

**University Health Network's
Research Data Management Strategy**



Table of Contents

Introduction	1
UHN Research Data Management Strategy.....	1
Alignment, Oversight & Stakeholders.....	2
UHN Approach to Research Data Management.....	3
Ethics, Privacy, & Legal Considerations.....	4
Research Ethics & Privacy.....	4
Research Security.....	4
Data Sharing & Intellectual Property.....	5
Indigenous Data Considerations.....	5
Priorities & Objectives.....	6
Looking Ahead – Multi-year RDM Roadmap.....	7
Priority 1: Ensuring Research Integrity & Reproducibility.....	8
Priority 2: Preserving Data & Maintaining Security.....	9
Priority 3: Federating data.....	10
Priority 4: Improve Collaboration.....	11
Definitions.....	12
Version History.....	13

Introduction

UHN is committed to research excellence, open science, and public accountability by ensuring our research data has a robust data oversight and management framework which will enable data to be collected, secured, managed, and shared responsibly and ethically.

This requires promoting and advancing institution-wide principles, practices, and support services to enable Research Data Management (RDM) that meets the needs of our research community and aligns with broader UHN policies and data oversight goals.

The UHN Research Data Management Strategy promotes adherence to the [Tri-Agency Research Data Management Policy](#), [Tri-Agency Framework on Responsible Conduct of Research](#), [Tri-Agency Statement of Principles on Digital Data Management](#), and aligns with other national and international RDM policies and standards, including those increasingly adopted by journals for publication to promote reproducibility, responsible conduct of research and dissuade research misconduct.

UHN Research Data Management Strategy

Research data management (RDM) practices are integral to conducting responsible research. RDM involves the processes and standards applied throughout the lifecycle of a research project to guide the planning, creation and collection, processing, analyzing, documenting, disseminating and sharing, storage and preservation, and the reuse of research data. As Canada's largest research hospital, UHN recognizes data as an important research output. Traditionally, UHN Research has followed standards adhering to data management practices on a more localized scale, such as with signed hard-copy lab books. As processes in research are increasingly enabled digitally, the ability to expand and refine RDM has become much more feasible. When data is collected, stored, and governed appropriately in a digital format, it can be made more readily available for sharing and re-use outside of individual labs and research programs. This contributes to the impact of our research within the relevant scientific communities, improved outcomes within our patient communities, and increased health impacts for the broader public.

Our RDM Strategy is guided by the FAIR principles that promote research data that is *Findable, Accessible, Interoperable, and Reusable*. Our RDM Strategy aims to enhance institutional RDM capacity by building upon existing infrastructure, services, training, and good data management practices that:

- Promote institutional policy, standards, and leading practices in planning for data management.
- Align to and enhance the Research Strategic Plan.
- Ensure data security through digital storage and data repository infrastructure.
- Enable public access, collaboration, data sharing and reuse by internal and external stakeholders.
- Address key considerations in research ethics, privacy, legal and commercialization interests.
- Incorporates the values of community stakeholders in keeping with principles of inclusivity and equity.

Alignment, Oversight & Stakeholders

The UHN Research Data Management (RDM) Strategy aligns with the key priorities of the [UHN Research Strategic Plan 2019-2023](#) to *empower research teams and collaboration, unleash the power of technology and innovation, and accelerate the translation of discovery to practice.*

The UHN RDM Strategy is developed by the UHN Research Data Management Working Group. The Working Group is comprised of UHN scientists, UHN Digital leadership, as well as policy and regulatory experts. A needs assessment survey was conducted across UHN to gain a broader perspective of where our current RDM strengths and limitations lie, and where we need to prioritize our future investment in building RDM capacity.

The UHN Research Data Management Working Group also consults with other key organizational stakeholders including the UHN Data Governance Committee, UHN Research Council Executive Committee, UHN Clinical Research Executive Committee, UHN Indigenous Health Program, and UHN Commercialization. Accountability and final approval of the Strategy resides with the UHN EVP Science & Research.

