

Research Data Management (RDM) Strategy Lady Davis Institute for Medical Research (LDI)

The LDI, being part of a hospital eligible to administer Tri-Agency funds, annually receives and administers, on behalf of its investigators, millions of dollars of funding from one of the tri-agency agencies, the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC). This funding is the backbone supporting the LDI's major scientific and academic contributions in a variety of fields, especially:

- Oncology;
- Clinical epidemiology;
- Molecular and regenerative medicine; and
- Psychosocial aspects of disease.

In March 2021, the Tri-Agency launched a Research Data Management (RDM) Policy with the objective of promoting RDM and data stewardship practices amongst Canadian researchers and research institutions. The Tri-Agency RDM Policy will be implemented with an incremental approach, in step with continuing development of RDM practices and capacities in Canada and internationally.

Three key deployment phases have been set by the Tri-Agency RDM Policy:

- Institutional strategies: By March 1st, 2023, each post-secondary institution and research hospital eligible to administer Tri-Agency funds is required to create an institutional RDM strategy, publicly post the strategy and notify the agencies when completed. The current document is the LDI's answer to this requirement.
- Data management plans: By spring 2022, the agencies will identify an initial set of funding opportunities where researchers will be required to submit data management plans with their grant proposals.
- Data deposit: After reviewing the institutional RDM strategies, and in line with the readiness of the Canadian research community, the agencies will phase in the data deposit requirement. In addition to any existing sponsor requirements, grant recipients will be required to archive all digital research data, metadata and code that directly support research conclusions in journal publications and pre-prints into a digital repository. There is no current timeframe for this requirement. Some similar requirements may also stem from provincial authorities in the future.

The LDI, being part of a hospital eligible to administer Tri-Agency funds, and its academic partners, notably McGill University, are committed to meeting these Tri-Agency RDM requirements and supporting their researchers in adopting these practices. The LDI, in collaboration with McGill University, therefore aims to provide researchers with the best possible support in terms of project planning, guidelines, policies, and infrastructure, to foster research excellence across the institution.

The present RDM Strategy outlines the approach that the LDI will take over the next two to five years to equip its research community with the knowledge, tools, and support to adopt meaningful and robust RDM practices. The RDM Strategy is intended to meet actual needs voiced by its research community and to meet regulatory requirements. In consequence, over the next five years, this strategy will be routinely updated and adapted to the evolving RDM ecosystem.

What is RDM?

RDM is a framework for actively organizing research data through the life cycle of a research project or program (please see **Appendix A** for a full list of definitions). RDM is both a field within the academic discipline and a set of methodological guidelines that involve the planning, organization, description, storage, and sharing of research data in a secure fashion. Good RDM practices are also expected to improve the dissemination and reproducibility of research outcomes.

Why is RDM Important?

Recognizing research data as a major research asset is an important steppingstone in the pursuit of academic excellence. Research activities in many domains, especially in health-related research, create increasingly larger volumes of data that are challenging to manage and analyze effectively. Making research outputs discoverable, reproducible, and reusable, are foundations and principles of modern scholarship. While not all research data are suited to be shared broadly, for ethical, legal, or commercial reasons, adopting best practices in research data management applicable within and between research units is crucial to maintain and maximize public trust and participation in academic research.

Governments, funders, institutions, and research communities recognize that RDM best practices are essential to raise research standards and increase its potential impact and relevance. Properly managed data have both practical and financial benefits to research, such as reducing research duplication, lowering unnecessary burdens on participants due to repetitive sampling, increasing accountability and transparency, allowing replication of research results, fostering collaborations, and accelerating new discoveries.

RDM is an integral part of research. RDM practices enable compliance with fast evolving ethical, legal, and commercial requirements and are a key factor in safeguarding research when necessary. Therefore, it is critical to strive to equip researchers, staff, and trainees with sound RDM practices and stewardship to achieve scientific rigor and enable collaboration.

Vision

The LDI vision is to advance health and social sciences knowledge and practices through excellence in research, teaching, and innovation. Within this context we recognize the exceptional and unique importance of the quality and integrity of the research data throughout its lifecycle and therefore are committed to developing and promoting a Research Data Management (RDM) Strategy aligned with world-class practices. We will build on areas of strength and expertise, improving tools, technologies, and services to allow our research community to achieve this goal. The LDI encourages a cost-efficient approach, and we will leverage our relationship with the *Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal* (CIUSSS COMTL) and McGill University to find and promote synergies, such as training strategies and content and data repositories.

Guiding Principles

The LDI will develop its RDM strategy, including its data governance policies, training, data management tools and associated technologies, in accordance with the following guiding principles:

- **Data Integrity**

“Integrity describes an uncompromising adherence to ethical values, strict honesty, and absolute avoidance of deception. Integrity also describes the state of being whole and complete, of being totally unimpaired”⁽¹⁾. Our institution adheres to both meanings of the word and shall develop policies and tools to promote these values.

