Institutional Research Data Management Strategy

Prepared By: Institutional RDM Working Group

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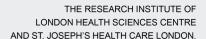
Table of Contents

INTRODUCTION

1   OVERVIEW

The federal research funding agencies (Tri-Agency: Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC), Social Sciences and Humanities Research Council (SSHRC)) released a Research Data Management Policy in March 2021. They have set a deadline for March 1, 2023, for each postsecondary institution and research hospital eligible to administer CIHR, NSERC, or SSHRC funds to develop an institutional strategy for Research Data Management (RDM), and notify the agencies when it has been completed. Additionally, for specific funding opportunities, the agencies require data management plans (DMPs) to be submitted to the appropriate agency at the time of application. Furthermore, grant recipients are required to deposit into a digital repository all digital research data, metadata, and code that directly support the research conclusions in journal publications and pre-prints that arise from agency-supported research.

Lawson Health Research Institute is the research institute of London Health Sciences Centre (LHSC) and St. Joseph's Health Care London. Lawson recognizes the impact of funding on research, the RDM requirements and obligations implemented by funding agencies, and the importance of research data management. Lawson is fully engaged in developing and implementing the Institutional RDM Strategy.

2   BACKGROUND

The Tri-agency is committed to funding research that is conducted to the highest professional and disciplinary standards, is performed ethically, makes effective use of public funds, is verifiable and replicable, and that makes results as accessible as possible. The agencies support the FAIR (Findable, Accessible, Interoperable, and Reusable) guiding principles and accordingly advocate an increased ability for research data to be archived, found, and responsibly reused to fuel discoveries and innovation across multiple disciplines and geographical borders. Research data management is, therefore, a necessary component of achieving research excellence.

3   RESEARCH DATA AND IMPORTANCE OF RESEARCH DATA MANAGEMENT

Research data is the data used as evidence to support and validate research findings or results and used as input for analysis. Research data is derived from source data. This can include information extracted from original sources such as clinical systems, experiments, simulations, etc. It is to be noted that any data containing identifiable personal information must remain private and confidential.

Research Data Management is the organization and maintenance of research data throughout the entire research project lifecycle. This includes setting up protocols before initiating data collection, and then

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2

collecting, tracking, and creating backups of the data during study execution, and eventually, data sharing, archiving, and publishing upon project completion. This is not a new concept. In fact, Lawson researchers have been employing these processes and procedures and performing RDM in varying capacities. However, with the new policy requirements, obligations for regulatory compliance, concerns for privacy and security, initiatives for data sharing and reproducibility, a push for the FAIR principles, the open science movement, and a need to elevate the availability of Canadian data on the world stage, it is imperative for Lawson to implement and support RDM best practices and procedures.

4   SCOPE

The Lawson institutional RDM strategy is a concise and directive document that outlines how Lawson will increase its capacity to support and foster a culture of effective research data management. This institutional strategy is a collaboration between internal and external key stakeholders. It will support Lawson researchers in managing their data throughout the research lifecycle using appropriate data stewardship and data management practices.

This strategy applies to all research data generated and collected by Lawson researchers, research trainees, and research staff, whether the research was funded by the Tri-agency or other funders, or self-funded.

This strategy does not propose the creation of new or amendment of existing hospital policies.

5   OVERSIGHT AND REVIEW

The RDM Advisory Committee supports establishing and implementing the overall institutional strategy. Drafting of the institutional RDM strategy is being led by the RDM Project Team, comprising Research Informatics, Grants Development, Quality Assurance, and Research Administration team members.

The RDM Advisory Committee, comprising key institutional stakeholders, acts as a resource to the RDM Project Team on the planning, implementation, and ongoing evaluation of the strategy. These stakeholders include Lawson's Chief Operating Officer, representatives from the hospital Privacy Offices, Information Technology Services, LHSC Data Governance, Research Ethics Boards, Western Libraries, Lawson Approvals, Grants Development, Quality Assurance, Research Directors, research teams, and research trainees. The RDM Project Team consults with other stakeholders and community partners as needed to support the RDM rights of all stakeholders involved in research.

