University of Central Lancashire

Human Participant Research Data Management Policy Statement

Document type	Policy Statement
Document owner	Research and Enterprise Service
Approved by	Open Research Steering Group
Approval date	1st December 2021
Approved by	Research & Knowledge Exchange Committee
Approval date	9th February 2022
Review date	Annually
Version	1.0
Summary of changes	

University of Central Lancashire
Human Participant Research

1. Scope

The purpose of this document is to inform researchers about the process of research data management, before, during and after completion of a research project and sharing research data which concerns human participants. The data generated, which will be of varying levels of sensitivity depending on subject matter, will require a level of protection that adheres to research data management compliance regulations and external funder policies. Guidance[1] has been developed which looks specifically at sharing data from Human Participant Research, in addition to this, the Research Data Management Officer can offer advice on any aspects of this addendum which relates to managing/sharing research data.

This policy applies to staff and postgraduate research students.

2. Statement

UCLan supports the principles of Open Access to publicly funded research outputs and the data underpinning this research. Research data generated at the University is recognised as an institutional asset that when shared openly not only increases the visibility of UCLan's research but also facilitates public engagement and creates new opportunities for knowledge exchange and collaboration.

3. Responsibilities

All researchers should familiarise themselves with relevant UCLan policies, in particular the Research Data Management Policy, the Open Access Policy, the Policy on Intellectual Property for staff and students, the Data Protection guidance for researchers and UCLan's Ethical Principles for Teaching, Research, Consultancy, Knowledge Exchange and Related Activities.

Overall responsibility for research data management during any research project lies with the most senior UCLan researcher (the PI/data steward for the project). In cases where the project is led by an external partner there is still a requirement for data generated or shared by UCLan to be managed by a named individual at UCLan.

4. Research Data Management

Staff/researchers are advised to refer to UCLan's Research Data Management Policy which requires data sharing[2] wherever feasible. When sharing research data, the following principles of good practice are recommended.

[1] This guide will be made available once the policy has been approved, this will include an appendix, which will provide suggestions for wording consent forms in a way which permits data sharing.

[2] Guidance on selecting data for archiving and sharing on Open Access http://clok.uclan.ac.uk/14212/

4.1 Prior to the commencement of a research project

4.1.1 Prior to commencement of a research project or trial, the project team must ensure that data management is fully considered and that good practice guidelines are followed.

4.1.2 Ethics approval should be in place relating to data collection, retention and subsequent sharing.

4.1.3 Before starting a new research project, the PI/data steward and project team must address the following data management requirements:

a) All research projects (including trials) that involve human participants should adhere to the UCLan Open Access Policy, Research Data Management Policy, Ethical Principles, Code of Conduct for Research and Data Protection Policy.

b) As stated in UCLan's Research Data Management Policy, all research projects whether **funded or unfunded** should have Data Management Plans in place.

4.1.4 Standardisation of data collection, management, including anonymisation protocols, and sharing plans should be formulated and documented in the consent form before commencement of each research project/trial.

4.1.5 Where permissible, costs of data storage during and post-research project/trial should be estimated and included in funding bids. Contact LIS prior to commencing a research bid for support with data storage/costs.

4.1.6 When planning for the management of data collected from research participants, the PI/data steward and project team have an ethical and legal responsibility to ensure that confidential and personal data are shared and stored securely and that these are not disclosed to unauthorised persons. All personal data from a project/trial must be handled in compliance with Data Protection legislation, and Data Protection principles should be followed.

4.1.7 During a project/trial when sharing personal data, researchers must comply with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018. Note that when collecting data from participants who are in the European Economic Area, researchers must comply with the EU GDPR. Researchers must also comply with the Human Tissue Act (HTA) 2004 and the Medicines for Human Use (Clinical Trials) Regulations 2004 where applicable.

