of the research and to enable the researcher to defend the outcomes if they are challenged.

Guidance on ethical issues in retaining primary materials used in research involving humans or animals is found in the Griffith University Research Ethics Manual. Information on health and safety issues in the management of materials that may be hazardous is found on the Health, Safety and Wellbeing sections of the Human Resources Management website.

### 5. DATA RETENTION

The Table of Minimum Retention Periods for Research Data at the end of this Schedule prescribes the minimum periods for which research data should be retained. The table categorises the data by subject of research, patent status, researcher type, and dissemination status as factors relevant to determining the minimum period.

#### RESEARCH RECORDS OTHER THAN RESEARCH DATA 6.

There are records relating to research that do not fit the definition of research data, but may still need to be retained for various reasons. The Australian Code for the Responsible Conduct of Research mentions 'primary research records, such as laboratory notebooks' in section 2.6 where it advises researchers to provide the same level of care to them as to the analysed research data. The University Sector Retention and Disposal Schedule in section 601.2/F8 RESEARCH deals with various administrative records specific to research in addition to research data.

### 6.1 Laboratory notebooks

For guidance on maintaining, storing, and retaining laboratory notebooks, researchers should consult the appropriate Head of School or Research Centre Director, or other senior researcher.

### 6.2 Signed consent forms and related documents

The signed consent forms for any research project, student or staff, that has gone through the University's human ethics clearance process must be retained for 15 years. This is in accordance with section 601.2/C111 of the University Sector Retention and Disposal Schedule:

'Records relating to consent obtained from individuals to participate in research activities. Includes consent notices, signed consent and records of suitability card for interviewing juveniles. Retain for 15 years after project concluded or abandoned.'

### Other records relating to ethical clearances

These are managed by Information Management and Office for Research in accordance with the University Sector Retention and Disposal Schedule.

Records relating to the management of certain materials that are used in research activities

Section 601.3/A15 of the University Sector Retention and Disposal Schedule specifies retention periods for records relating to the management of certain materials that are used in research activities. It covers records relating to the acquisition, management, use, or disposal of such substances as

- Chemicals, specimens, drugs, poisons etc
- human bodies or body parts
- hazardous materials and waste
- controlled and restricted drugs
- radioactive substances and radiation equipment

Records on these activities are stored and managed by the University as general files of the University in accordance with the Information Management Policy.

#### 7. TABLE OF MINIMUM RETENTION PERIODS FOR RESEARCH DATA

#### 7.1 Definition

In the context of this Schedule of Retention Periods for Research Data and Primary Materials, research data are defined as:

factual records, which may take the form of numbers, symbols, text, images or sounds, used as primary sources for research, and that are commonly accepted in the research community as necessary to validate research findings.

This definition aims to be technology-neutral, in that it omits any reference to the media in which the records are made. The media could be paper, electronic, film, magnetic tape or any digital, analogue or other media in existence now or yet to be invented.

### Judgment necessary

It is not physically or humanly possible for the University to retain research data for every project undertaken under its auspices. A judgment must be made as to when the costs of retaining data far outweigh the benefit to the University and society at large. The central aim of the University's policy is to retain data sufficient 'to justify the outcomes of the research and to defend them if they are challenged.' It is important that the University and the researcher retain the data that support research findings that have been disseminated. It is less important to retain data from research projects that do not result in dissemination of findings, because their findings, if any, are unlikely to be challenged or arouse any interest.

However, in some cases, research data need to be kept for other reasons as well, sometimes to satisfy legal obligations or reduce litigation risk. Whether the findings are disseminated or not, data from clinical trials are a special category. Clinical trial data are preserved for longer periods than is usually necessary for other kinds of research, in case evidence emerges of unexpected late effects. Research projects that lead to a patent are another special category where it is necessary to keep data for legal reasons, whether findings are eventually disseminated or not.

There are many ways of disseminating research findings. Formal publication of the results of research most commonly takes place in refereed academic journals or books, and this is the most critical to academic careers. However, research findings may be disseminated by other means confidential reports to sponsors, public release of findings in the media, or open-access web documents - for example.

In the case of research undertaken by students, submission of thesis or project report for assessment or presentation of PhD/MPhil confirmation research seminar does not constitute public release or dissemination in the context of this document. However, making the thesis or report available on the World Wide Web does constitute public release and dissemination, although it is not considered formal publication in the academic sense.

## Categories of data

The table categorises the data by subject of research, patent status, researcher type, and dissemination status as factors relevant to determining the minimum period.