The Advisory Committee further understands that as the research landscape advances, the RDM requirements and obligations implemented by Tri-agency and other funders may change; as RDM progress is made as outlined in this strategy, the resources and priorities will also change, necessitating re-evaluation of RDM maturity and revision of this RDM strategy. Hence, the strategy will be considered a living document that will be reviewed on an annual basis by the Advisory Committee.

6 INSTITUTIONAL SUPPORT

Lawson aims to meet RDM requirements and implement RDM best practices and processes to fully support its researchers and research communities. Through the implementation of the institutional RDM strategy, Lawson will provide sustainable support and solutions by documenting existing support and processes, formalizing responsibilities, and expressing and promoting RDM best practices. Lawson aims to support researchers in establishing and implementing data management practices consistent with ethical, legal, and commercial obligations.

6.1 Awareness-Raising Activities

The Lawson research community was engaged through various means to raise awareness about the Tri-Agency RDM policy requirements and RDM.

- Data champions were recruited from different departments to help promote the value of RDM and engage with various communities.
- The research community was invited to participate in an anonymous survey to understand the current state of Lawson in developing and allocating human, organizational, infrastructure, and financial resources for Research Data Management within the Lawson research community.
- The RDM Maturity Assessment, based on Maturity Assessment Model in Canada (MAMIC), was conducted to take stock of the current services and identify areas for future growth and development. It helped to capture the perceptions of the current RDM service offerings.
- Lawson also established an internal RDM website to provide information about research data management, Tri-Agency RDM Policy requirements, data management plans, institutional RDM strategy, frequently asked questions, and resources. This website provides up-to-date information and keeps the research community informed.
- The RDM Project team hosted webinars on research data management, data management plan templates, and DMP Assistant.

The objective is to assist the broader research community in understanding the institution's current and planned RDM capacity, challenges, and needs. Therefore, to facilitate an ongoing dialogue and collaboration on the advancement of RDM on a national level, Lawson has created web pages dedicated to RDM on an external-facing website.

6.2 Hire and Train Staff

Lawson has research data management expertise and skills within different departments. However, a centralized and integrated approach to support RDM is required. Infrastructure support for large data sets can also generate some human resources issues. New research data management approaches also require the upkeep of skills, techniques, processes, and solutions. Accordingly, appropriate knowledge and skill development will be needed for the team to support RDM.

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6.3   Promote and Support RDM Practices

Lawson will continue to support researchers and their staff by encouraging a data management culture and an environment that promotes and facilitates research data management. Lawson's Research Informatics and Grants Development teams will provide Data Management Plans and data deposit consultation services.

6.4   Access to RDM Tools, Resources, and Infrastructure

6.4.1   Information Technology (IT) Infrastructure

Lawson's IT infrastructure is managed and supported by the hospitals' Information Technology Services (ITS) department.

- ITS provides access to OneDrive, Teams, SharePoint, Webex, Office 365, MS Project, and many more solutions and platforms available for research purposes.
- All systems available to Lawson researchers through ITS are backed up on a nightly and monthly basis. Backups on tapes are also stored at an off-site location for disaster recovery.
- Lawson-supported servers are hosted at the secure ITS data centre. These servers are configured and secured as per hospital guidelines.
- Various safeguards have been implemented and documented to prevent, detect, and mitigate the effects of computer viruses, worms, or other potentially harmful software code on study data and software.
- The virtual servers hosted at the hospitals' data centre employ vMotion. It allows IT to move running virtual machines from one physical server to another without impacting end-users. vMotion keeps the IT environment up and running, providing unprecedented flexibility and availability. It also decreases downtime and improves reliability by supporting business continuity and disaster recovery procedures.

6.4.2   Support Services

Lawson researchers have access to many support services through different departments.