4.1.8 All research conducted in the NHS should comply with the UK Policy Framework for Health and Social Care Research.

4.1.9 There is an ethical requirement that consent is obtained when collecting data from human participants.

4.1.10 Protocols on obtaining informed consent from participants should be followed for data sharing and long-term preservation/curation where possible. Consent forms should include appropriate consent for anonymised data sharing[3]. Informed consent for data sharing and long-term preservation should be made clear in the Data Management Plan[4]. The project funder may also have specific consent requirements which should also be adhered to.

[3] Consent forms must be retained securely for the length of time designated at the onset of the research project/trial and in line with any funding body requirements.
[4] Funder DMP templates are available here: https://dmptool.org/public_templates

4.1.11 All participant data must be stored on UCLan servers and not on any external server, so that we can ensure security. In instances where data subjects/data are outside the UK, participants should consent to their data being stored outside of their home country.

4.1.12 The participant(s) should be informed what the project team will do with the research data collected throughout the project and beyond. Participants should be advised of their rights regarding their research data, including the right to withdraw consent and the time parameters beyond which this consent cannot be withdrawn as the data has been anonymised and anonymisation protocols applied.

4.1.13 Researchers should ensure that **accurate information** regarding participants is available, including consent forms that include appropriate consent for data sharing. Guidance is available for research that is conducted remotely.

4.1.14 Retention periods for primary/raw data and related material should be considered at the outset and should reflect institutional, legal and regulatory requirements and, where possible, aim to support new research. Most major research funders have guidelines or requirements regarding data retention periods.

4.1.15 PI's/data stewards and the project team have a duty to the University, and current and future participants of the study, to ensure that the results of the study are adequately managed. Failure to do so may be regarded as a form of research misconduct.

4.1.16 All funded projects should comply with their funder's data management and sharing policies. As per the University's Research Data Management Policy, in cases where researchers may be affected by a number of policies, external funder policy should take precedence.

4.2 Data Management during a research project

4.2.1 Safe storage of data during a project/trial must be addressed in line with current Data Protection protocols, including encryption/restricted access[5]. Both local network storage and OneDrive will provide data security (OneDrive for Business is the only UCLan-approved cloud storage and sharing tool [6] . Network storage has automated backup. Both sensitive/confidential data can be stored in these locations.[7] . For more information about how to manage data safely, contact the Legal and Governance team.

4.2.2 Some projects will have designated databases for live data storage[8].

4.2.3 When giving consent, participants need to understand and give explicit permission for possible future uses of their data. The participant consent form should include details of any anonymisation, the extent of planned sharing, future data storage and conditions of access.

4.3 Data management after the completion of a research project

[5] Research data can be encrypted, and password protected by using the software 7-Zip, which is recommended by LIS.
[6] OneDrive is currently not backed up, data deleted is not recoverable beyond 90 days, LIS are working on the automated backup and recovery processes for this. OneDrive is a personal storage area, anything stored here will be deleted when a user leaves the University. For further advice contact LIS before commencement of project.

[7] Under certain circumstances, i.e. for sharing data with external collaborators, contact LIS for further advice.
[8] For example, CTU uses REDCAP

4.3.1 Post-project consent for participants' anonymised data to be made public should be received and documented on consent forms. If consent is not received, then that data should not be subsequently included in the data to be made Open Access.

4.3.2 If datasets can be anonymised, and approval has been obtained from the appropriate Ethics Committee and/or the Confidentiality Advisory Group (CAG) where applicable, data can be prepared for data-sharing and lodged in an appropriate repository. It is recommended that the designated repository is UCLanData[9] unless a funder or publisher requires an alternative location.

4.3.3 Once data have been truly anonymised for publication, participant permission is not required for future work on the specific dataset(s). Note that it can be very difficult to anonymise qualitative data relating to human participants.

4.3.4 If data cannot be anonymised it should be stored securely in an area on the University network where it is backed up[10] and access is restricted to designated project/trial team members[11] .