- Subject categories are:
  - Clinical trial
  - Any subject other than a clinical trial
- 7.3.2 Patent status is categorised as:
  - Yes Patent sought by University

No - Patent not sought by University

### 7.3.3 Researcher types are:

- Staff
- Contractor conducting research on behalf of the University
- Student who has signed IP assignment deed to University
- Student in RHD or other research education program who has NOT signed IP assignment deed to University
- Other student no IP assignment and not RHD/research education.

### 7.3.4 Dissemination status is categorised as:

- Refereed publication
- Other form of public release to an audience outside the University
- Not disseminated. Submission of thesis or project report for assessment or presentation of PhD/MPhil confirmation research seminar does not constitute public release or dissemination in the context of this document.

### Ownership issues

University policy on the ownership of intellectual property in research data and other outputs of research is found in the Intellectual Property Policy. The use of University facilities to store research data does not alter the ownership arrangements. For example, if copyright subsists in the research data, and the copyright is owned by a staff member, student, or external organisation, storing the data on University facilities will not of itself cause a transfer of copyright to the University.

### When researchers leave

When researchers leave, the University will no longer be responsible for the storage of their research data and primary materials, unless:

- an agreement to this effect has been made between the researcher and the University; or
- a funding or other agreement to this effect has been made between the University and a third party; or
- the University is the legal owner of the primary materials or the intellectual property in the data.

In cases where the University is no longer responsible, the researcher will be responsible for continuing storage, management, and disposal of the retained data for the minimum period as indicated by this table, under conditions that comply with security, safety, privacy, and confidentiality requirements of any ethical clearance the project was granted, any funding agreement, and any data licence agreement.

| Subject of research                     | Patent<br>sought by<br>University<br>(Yes or No) | Researcher Type  | Dissemination status of research findings  | Minimum period   | Responsibility for retention                     |
|---|--|--|--|--|--|
| Clinical trial                          |  |  |  |  |  |
| Clinical trial                          | Y  | Any type   | Any status   | 7 years after expiry of patent (601.3/C149) (minimum of 27 years)  | University                                       |
| Clinical trial                          | N  | Any type   | Any status   | 15 years from completion of clinical trial AND 10 years after last patient service provision or medico-legal action (601.3/C148)   | University, until researcher leaves              |
| Any subject other                       | than a clinical                                  | trial - patent sought by Univ                              | versity  |  |  |
| Any subject other than a clinical trial | Y  | Any type   | Any status   | 7 years after expiry of patent (601.3/C149)  | University                                       |
| Any subject other                       | than a clinical                                  | trial - no patent sought – sta                             | aff and contractors  |  |  |
| Any subject other than a clinical trial | N  | Staff  | Refereed publication   | 5 years after the end of the year of publication of the last refereed publication that is based on the data, or longer if dictated by the research funding agreement or the publication's editorial policy. (601.3/C150) | University, until researcher leaves              |
| Any subject other than a clinical trial | N  | Staff  | Other form of public release to an audience outside the University, e.g.  report to a sponsor  conference presentation,  non-refereed publication  submission to government  posted online | 5 years after the end of the year of release of findings, unless there are contractual obligations that dictate otherwise (601.3/C150)   | University, until researcher leaves              |
| Any subject other than a clinical trial | N  | Staff  | Not disseminated   | 5 years after the end of the year that the project was concluded or abandoned, unless there are contractual obligations that dictate otherwise (601.3/C150)  | University, until researcher leaves              |
| Any subject other than a clinical trial | N  | Contractor conducting research on behalf of the University | Refereed publication   | 5 years after the end of the year of publication of the last refereed publication that is based on the data, or longer if dictated by the research funding agreement or the publication's editorial policy. (601.3/C150) | University, unless contract stipulates otherwise |
| Any subject other than a clinical trial | N  | Contractor conducting research on behalf of the University | Other form of public release to an audience outside the University, e.g.  report to a sponsor  conference presentation,  non-refereed publication  | 5 years after the end of the year of release of findings, unless there are contractual obligations that dictate otherwise (601.3/C150)   | University, unless contract stipulates otherwise |