- The RDM Project team hosts workshops related to RDM and DMPs.
- The Research Informatics team hosts workshops to build capacity in researchers to accelerate the build of high-quality data capture projects.
- Quality Assurance and Education Program hosts 'Lunch 'n Learn' sessions related to policies and regulations, and educates researchers and staff on compliance requirements and best practices.
- ITS has partnered with Microsoft and peer Ontario hospitals to develop Live Virtual Training sessions to allow learning at an individual pace.

6.4.3   RDM Tools

Several tools are available to Lawson researchers to support their RDM requirements.

- REDCap is a Research Electronic Data Capture web-based tool for creating and managing online database applications and surveys. Hosted at the hospitals' data centre, Lawson Research Informatics administrates this secure platform to meet the diverse research needs of the Lawson community.
- Lawson supports its researchers by providing robust infrastructure to support their research activities on a safe, secure IT platform to ensure patient confidentiality for clinical activities; and by providing hosting for customized web applications for research studies. Lawson manages several research applications on Windows and Linux servers, securely hosted at the London hospitals' data centre.
- File Safe and M365 are the recommended tools available to Lawson researchers to securely transfer files, large and small, including confidential or patient-identifiable information, instead of using email attachments.
- DMP Assistant is a national, online, bilingual data management planning tool to assist researchers in preparing data management plans (DMPs). Lawson researchers and their team members can create an account on this platform. They can select 'Lawson Health Research Institute' as their organization to develop their discipline or study-specific Data Management Plan through a series of critical data management questions supported by best-practice guidance and examples.
- Lawson researchers also have access to the Lawson DMP Template that guides them through all the elements of a data management plan and provides example answers to several questions.

Canadian Repository Options
- Borealis, a publicly accessible, secure Canadian data repository system managed by Western Libraries, allows for data to be released and shared openly or privately with precision at the file level using Dataverse software. This is available to Lawson researchers who are faculty members at Western University.
- Lawson researchers can utilize the national Federated Research Data Repository (FRDR) platform to deposit data or to search for and download data across Canadian repositories. This platform can efficiently ingest datasets of any size, and preservation processing is done automatically. Research data can be ingested, curated, preserved, discovered, cited, and shared from this single platform.

International Repository Options
- The Directory of Open Access Repositories (OpenDOAR) provides a quality-assured list of open-access repositories worldwide. OpenDOAR staff harvest and assign metadata to allow categorization and analysis to assist the wider use and exploitation of repositories. OpenDOAR is based at the University of Nottingham.
- Re3data.org is a global registry of research data repositories that covers research data repositories from different academic disciplines. It includes repositories for the permanent

storage and access of data sets to researchers, funding bodies, publishers, and scholarly institutions. Re3data.org promotes a culture of sharing, increased access, and better visibility of research data.

7   STAKEHOLDERS

Several key stakeholders were identified internally and externally from the organization. The RDM Advisory Committee was formed in March 2022 to include relevant stakeholders who are directly impacted by the implementation of the Institutional Strategy. This committee included stakeholders from Executive Administration, Research Informatics, Grants Development, and representatives from LHSC and St. Joseph's Privacy Offices, Information Technology Services, LHSC Data Governance, Western University's Health Sciences Research Ethics Board, Western Libraries, Lawson Approvals, Quality Assurance, Research Directors, Research teams, and a Postdoctoral Fellow. The Advisory Committee meets monthly to help raise awareness, assess institutional readiness, and serve as a communication medium. Appropriate delivery mechanisms for outreach were implemented to engage the Lawson research community. The input and feedback from the research community were solicited through surveys, webinars, online RDM sites, email, ad hoc meetings, etc.

Perceiving the significance of collaboration with external stakeholders and community partners, the RDM Project Team has been reaching out to Indigenous Cancer Care Unit Clinical Institutes & Quality Programs and the Office of Inclusion & Social Accountability (Indigenous Health) at LHSC, and the Knowledge Exchange, Impact & EDI-D in Research office and Indigenous Health Lab at Western University for finding a common intersection of work and continued consultation and consideration concerning RDM training and processes.