4.3.5 Personal data from a project/trial should be securely destroyed when there is no business, regulatory or archival reason for retaining it. Participants should be informed in the participant information sheet and the research privacy notice about how long their personal data will be retained in identifiable form for the purposes of research. Researchers should clearly distinguish between the personal data that will be held securely and ultimately destroyed, and anonymised research data that will be retained indefinitely and made available to others. Consult the Information Governance pages of the UCLan intranet for the current guidance or contact the Information Governance team for further advice.

4.3.6 Under Data Protection legislation, personal data from a project/trial should not be retained for longer than is necessary for the purposes for which they were originally collected. Personal data held for public interest, archiving, scientific or historical research, or statistical purposes may be retained indefinitely if certain conditions are met. Check external funder retention guidance and UCLan's retention schedule.

4.3.7 A metadata[12] only record can be created in UCLanData for final project data[13], except in any instance where disclosure of descriptive metadata about the research participants may impact individuals' privacy/identify participant(s); in this case a metadata record should not be created on UCLanData.

4.3.8 If the research funder has an open data policy, the funder should be informed as soon as possible about plans for sharing or safeguarding data.

---

[9] http://uclandata.uclan.ac.uk/ please be aware that a funder may require data to be deposited in specifically named data repository (for example ESRC require deposit of data in the UK data archive).

[10] Data is backed up daily overnight.

[11] Access to the university shared drive data and hence folders is managed using groups, access is controlled by the owner of the shared area.

[12] Details the characteristics of, for example, a dataset. It is a bibliographic description of the record for resource discovery and preservation.

[13] This is where the details of the project or trial data are recorded in UCLanData. It is a descriptive record of a research data output without any file attached/the file may be restricted.

4.3.9 A designated data steward is required for each project. It is recommended that the PI is automatically assigned as the data steward.

5. Sharing Research Data

5.1 Each research project/trial that involves human participants, and where consent for sharing research data is a requirement, should be reviewed on a case-by-case basis by the Research and Knowledge Exchange Committee, via the Ethics Review Panels**.**

5.2 Obtaining consent to share research data should be an integral part of the consent process. In cases where data sharing is not possible, researchers should explore alternative options to make subsets of the data available. The PI/data steward should provide a valid reason to opt out of Open Access. In cases where data cover sensitive topics and cannot be shared, it is the responsibility of the PI/data steward to inform the Research and Knowledge Exchange Committee, via the Ethics Review Panels, before commencement of the project. If all options to make a subset of the data open have been explored, and it is still not possible to share the data, then this data may be exempt from Open Access. However, if there is a funder requirement, the researcher should instead use the statement as an explanation of why the data cannot be made accessible[14].

5.3 In some cases, data may be rendered inaccessible until after a specified period of time[15] has elapsed with a 'request a copy' option - this must be agreed by the Research and Knowledge Exchange Committee via the Ethics Review Panels.

5.4 In some cases, data may require access control[16] and access to specific data may be closed/restricted. Access to this data would be on a case-by-case basis and should meet funder and University data sharing requirements and criteria[17].

5.5 Data will be maintained in perpetuity within UCLanData (unless the funder or commissioning body dictates a specific period of retention). If the PI/research team are not available because they have left the University, decisions on whether to grant requests for access to restricted access dataset(s) will be taken by the Research and Knowledge Exchange Committee via the Ethics Review Panels.

5.6 A notification on how to request access to a closed/restricted dataset(s) should be clearly visible on the individual UCLanData record so that the user can follow the appropriate access control routes.[18]

6. Research Data Compliance

6.1 All funding bodies (and other stakeholders) should be acknowledged on the UCLanData record. Where sharing is covered by a data sharing agreement, researchers should refer to the agreement for guidance.

---

[14] For example: children, vulnerable adults.

[15] An embargo period can be set on UCLanData, and the data will become available on Open Access once the embargo period has lapsed.

[16] There are three tiers of access control i.e. open data, restricted data and controlled access data. These are outlined in the guidance document.