- **Data Transparency**

Data governance and stewardship processes will exhibit transparency by describing and documenting data management plans in ways that can be understood by all participants, auditors and any relevant third-party to see how data-related decisions were made, how sensitive data gets handled and what it is used for, as well as what controls were introduced into the processes.

- **Data Accountability**

Our data governance will define clear accountabilities among the different departments and teams involved in the data management process, ensuring stewardship for those who collect, manage, and use information, and those who are responsible for establishing standards and compliances.

- **Data Compliance**

The LDI will support its research community in its efforts to establish and implement data management practices that are consistent with ethical, legal and commercial obligations, as well as Funding Agencies requirements, including the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - 2nd edition, the Tri-Agency Framework: Responsible Conduct of Research⁽²⁾ the *Politique sur la conduite responsable en recherche du Fonds de recherche du Québec (FRQ)*, and any other relevant and pertinent legislation and institutional guidelines.

- **Data Standardization**

“Data should be managed in accordance with the most appropriate and relevant standards and best practices, while recognizing that these are in a state of rapid evolution”⁽²⁾

- **Data Protection**

“Data should be collected and stored throughout the research project using software, formats and technologies that ensure secure storage, and enable preservation of and access to the data well beyond the duration of the research project”⁽²⁾. The LDI will support investigators so they can, for the required length of time, store and share the data in secured environments, use reliable networks and have a strong back-up and redundancy system in place.

The following guiding principles should also be promoted:

- **Equity, Diversity, and Inclusion**

It is important to recognize that the risk of introducing bias into research data and management exists throughout the data lifecycle. As such, Equity, Diversity and Inclusion principles should be fully integrated in the RDM strategy and guiding principles.

- **Respect for the rights of Indigenous communities**

Ensuring that the unique rights, interests and circumstances of the First Nations, the Métis Nation and Inuit are respected by adopting a distinction-based RDM approach for research involving Indigenous communities and their data (e.g., OCAP[®] 4 and CARE5).⁽³⁾

- **Open dissemination of research results**

In accordance with the *Fonds de recherche du Québec* and Tri-Agency policies, research results should be made as open as possible and as closed as required to facilitate access and reuse by the scientific community. Data management plans should always include metadata that allows future users to access, understand and reuse the data. The metadata should be kept in accordance with best international practices, such as the FAIR Guiding principles (Findable, Accessible, Interoperable and Reusable).

- **Flexible Approach**

Data management practices are so varied across research fields that a “one size fits all” approach could not address important issues and might be ineffective. Therefore, the LDI will promote a flexible RDM model that is adaptable to all research domains recognizing that different fields have different needs.⁽³⁾

- **Efficiency and cost-effectiveness**

As indicated by the Tri-council statement of principles on digital data management: “Data management should be efficient and cost effective. All data need to be managed, but not all data need to be shared or preserved - costs and benefits of doing so should be considered in the data management planning process” ⁽²⁾

The LDI will strengthen the communication and coordination with McGill University, establishing more streamlined RDM workflows and processes. The LDI will also seek synergies with the CIUSSS COMTL when possible while leveraging relationships with stakeholders at the institutional, provincial, national, and international levels.

Scope

This strategy applies to all LDI researchers, staff, trainees, and volunteers in all disciplines, including consultants and/or third parties given access to our resources.

Oversight and Overview

The Scientific Director and the Chief Operating Officer are responsible for overseeing the LDI Institutional RDM Strategy.

The RDM Advisory Committee and the RDM Working Group are leading the writing and consultation efforts for the LDI Institutional RDM Strategy.

Existing Institutional Support for RDM

Clusters of individual initiatives for RDM exist at the LDI but there is currently no institution-wide support for research data management. In consequence, this RDM strategy is an opportunity to set up an improved way of conducting research at the LDI.

Goals and Objectives of the RDM Strategy

In order to achieve the goals set out in this RDM strategy, numerous steps will need to be taken. First, the LDI administration and research community needs to be aware of and assess its RDM needs and current practices. Once this analysis is complete, it will need to refine its vision for the future of RDM at the LDI and the services to be offered by the institution. This will then be articulated through a sturdy governance framework. In order to meet the needs of the LDI research community, these steps and the specific actions related thereto will need to be done through consultation.

Step 1: Awareness
Identification of the stakeholders
Recruitment of champions
Participation in consultations
Step 2: Assessment of the current stage of RDM
RDM Maturity Assessment
Survey of the RDM practices across the CIUSSS
Drafting, use and compilation of the RDM survey
Step 3: Vision for the future state of RDM at the LDI
Project roadmap
Project timeline
LDI service offer in RDM
Step 4: Articulation of the path forward
<i>Information Management Policy</i>
Scope
Definitions