8   ETHICAL CONSIDERATIONS

Lawson Health Research Institute supports researchers in adopting and complying with ethical, legal, and commercial obligations through various means. Research oversight and compliance are overseen by Western University's Health Sciences Research Ethics Board (HSREB), Clinical Trials Ontario (CTO), and Ontario Cancer Research Ethics Board (OCREB). They also oversee the ethical conduct of research studies involving human participants. Additionally, the Tri-Agency's Tri-Council Policy Statement: Ethical Conduct Involving Humans – TCPS2 (2018) provides guidance to researchers conducting research involving human participants.

Lawson's Quality Assurance and Education Program (QAEP), which is a part of Lawson's Quality Management System (QMS), facilitates research compliance across the organization through Standard Operating Procedures, Guidance Documents, Lunch and Learns, Clinical Research Training, Quality Assurance Reviews as well as providing research support to Investigators, research teams and other stakeholders on the regulations, policies and best practices governing clinical research.

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Research compliance with legal and commercial obligations falls under the Lawson Research Approval Systems (Contracts) and WORLDiscoveries, a joint business development arm for Lawson, Western University, and Robarts Research Institute. Lawson's Contracts team is responsible for drafting, reviewing, negotiating, and coordinating all contracts for research under Lawson's auspices.

9   INDIGENOUS DATA CONSIDERATIONS

Lawson intends to support researchers involved with Indigenous research and ensure that Tri-Agency RDM policy requirements are addressed. We recognize that there are many Indigenous communities, peoples, cultures, languages, and protocols and therefore no singular approach can be applied. We also acknowledge the validity of Indigenous epistemologies and ontologies.

Lawson recognizes, supports, and respects Indigenous data sovereignty and their right to own, control, access, possess, and protect the information collected from these communities, based on free, prior, and informed consent. We are committed to respect and adhere to nation and community specific protocols by following research data management principles developed and approved by these communities, collectives and organizations such as the First Nations Information Governance Centre's OCAP (Ownership, Control, Access, Possession) principles, the Inuit Tapiriit Kanatami National Inuit Strategy on Research, and Global Indigenous Data Alliance's CARE principles. These govern data collection, ownership, protection, use and sharing to encourage inclusive development and innovation, and equitable outcomes. Lawson will ensure that the DMPs are co-developed with these communities, collectives, and organizations, in line with RDM principles and DMP formats that they accept. We acknowledge that they have the right to repatriate the data and this could result in exceptions to the data deposit requirement.

Lawson researchers are also guided through TCPS 2 (2018) – Chapter 9: Research Involving the First Nations, Inuit and Métis Peoples of Canada to ensure that research involving Indigenous peoples is postulated on respectful relationships that encourage collaboration and engagement between researchers and participants. It is a policy that serves as a framework for the ethical conduct of research involving Indigenous peoples in Canada.

It is our institutional responsibility to build capacity for doing this work in an effective way. Lawson is working with the Indigenous Cancer Care Unit Clinical Institutes & Quality Programs and the Office of Inclusion & Social Accountability (Indigenous Health) at LHSC. Lawson is also collaborating with the Office of Equity, Diversity, and Inclusion (EDI) and the Indigenous Health Lab at Western University.

Lawson aims to strengthen Indigenous research capacity by facilitating and promoting equitable access and support for Indigenous students and researchers. Lawson Scientists usually have Western faculty appointments and/or have employment as clinicians with LHSC and/or St. Joseph's. Lawson supports Indigenous researchers with these affiliations and encourages non-Indigenous researchers to co-develop new models for Indigenous research and research training with Indigenous communities. This may include co-developing research questions, agendas, respectful relations, and impactful solutions built on trust,

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respect, and mutual interests. Indigenous researchers and leadership will help non-Indigenous researchers understand Indigenous perspectives, needs, concerns and aspirations for Indigenous research. Indigenous researchers can help foster positive collaboration with Indigenous partners, collect organic responses from Indigenous participants and provide an Indigenous research lens on the collected information and analyzed data.