[17] The committee will set the University's criteria, anticipate some of the criteria will only be shared with bona fide researchers, the research project brief meets the criteria for access, PI/data steward agrees with access being granted and must also ensure that funder requirements are met.

[18] Relevant guidance will be made available.

6.2 If research publications are produced as a result of the research project/trial then the publisher/journal data sharing policies should be checked to ensure that they are compatible with the UCLan Open Access Policy, Research Data Management Policy, funding bodies' criteria and Clinical Trials Regulations (if applicable). An alternative publishing outlet should be sought where policy requirements are not met.

6.3 A metadata record of all dataset(s) should be recorded in UCLanData (even if the dataset(s) cannot be made Open Access) unless the project team can provide a valid reason to the Research and Knowledge Exchange Committee, via the Ethics Review Panels, for not doing so.

6.4 Some funders specify time frame parameters for exposure of data after completion of trials - researchers are expected to comply with these parameters.

6.5 Deposited data should indicate whether the data will be retained in perpetuity or made openly available only for a specified time period as per external funder requirements.

6.6 Data deposited in a data repository should follow standard formats. See UK Data Service guidelines.

6.7 A data access statement is required for each project/trial. If access to the data is restricted this should be justified in the data access statement.

6.8 Supporting documents must be made available in the UCLanData record to facilitate analysis and re-purposing of data such as a readme file/access key and a data dictionary so that the data can be re-usable and understood by a user, see UCLanData guidance for further information.

7. Legal, contracts and agreements

7.1 When working with research data, researchers must be aware of legal issues surrounding research data, particularly sensitive and personal data.

7.2 When receiving, sharing, acquiring, or generating sensitive and personal data, the PI/data steward and project team may need to enter into various contracts with external third parties and partnership institutions and agreements.

7.3 The PI/data steward and the project team should be aware of research data terms and conditions contained in documents and consult with the Legal and Governance team for further advice as required.

8. Intellectual property and rights relating to research data

Intellectual Property Rights (IPR) (e.g. copyright, patents) affect the way that the research outputs can be used by the project team and other parties. In general, raw data on their own are considered facts and thus cannot be copyrighted. However, data that are gathered together in a unique and original way, such as databases, can be copyrighted or licensed. It is important to understand data licensing[19] from the perspective of both the data user and data creator when collecting data and sharing data. Ownership of Intellectual Property (IP) created by UCLan staff is outlined in the University Policy on Intellectual Property (Section 3).

[19] Creative Commons License - https://creativecommons.org/licenses/
Open Data Commons License - http://opendatacommons.org/licenses/

9. Data Protection and related policies

The University currently has various documents and policies which refer to different aspects of research data management. If a researchers data contain personal data (information that relates to a living individual(s) where the individual(s) can be identified from those data or from those data and other information that is reasonably available) then researchers must comply with Data Protection legislation. Data Protection legislation in the UK is the UK GDPR and the Data Protection Act 2018. If a researcher processes personal data about individuals who are physically in the European Economic Area, the researcher must also comply with the EU GDPR. Key University documents and policies can be found here: Data Protection guidance for researchers, Data Protection Policy, Email Use Policy, Information Management Policy, Data Protection Checklist, University code of conduct for research and the IT Security Policy.

9.1 Freedom of Information

Any information held by or on behalf of the University can be requested under the Freedom of Information Act 2000. In some cases, information requested may be exempt from disclosure, particularly if it relates to an ongoing programme of research and its disclosure into the public domain at the time of the request would be prejudicial to the research or to another party. Each request must be considered on its own merits. Any information disclosed in response to a request is disclosed into the public domain. All requests under the FOIA will be handled in line with the University's Freedom of Information Policy and managed by the Information Governance team.

10. Statement Review

The Research and Knowledge Exchange Committee will be responsible for approving this policy statement as recommended by the Open Research Steering Group. The policy statement will be reviewed at least annually by the Open Research Steering Group and updated as deemed necessary.

Next Review date: December 2022