UNIVERSITY OF ABERDEEN

GUIDELINES ON KEEPING RESEARCH RECORDS

Introduction:

The effective management of research records is an integral part of good research governance and high quality research practice.

Keeping clear, complete and authentic records as part of the research process, and beyond, provides the evidence base, which strengthens the reliability of research findings, exhibits integrity in research processes, safeguards researchers and the University from allegations of research misconduct and demonstrates compliance with relevant University policies, legal and regulatory obligations and requirements from auditors, sponsors or research funding bodies.

The maintenance of records is also important for managing and protecting legitimate rights and interests of individuals, the University and stakeholders, where restrictions are placed on the level of access, sharing and use, specified on ethical, legal, regulatory or commercial grounds; to protect, intellectual/ property rights, commercial confidentiality, or the personal data of living identifiable individuals.

External Context:

- Making research data available to users is core to the remit of the Research Councils UK and increasingly Research Councils require plans for data management to be a condition of grant.
- RCUK Common Principles on Data Policy is available here and further guidance on best practice is available here.
- A summary of UK Research Funders' data policies is available here.
- The UK Research Integrity (UKRIO) provides good practice guidance for researchers, which includes the collection and retention of data, available here.

University policy and guidelines:

The University's commitment to research excellence and the standards, principles and expectations for research conduct, is outlined in the University of Aberdeen Research Governance Handbook .

Section 4 of the Handbook outlines the University of Aberdeen Policy and Guidelines on Good Research Practice which requires that all researchers must keep clear and accurate records of the procedures followed and approvals granted during the research process, including records of the interim results obtained as well as of the final research outcomes. This is necessary not only as a means of demonstrating proper research practices, but also in case questions are subsequently asked about either the conduct of the research or the results obtained. The maintenance of accurate records is also important for potential subsequent commercialisation of research.

Researchers must adhere to these University Guidelines on *Keeping Research Records,* in conjunction with this policy and other relevant University information management policies and guidance, which are available on the Policy Zone.

When developing your data management plans, consider how your records will be generated, collected, recorded and stored. These guidelines provide a practical basis for assuring that all research records are managed, maintained and kept appropriately throughout the duration of your research project and for the longer term.

What are research records?

The term "record" is used to describe any recorded information, which is created or received and retained as evidence of specific activity, actions, decisions, transactions, necessary to document your research work and validate the research project's observations, findings or outputs, or because the record has other informational value.

Research records are your source evidence for validity of your research findings and are crucial for clarifying any potential challenges to authentication, authorship or intellectual property. Records demonstrate research integrity and compliance with relevant legislative and regulatory requirements.

These records can be digital or hard copy and come in various forms, such as logs, notebooks, lab books, databases, audio files, correspondence or emails.

The recorded information may be in any format (text/sound/image etc.) and stored in any medium (paper/digital). In terms of a record, it is the content and context which is significant, not the format.

Typically research records and records associated with the research process fall into the following key categories;

i. Records which document the research process e.g. grant applications, research protocols, ethical and peer reviews, standard operating procedures (SOPS), grant approvals, risk assessments, audit assessments.

ii. Records which document research outcomes/products, such as reports, monographs, patents.

iii. Records which document the management of the research project, such as financial records, staff records, invoices, correspondence, including emails, contracts, intellectual property rights, consent forms etc.

iv. Research Data in both "raw" and "analysed" forms, such as lab book notes; questionnaires; instrument readings, samples, primary and derived datasets, images etc.

Each research project will generate or collect its own specific records, depending on the research discipline and circumstances of the individual project. Effective management of the retention of your research records will ensure you meet these requirements.

Keeping research records:

Simply put, good record keeping requires you to establish what records are being created or held as a result of your research activities, what records must be kept for evidence of those activities, for what length of time, in what format, how and where these records will be kept, when they will be reviewed for disposal, or archived for the longer term and documenting the decision making to select, dispose or keep, throughout the record lifecycle.

The following guidelines, based on sound record keeping principles, provide a useful checklist for developing your research data management plan and for managing your paper and digital records effectively throughout the duration of your research project and, where appropriate, ensuring continued accessibility and use, in the longer term, at the end of your project and active research activities have concluded.

Record Keeping Principles

1. Accountability

1.1 Overall responsibility for managing research records lies with the Principle Investigator. Define and assign clear roles and lines of responsibilities for record keeping activities to individuals, at the outset of the project.

1.2 Individual researchers have a responsibility to keep clear and accurate research records. Researchers should keep a formal valid record of their work in a notebook, or electronic record equivalent, used specifically for this purpose, to demonstrate good research conduct and evidence the results, obtained. Record books should

include a table of contents. For laboratory based sciences, for instance, the primary record will be the “lab book” or “electronic lab book” (ELN).

1.3 Where practicable, one central master record should be maintained for each research project. However, in some instances several records may be required, for example, for interdepartmental or multiple site projects.

1.4 There is no requirement to duplicate all paperwork or digital files associated with the project, or to record all minor activities, however the project should identify and document the significant records which will be generated and held, sufficient to allow the project to be understood, audited or replicated, including appropriate reference to any relevant secondary records, associated with the primary research activities. Examples of research records have been listed in Appendix A.