These efforts will help us create research data management guidelines for our researchers involved in Indigenous research, assuring the best practices reflect the Four R's - Respect, Relevance, Reciprocity, and Responsibility.

10 OTHER RELEVANT STRATEGIES AND POLICIES

Lawson Health Research Institute is governed by several LHSC and St. Joseph's policies, processes, and procedures that are relevant to various aspects of RDM.

The Lawson RDM Strategy is also intended to align with external requirements and guidance, including provincial, federal, and international laws.

The pertinent policies and documents that were reviewed are listed below.

10.1 London Health Sciences Centre Corporate Policies and Procedures

Acceptable Use of Information Technology Resources
Breach of Privacy
Privacy
Confidentiality
Electronic Mail (Email) Use
Acceptable Use of Information Technology Resources
Records Retention and Disposition
Remote Access to Computer Network Resources
Security of Confidential Information and Information Technology Systems
Use of Cellular Phones and Other Wireless Devices
Use of Personal Health Information for Research, Education, and Quality Improvement
Invention - Lawson
Lawson Approval for Clinical Research

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9

10.2 St. Joseph's Health Care London Policies and Procedures

Acceptable Use of Information Technology Resources
Access and Disclosure of Personal Health Information
Breach of Patient Privacy
Clinical Trials Involving Investigational Drugs
Confidentiality
Disclosure of Patient Information, Samples, and/or Belongings to Law Enforcement Agents
Electronic Mail (Email) Use
Freedom of Information and Protection of Privacy Act (FIPPA)
Health Record Management
Interpretation and Translation Services
Patient Requests to Restrict the Use and Disclosure of Personal Health Information
Privacy
Records Retention and Destruction
Remote Access to Computer Network Resources
Security of Confidential Information and Information Technology Systems
Use of Personal Health Information for Research, Education, and Quality Assurance

10.3 External Strategies/Policies

CARE Principles for Indigenous Data Governance (2020), Global Indigenous Data Alliance
CIHR Research Data Management Learning Module (2022), Government of Canada
Guidance on Depositing Existing Data in Public Repositories (2021), Government of Canada
National Inuit Strategy on Research (2018), Inuit Tapiriit Kanatami
Principles of Ethical Métis Research (2010), Métis Centre, National Aboriginal Health Organization
Principles respecting the Government of Canada's relationship with Indigenous peoples (2021), Government of Canada

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Research Involving First Nations, Inuit, and Métis Peoples of Canada (2022), CIHR

Research Involving the First Nations, Inuit and Métis Peoples of Canada: Chapter 9 - TCPS 2 (2018), Government of Canada

The FAIR Guiding Principles for scientific data management and stewardship (2016), Wilkinson et al. Sci Data

The First Nations Principles of OCAP (2022), First Nations Information Governance Centre

First Nations and Higher Education: The Four R's - Respect, Relevance, Reciprocity, Responsibility (2001), Kirkness, V. J. and R. Barnhardt

Tri-Agency Framework: Responsible Conduct of Research (2021), Government of Canada

Tri-Agency Research Data Management Policy (2021), Government of Canada

Tri-Agency Statement of Principles on Digital Data Management (2021), Government of Canada

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018), Government of Canada

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11

11 ACRONYMS & ABBREVIATIONS

Acronym/Term	Definition
CARE	Collective Benefit, Authority to Control, Responsibility, and Ethics
CIHR	Canadian Institutes of Health Research
DMP	Data Management Plan
EDI	Equity, Diversity, and Inclusion
FAIR	Findable, Accessible, Interoperable, and Reusable
HSREB	Health Sciences Research Ethics Board
ITS	Information Technology Services
Lawson	Lawson Health Research Institute
LHSC	London Health Sciences Centre
MAMIC	Maturity Assessment Model in Canada
NSERC	Natural Sciences and Engineering Research Council of Canada
OCAP	Ownership, Control, Access, and Possession
OCREB	Ontario Cancer Research Ethics Board
QAEP	Quality Assurance and Education Program
QMS	Quality Management System
RDM	Research Data Management
SSHRC	Social Sciences and Humanities Research Council
St. Joseph's	St. Joseph's Health Care London
Tri-Agency	CIHR, NSERC, SSHRC
WORLDiscoveries	WORLDiscoveries is the commercialization arm of Western University, Robarts, and Lawson and represents our commitment to protecting and transferring technologies developed by our partners to market.