Data collection guidelines
Use of the data <i>Should define how access rights will be granted and audited and the acceptable uses of the data.</i>
Access process
Databases / databanks governance framework template
Archiving guidelines
Archiving and data management fees and use of LDI Resources
Master data sharing agreements
Research data risk management
Data users' responsibilities <ul style="list-style-type: none"> a) Confidentiality and protection of personal information b) Discovery of an accidental breach c) Intellectual property d) Publications e) Contribution to open science repositories f) Return of results g) Maintenance of data h) Destruction of data
Sanctions for contravention
RDM committee
<i>Information Security Policy</i>
Scope
Definitions
Internal security requirements
Minimum security requirements for third parties accessing and transferring our data
Privacy
<i>Governance Tools: Standard Operating Procedures (SOPs), Templates and Plans</i>
Use of confidentiality agreements (SOPs)
Cybersecurity readiness plan
Infrastructure and software (SOPs)
Data management plan validation and approval (SOPs)
Data access request templates
Data management plan templates
List of RDM compliance standards met by the LDI
Step 5: Strategy Launch and Assembly
Policy Approval
Evaluation and monitoring of the policies and standard operating procedures
Creation of a committee to monitor the application of the policies and standard operating procedures
Update of existing policies, procedures, and SOPs, as applicable: <ul style="list-style-type: none"> • Biobank Policy • Regulatory framework for research involving humans at the Centre intégré universitaire en santé et services sociaux du Centre-Ouest-de-l'Île-de-Montréal • Gestion et confidentialité du dossier médical de l'utilisateur - CIUSSS • Procédure de signature de l'Engagement de confidentialité du Centre intégré de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal (d'un employé, d'un prestataire de services ou d'un stagiaire ou de toute autre personne contribuant à la mission du CIUSSS et devant avoir accès à des actifs informationnels du CIUSSS) • Politique de gestion des accès aux actifs informationnels du CIUSSS du Centre-Ouest-de-l'Île-de-Montréal • Politique de sécurité des actifs informationnels du CIUSSS du Centre-Ouest-de-l'Île-de-Montréal

RDM services offer
Budget and staffing for RDM services
Creation of synergies and content for training and raising awareness on RDM
Definition of the research repository strategy

Timeline

In view of the magnitude of the exercise and in order to ensure that the RDM strategy meets the LDI research community's actual needs, the implementation of the RDM strategy is viewed as a five-year plan.

Next steps

The development and rapid advance of digital technologies around the world is transforming research across all fields, providing a unique opportunity to extend the openness and collaborative nature of research. The importance of data in research will continue to increase as technology continue to evolve requiring adaptability to the new realities. In this regards our RDM Strategy must remain a living document subject to recurrent evaluation and reviews.

The next steps in the development of our RDM Strategy are described in the Road Map summarized above, as proposed by the RDM Working Group and approved by the RDM Advisory Committee on May 30, 2022.

The LDI will continue working together with McGill University, the CIUSSS COMTL and other stakeholders to expand the resources available to our research community, providing training and awareness to ensure the success of this endeavour within a cost-efficient approach.

Contact Us

For general enquiries about the LDI RDM Strategy, please contact [Gustavo Wendichansky](#).
For technical enquiries about the LDI RDM Strategy, please contact [Stephane Benhamou](#).

References:

- (1) *Ensuring the Integrity, Accessibility, and Stewardship of Research Data in the Digital Age.* (<https://www.ncbi.nlm.nih.gov/books/NBK215260/>)
- (2) *Tri-Agency Statement of Principles on Digital Data Management.* (https://ic.gc.ca/eic/site/063.nsf/eng/h_83F7624E.html)
- (3) *McGill University – Draft Research Data Management Strategy*

Appendix A – Definitions

- Data are facts, measurements, recordings, records, or observations collected by researchers and others, with a minimum of contextual interpretation. Data may be in any format or medium taking the form of text, numbers, symbols, images, films, video, sound recordings, pictorial reproductions, drawings, designs or other graphical representations, procedural manuals, forms, diagrams, workflows, equipment descriptions, data files, data processing algorithms, software, programming languages, code, or statistical records. (Adapted from: Tri-Agency RDM Policy FAQ)
- Data Lifecycle refers to all the stages in the existence of data from creation to destruction. The data lifecycle provides a high-level overview of the stages involved in successful management and preservation of data for use and reuse. This broadly includes the following stages: Plan, Create, Process, Analyze, Disseminate, Preserve and Reuse. (Adapted from: CASRAI Definition of Data Lifecycle, DataOne, & Alliance-Portage)
- Data Stewardship refers to knowledge and skills required to effectively manage data assets. Data stewardship is often described as data governance in action. This includes the oversight of data to ensure fitness for use, the accessibility of the data, and compliance with policies, directives and regulations. (Adapted from: Statistics Canada Data Literacy Training)
- Research Data Management refers to the processes applied through the lifecycle of a research project to guide the collection, documentation, storage, sharing and preservation of research data. (Adapted from: Tri-Agency RDM Policy FAQ and Alliance-Portage Definition)
- Researcher means a person to whom the CCOMTL has awarded research privileges, excluding research personnel or students. (From: Regulatory framework for research involving humans at the Centre intégré universitaire en santé et services sociaux du Centre-Ouest-de-l'Île-de-Montréal)