1.5 Where appropriate, information can be printed and copies of substantial documentation (e.g. questionnaires or consent forms) affixed, however within a digital environment, reference to clearly signposted, or linked original electronic files will often be sufficient.

1.6 Records should be cross-referenced, by means of unique identifiers and use of quality metadata (e.g. title, code, persistent identifier, file name, date, named person) to enable all related research records to be brought together, physically or virtually, at any given time, making them more findable, accessible and usable, throughout the duration of the research activity and beyond. The identification and location of these will also be recorded in research records, logbooks and digital research project management folders.

1.7 Research records which are shared, in partnership with other bodies, through collaboration, outsourced through contracts or may be held by the University, on behalf of other bodies, should be identified and an agreement developed, which explicitly sets out the nature of the relationship, the responsibilities and proposed record management controls to be put into place on how records will be accessed, shared, held or disposed.

1.8 Concerns about the loss, damage or unauthorised access or use of research records should be reported immediately to the Principal Investigator.

2. Integrity

2.1 It is important to protect the integrity and auditability of your research.

2.2 Establish appropriate quality assurance and monitoring processes to ensure reliability in your records and record keeping practices. Records should be clear, legible, accurate, complete and authentic, in other words, trusted to be what they purport to be.

2.3 Establish appropriate audit trails and ensure that there are adequate work practices and safeguards in place to create an auditable paper or digital trails, which enable decisions or actions to be recorded and linked back to the source content, relating to how a decision or action was arrived at.

2.4 Record entries should be made, contemporaneously with the research, as the work is done. Any amendments to records, should be clearly noted as such, and reasons for the change(s) documented and dated. Undocumented modifications to records or use of incorrect metadata, for instance, compromises the integrity of research records. On completion of active research, when records are selected for retention/archive, they should be a complete and immutable record, fixed and unable to be changed.

3. Protection

3.1 Research records should be appropriately safeguarded, in paper or digital format, to ensure and maintain appropriate levels of confidentiality, integrity and availability of the research records from the point of creation and throughout the records’ lifecycle.

3.2 Define appropriate security control measures to ensure that you records remain secure and usable for as long as they are required, include risk mitigation steps for your archived research material, for continued access and any retrospective audit contingency plans. The level of protection will be governed by the nature, content, sensitivity and value of the records for each research project and the negative impact, should they be lost, damaged or accessed without permission.

3.3 Establish appropriate information security protections to underpin authorised access, handling procedures, and arrangements and for any transmission of your paper and digital research records at the start of your research project. Document your requirements and decisions within your research data management plan. Summarise what records you hold and where and who has legitimate rights of access to the content, at all stages of the research process.

3.4 Access to research records should be controlled. Restrict access to research records to identified co-investigators or approved collaborators, or third parties. Back-up records should always be made and held in a separate location, for digital records. Keep research records in password protected folders.

3.5 Security requirements for storage and access will change over the course of the project, particularly if research personnel leave the University, and crucially at the point when active research ceases. Information security contingency plans need to be developed, within the research data management plan and reviewed regularly for continued assurance that research records have suitable protections in place.

3.6 Research personnel are expected to comply with the University's Information Security Policy and Conditions for using IT Services to provide the necessary assurances that research records held and processed have sufficient protections in place, within appropriate University managed network storage and backup IT systems, or approved external services. Consult IT Services about the secure research data storage facilities available to researchers. Further details are available here. External transmission of research records, especially outside the University, should have clear and legitimate authorisation. Transmission decisions should be risk assessed and documented for audit purposes.

3.7 Ensure the storage of physical research records are of an acceptable standard in respect of the storage environment, with suitable protections and controls, to mitigate against water or fire damage, health and safety risks, or unauthorised access. Consideration should also be given to other forms of research samples in other formats, such as biological specimens.

4. Compliance

4.1 Research records are kept to demonstrate how research activities comply with legal and regulatory obligations, requirements from research funders, commercial partners, as well as the University's own wider organisational policies and codes of practice.

4.2 The most appropriate method of recordkeeping required to demonstrate compliance will depend on the type of research being undertaken and the legal and regulatory frameworks which apply to the particular circumstances of the research project, the terms and conditions stipulated by the University, research sponsors, funders or publishers. Consider also potential commercial, political or ethical sensitivities relevant to particular types of your research records, in terms of what may or may not be permitted, in the way research records are handled, disclosed or published.

4.3 Researchers should ensure that they are fully aware of their compliance obligations at the start of the research project and develop appropriate record keeping practices relevant to the compliance regime(s) in which the project operates and ensuring the protection of legitimate rights of individuals and third parties.

4.4 Make contact with the University information management expertise, which is available to researchers, at the earliest stages in the development of the research data management plan to advice and guide on your record keeping compliance requirements;

(i) Contact dpa@abdn.ac.uk for advice on protecting and handling personal data, the Data Protection Act 1998, the General Data Protection Regulation (GDPR).