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12 DEFINITIONS

The definitions below are as per the Tri-Agency Research Data Management Policy, Frequently Asked Questions, and Social Sciences and Humanities Research Council Definition of Terms, 2021, Government of Canada.

Data Deposit

"Data deposit" refers to when the research data collected as part of a research project is transferred to a research data repository. The repository should have easily accessible policies describing deposit and user licenses, access control, preservation procedures, storage and backup practices, and sustainability and succession plans. The deposit of research data into appropriate repositories supports ongoing data-retention and, where appropriate, access to the data.

Data Management Plan

A data management plan (DMP) is a living document, typically associated with an individual research project or program that consists of the practices, processes, and strategies that pertain to a set of specified topics related to data management and curation. DMPs should be modified throughout a research project to reflect changes in project design, methods, or other considerations.

Indigenous Research

Research in any field or discipline that is conducted by, grounded in or engaged with First Nations, Inuit, Métis or other Indigenous nations, communities, societies or individuals, and their wisdom, cultures, experiences or knowledge systems, as expressed in their dynamic forms, past and present. Indigenous research can embrace the intellectual, physical, emotional and/or spiritual dimensions of knowledge in creative and interconnected relationships with people, places and the natural environment.

Metadata

"Metadata" are data about data—data that define and describe the characteristics of other data. Accurate and relevant metadata are essential for making research data findable. A principle to help determine what information should be included in metadata is the open archival information system model criterion that the information be "independently understandable."

Research Data

Research data are data that are used as primary sources to support technical or scientific enquiry, research, scholarship, or creative practice, and that are used as evidence in the research process and/or are commonly accepted in the research community as necessary to validate research findings and results. Research data may be experimental data, observational data, operational data, third party data, public sector data, monitoring data, processed data, or repurposed data. What is considered relevant research data is often highly contextual, and determining what counts as such should be guided by disciplinary norms.

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13

Research Data Management

Research data management (RDM) refers to the processes applied through the lifecycle of a research project to guide the collection, documentation, storage, sharing, and preservation of research data.

13 LOOKING AHEAD

The Lawson Research Data Management Strategy is a living document that will be reviewed and shared on an annual basis. It will be revised and updated as the institutional and researchers' research data management requirements, practices, and understanding advance.

In the coming years, Lawson will:

- evaluate the changes in policy requirements,
- assess evolving institutional RDM training needs
- gauge availability of the supporting resources
- ensure compliance with the RDM policies and requirements by funders, publishers, and legislative bodies
- evaluate technological infrastructure and meet expanding storage requirements – this may include assessment of access on platforms like Borealis for Lawson researchers who are not Western faculty members
- facilitate capacity-building events for RDM and DMP development
- provide training and educational services and support
- examine DMP evaluation criteria and guidelines
- consider requirements for data deposit certifications
- adjudge implications on the involved stakeholders
- consult with community stakeholders to confirm Indigenous data sovereignty considerations

It has been clear that implementation of the institutional RDM strategy requires collaboration on a broader scale. To that end, the RDM Project Team will build additional meaningful connections and identify subject matter experts for future RDM projects. Furthermore, the RDM project team is also proposing to establish a Community of Practice to manage RDM requirements in a sustainable method. This Community of Practice may comprise key stakeholders and experts from groups such as Ethics, Privacy, QA, Indigenous wellness group, Office of Inclusion and Social Accountability, research investigators, research coordinators, and research personnel.

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