| Subject of research                     | Patent<br>sought by<br>University<br>(Yes or No) | Researcher Type  | Dissemination status of research findings   | Minimum period   | Responsibility for retention                     |
|---|--|--|---|--|--|
|   |  |  | <ul><li>submission to government</li><li>posted online</li></ul>  |  |  |
| Any subject other than a clinical trial | N  | Contractor conducting research on behalf of the University   | Not disseminated  | 5 years after the end of the year that the project was concluded or abandoned, unless there are contractual obligations that dictate otherwise (601.3/C150)  | University, unless contract stipulates otherwise |
|   | than a clinical                                  | trial - no patent sought – stu   |   |  |  |
| Any subject other than a clinical trial | N  | Student who has signed IP assignment deed to University  | Refereed publication  | 5 years after the end of the year of publication of the last refereed publication that is based on the data, or longer if dictated by the research funding agreement or the publication's editorial policy. (601.3/C150) | University, until researcher leaves              |
| Any subject other than a clinical trial | N  | Student who has signed IP assignment deed to University  | Other form of public release to an audience outside the University, e.g.  report to a sponsor  conference presentation, non-refereed publication including online submission to government  Submission of thesis or project report for assessment does not constitute public release. Presentation of PhD/MPhil confirmation research seminar does not constitute public release. | 5 years after the end of the year of release of findings, unless there are contractual obligations that dictate otherwise (601.3/C150)   | University, until researcher leaves              |
| Any subject other than a clinical trial | N  | Student who has signed IP assignment deed to University  | Not disseminated  | 5 years after the end of the year that the project was concluded or abandoned, unless there are contractual obligations that dictate otherwise (601.3/C150)  | University, until researcher leaves              |
| Any subject other than a clinical trial | N  | Student in RHD or other research education program who has NOT signed IP assignment deed to University | Refereed publication  | 5 years after the end of the year of publication of the last refereed publication that is based on the data, or longer if dictated by the research funding agreement or the publication's editorial policy. (601.3/C150) | Student  May request assistance from University  |
| Any subject other than a clinical trial | N  | Student in RHD or other research education program who has NOT   | Other form of public release to an audience outside the University, e.g.  report to a sponsor   | 5 years after the end of the year of release of findings, unless there are contractual obligations that dictate  | Student  May request                             |

| Subject of research                     | Patent<br>sought by<br>University<br>(Yes or No) | Researcher Type  | Dissemination status of research findings  | Minimum period  | Responsibility for retention  |
|---|--|--|--|---|-------------------------------|
|   |  | signed IP assignment deed to University  | conference presentation,     non-refereed publication including online     submission to government  Submission of thesis or project report for assessment does not constitute public release. Presentation of PhD/MPhil confirmation research seminar does not constitute public release. | otherwise (601.3/C150)  | assistance from<br>University |
| Any subject other than a clinical trial | N  | Student in RHD or other research education program who has NOT signed IP assignment deed to University | Not disseminated  Submission of thesis or project report for assessment does not constitute dissemination. Presentation of PhD/MPhil confirmation research seminar does not constitute dissemination.  | At discretion of student as a general rule.  If the research project underwent ethics clearance, the student must comply with any conditions on data retention. | Student                       |
| Any subject other than a clinical trial | N  | Other student (no IP assignment and not RHD/research education)  | Not disseminated.  Purely for assessment.  | No need to retain.  If the research project underwent ethics clearance, the student must comply with any limits on data retention.                              | Student                       |

Subject categories: Clinical trial; Any subject other than a clinical trial

Patent status: Yes - Patent sought by University; No - Patent not sought by University

Researcher Type: Staff; Contractor conducting research on behalf of the University; Student who has signed IP assignment deed to University; Student in RHD or other research education program who has NOT signed IP assignment deed to University; Other student - no IP assignment and not RHD/research education.)

Dissemination status: Refereed publication; Other form of public release to an audience outside the University; Not disseminated. Submission of thesis or project report for assessment and presentation of PhD/MPhil confirmation research seminar do not constitute public release or dissemination in the context of this document.

#### RETAINING DATA BEYOND THE MINIMUM PERIOD 8.

A guiding principle is that research data be retained for sufficient time to allow reference to them by other researchers and interested parties; this may be for as long as interest and discussion persist following dissemination. However, the University may continue to store research data beyond the minimum period as long as they are of continuing value to the University and that value is worth the significant ongoing costs of data storage and management. In deciding on extended retention, the researcher should consider the potential value for further future research. This is especially the case where the research would be difficult or impossible to repeat or where repeating the research would place a significant burden on human participants or animals. For research involving humans, guidance on ethical issues in the re-use of data and its retention beyond the minimum period is found in the Griffith University Research Ethics Manual.

## 8.1 Highly significant research data

If the data has community or heritage value, consideration should be given to permanent retention, preferably within a national or state collection. The University Sector Retention and Disposal Schedule in section 601.2/C123 prescribes permanent retention for 'research data created in the conduct of a research project including clinical trials which is of high public interest or significance to the discipline such that it has or will change a commonly held view or approach irrespective of the field in which the research is conducted'.

### 8.2 When results are challenged

If results from research are challenged, all relevant data must be retained until the matter is resolved.