(ii) Contact foi@abdn.ac.uk for advice on handling research records under Freedom of Information (Scotland) Act 2002 and the Environmental Information (Scotland) Regulations 2004.

(iii) Advice on research funders, intellectual and other rights is available here.

5. Availability

5.1 Research records should be organised and maintained in a manner which ensures timely, efficient and accurate retrieval, by those authorised to do so.

5.2 Agree at the beginning of the project, the ground rules and practicalities for managing you research records, as a research team, so that all concerned, are aware of how research records will be captured, stored and shared throughout the research process. A well designed system, which provides a consistent and systematic approach to the use of quality metadata, storage facilities, use of backups, version control, persistent identifiers, file naming and selection criteria for longer term retention, will ensure the integrity and protection of valuable research records. Summarise the ground rules within your research plans or operational procedures and support staff with appropriate training, if required.

5.3 Establish role responsibilities for monitoring on a regular basis the ability to retrieve and use research records. Ensure file formats, software and hardware are fit for purpose and records remain intact, usable and understood. Develop a business continuity strategy for taking actions to protect and recover vital research records, in the event of a disaster. Paper records also require monitoring to ensure continued availability over time.

5.4 Ensure metadata for research records is also monitored and checked to ensure that meaning and context for your research records is not lost over time.

6. Retention

6.1 Each research project is unique and judgement is required to determine how long research records should be kept. Researchers must determine the retention requirements for their research records and data on a project by project basis**,** taking into account the aims and objectives of the study, funder requirements, and legal, regulatory, fiscal, operational and longer term research value.

6.2 Research data management plans should outline clearly what happens to records after the completion of the research project. Decisions need to be documented on what records should be kept and for how long, when active research has ceased. Develop a project records retention schedule, which outlines the minimum amount of time these records must be kept for (minimum retention period) and what actions (disposition) will be taken, when the time period has expired. Records will either be safely and securely destroyed, or permanently archived.

6.3 The appraisal and selection of records with significant value for permanent archiving also needs to be developed, so that it is clear which records will be preserved and which will be destroyed, at the end of the agreed retention period.

6.4 The University Records Retention Schedule is available here. This provides a starting point for developing your records retention schedule for your research project. Contact the Records Manager for any further advice or guidance.

6.5 Individual Research Councils also provide policy and guidance on data management plans and how long they require records to be kept, as a condition of grant award. Consult funder requirements in terms of your record

retention and disposal actions, as funder requirements will take precedence over the University's more general records retention schedule.

6.6 Research records which have been identified for permanent archive and associated metadata should be archived in a durable format, which cannot be subsequently amended or altered. These records may be transferred to an internal or external archive repository, in which case, all transfers should be documented as part of the research project record.

7. Disposal

7.1 Research records and metadata which have been identified for destruction, after the agreed length of time, must be destroyed according to University policies and procedures. Further details are available here. All research staff need to understand their roles and responsibilities regarding the safe and secure disposal process.

7.2 No record should be destroyed unless authorised by an approved records retention schedule.

7.3 A record of destruction should be kept, documenting what was destroyed, when it was destroyed and who authorised the destruction. Ensure that all versions and copies have been accounted for and destroyed also.

8. Transparency

8.1 Research records which are created should be documented in an open and verifiable manner, and should be available to the appropriate stakeholders and legitimate interested parties as and when required, including University executive committees, external funders, and auditors, for instance.

8.2 Ensure that the research project clearly records the principles, processes and activities undertaken to govern and implement the research project, relating to the rationales, decisions and outcomes of the project are also covered by these record keeping principles, alongside the primary research data itself. These research –related records also need to be readily identifiable, retrievable and available, when needed.

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July 2017

A record may consist of one or many types of content, which make evident related research activity, decisions or transactions to a single event in time, or purpose.

The following is a list (though not exhaustive) of the types of records which are typically generated and held as part of a research project;

Types of information that may be recorded and/or cross-referenced

- Assembled datasets (extracted/derived)
- Changes in data format (e.g. changes in coding)
- Contracts/data sharing agreements/licenses
- Data and sample storage procedures and dates of backup of data
- Data analysis
- Description of the Quality Assurance procedures (e.g. backup, data entry quality checks etc.)
- Data collection procedures
- Data entry procedures including name of current data file, and if/when renamed/updated
- Details of the research team
- Details of where and how study documentation is stored
- Deviations from protocol/design and reasons
- Evidence of ethical/peer review, or other approval, as required
- Funding
- Information about PhD or Training supervision
- Instrument calibrations
- Intellectual property and other rights
- Key data collection dates (e.g. biological samples, research clinic attendance, questionnaires, interview dates, focus group dates)
- List of outputs agreed and authorship
- Note of any conditions on publication
- Notes and minutes of any project meetings in particular outcomes and action points
- Periodic updates on project progress
- Project protocol or design
- Protocol/design amendments and relevant dates
- Reference data/reworked data
- Relevant study documentation (e.g. consent forms, questionnaires, clinical record forms etc.)
- Simulated data/outputs of models
- Source data (collected/created)
- Software/data codes and environment to enable results to be reproduced or understood
- Who has overseen the analysis