DLCM Data Management Template

Intro: DLCM project, Swiss context & legal dimension (Loi sur la Protection des Données or LPD)

Institution	
Name of the institution that the following data applies to	
Responsibilities	
Person in charge of the work: *(name and email)*	
Data management contact: *(name and email)*	

1. Description of the data

1.1 Type of study

Summarise the type of study (or studies) for which the data are being collected.

1.2 Types of data

Describe the types of research data to be managed e.g.: quantitative, qualitative; generated from surveys, clinical measurements, interviews, medical records, electronic health records, administrative records, genotypic data, images, tissue samples, experimental records / reports / designs / clinical validation.

1.3 Format and scale of the data

Detail the file formats that will be used and the approximate size of the data. Also detail software to be used, number of records, databases, sweeps, repetitions,… (in terms that are meaningful in your field of research). Do formats and software enable sharing and long-term validity of data?

2. Data collection / generation

2.1 Methodologies for data collection / generation

Describe how the data will be collected/generated and which data standards (if any) will be used at this stage. What quality assurance processes will be used. How will file naming be done and how will versioning of file names be handled.

2.2 Data quality and standards

How will consistency and quality of data collection / generation be controlled and documented, through processes of calibration, repeat samples or measurements, standardised data capture or recording, data entry validation, peer review of data or representation with controlled vocabularies.

3. Data management, documentation and curation

Keep this section concise and accessible to readers who are not data-management experts. Focus on principles, systems and major standards. Focus on the main kind(s) of study data. Give brief examples and avoid long lists.

3.1 Managing, storing and curating data.

Briefly describe how data will be stored, backed-up, managed and curated in the short to medium term. Specify any agreed or other formal data standards used (with URL references). [Enter data security *standards in Section 4].*

3.2 Metadata standards and data documentation

What metadata is produced about the data generated from the research? For example descriptions of data that enable research data to be used by others outside of your own team. This may include documenting the methods used to generate the data, analytical and procedural information, capturing instrument metadata alongside data, documenting provenance of data and their coding, detailed descriptions for variables, records, etc.

3.3 Data preservation strategy and standards

Plans and place for long-term storage, preservation and planned retention period for the research data. Formal preservation standards, if any. Indicate which data may not be retained (if any). Must data be retained / destroyed for contractual / legal or regulatory reasons. Are there any further uses for the data, e.g. additional studies. How long will the data be preserved.

4. Data security and confidentiality

*This section MUST be completed if your research data includes **personal data relating to human participants in research**. For other research, the safeguarding and security of data should also be considered. Information provided will be in line with you ethical review. Please note this section concerns protecting the data, not the patients.*

4.1 Formal information/data security standards

Identify formal information standards with which your study is or will be compliant. An example is ISO 27001.If your organisation is ISO compliant, please state the registration number.

4.2 Main risks to data security

All personal data has an element of risk. Summarise the main risks to the confidentiality and security of information related to human participants*, the level of risk and how these risks will be managed. Cover the main processes or facilities for storage and processing of personal data, data access, with controls put in place and any auditing of user compliance with consent and security conditions. It is not sufficient to write not applicable under this heading.*

5. Data sharing and access

Identify any data repository (-ies) that are, or will be, entrusted with storing, curating and/or sharing data from your study, where they exist for particular disciplinary domains or data types. Are there any costs associated with the use of the data repository?

5.1 Suitability for sharing

Is the data you propose to collect (or existing data you propose to use) in the study suitable for sharing? If yes, briefly state why it is suitable.

If No, indicate why the data will not be suitable for sharing and then go to Section 6.

5.2 Discovery by potential users of the research data

Indicate how potential new users (outside of your organisation) can find out about your data and identify whether it could be suitable for their research purposes, e.g. through summary information (metadata) being readily available on the study website. How widely accessible is this repository?

Indicate whether your policy or approach to data sharing is (or will be) published on your study website (or by other means).

5.3 Governance of access

Identify who makes or will make the decision on whether to supply research data to a potential new user.

Indicate whether you will share this data and under what conditions. Will the research data be deposited in and available from an identified database, repository, archive or other infrastructure established to curate and share data.

5.4 The study team's exclusive use of the data

What are the timescale/dependencies for when data will be accessible to others outside of your team? Summarize the principles of your current/intended policy.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

Restriction to data sharing may be due to participant confidentiality, consent agreements or IPR. Strategies to limit restrictions may include data being anonymised or aggregated; gaining participant consent for data sharing; gaining copyright permissions. For prospective studies, consent procedures should include provision for data sharing to maximise the value of the data for wider research use, while providing adequate safeguards for participants. As part of the consent process, proposed procedures for data sharing should be set out clearly and current and potential future risks associated with this explained to research participants.

5.6 Regulation of responsibilities of users

Indicate whether external users are (will be) bound by a data sharing agreement. If so what are the main terms of this agreement.

6. Relevant institutional, departmental or study policies on data sharing and data security

For your institution please detail below such internal policies and procedures that are relevant to this data management plan.

Please also provide pdf versions of the listed policies

Policy	**URL or Reference**
Data Management Policy & Procedures	
Data Security Policy	
Data Sharing Policy	
Institutional Information Policy	
Other:	
Other	

7. Author of this Data Management Plan (Name and contact details)