Recognizing the importance of a consistent and harmonized approach to research data management, the UHN Research Data Management Strategy was developed in consultation with the TAHSNr Tri-Agency Research Data Management Policy Table to promote consistency with the University of Toronto and other research hospitals as part of the Toronto Academic Health Science Network.

UHN Approach to Research Data Management

Research data management (RDM) is complex, dynamic, and entails discipline-specific standards and practices. RDM is not isolated to centralized research support structures: researchers are themselves responsible for developing plans to create, process, analyze, document, store, and share data throughout a project's research data lifecycle. RDM will require researchers to make data management decisions based on the type of data collected, adopt metadata standards commonly used within the specific field of research, and consider data repositories required or endorsed by their respective funders, journals or endorsed broadly within their field. To do this, researchers require a supportive environment that provides ongoing and coordinated support to meet the needs of the research. This support includes access to software tools, data deposit infrastructure, training and templates for data management planning that can all function within a policy and oversight framework that promotes data security, accessibility, and data sharing.

The Research Data Lifecycle



(Image adapted from Portage Network)

Principal Investigators at UHN are the stewards for all research data they generate. At UHN, this includes accountability for responsible management of research data. An important responsibility is the creation of research data management plans (DMPs), documents that outline the processes and tools to manage data effectively and efficiently throughout the project and after its completion. Essential elements of data management plans include:

- **Data collection** including data types, file formats, naming and version control.
- **Documentation** that enables data to be read and interpreted.
- **Data storage** and backup throughout the research enterprise.
- **Data preservation** strategy for long-term access.
- **Data sharing and reuse** mechanisms.
- **Responsibilities and resources** for data management.
- **Ethical, commercial, legal** considerations compliance.

(Content adapted from Portage Network)

As the custodian of data for all research conducted under its auspices or within its jurisdiction, UHN is committed to providing the infrastructure, services, and guidance to enable good RDM practices and facilitate the sharing, reuse, and impact of the data.

Ethics, Privacy, & Legal Considerations

Research Ethics & Privacy

Research ethics is integral to forming good research data management plans. Research involving humans includes important considerations around participant privacy and confidentiality, particularly when the research is collecting or otherwise using sensitive patient-level data. Research data management plans will carefully consider the risk of unauthorized release of sensitive data and will leverage UHN-provisioned tools to ensure adequate technical and procedural controls are in place to mitigate such risks. At UHN, research participant's personal health information collected for research purposes will continue to be collected, used, and shared in accordance with *UHN policy – Ethics Review of Research Involving Humans*, *UHN policy – Privacy*. This is essential for protecting the rights and well-being of research participants and communities.

Research Security

Good research data management plans should consider the security of the research data. Threats to UHN's research data pose a risk to the institution, intellectual property, UHN's researchers and patient and participant privacy. UHN is committed to protecting its research outputs from external security threats. Research involving animal subjects is an area of particular concern with the rise of personal attacks on those conducting such research. UHN Digital has a robust cybersecurity program in place to safeguard data created and stored at UHN. UHN has recently established a Research Partnership Security Working Group to develop and implement processes to flag and evaluate high-risk partnerships. As a best practice, researchers should always consider the security of their research data when engaging in research partnerships and collaborations.

Data Sharing and Intellectual Property

UHN is committed to the values of open science and sharing data responsibly to maximize the impact for patients, for the public, and all stakeholders involved. At the same time, research data must be managed in accordance with all commercial and legal obligations and objectives. For example, in the context of clinical trials initiated by industry partners, data sharing, and other data management considerations typically must adhere to trial sponsor requirements and contractual obligations while adhering to organizational RDM practices where possible. Similar restrictions may occur with other research sponsors.

The timing and extent of data sharing will also require consideration for protection of intellectual property (IP) where the research data and other outputs may give rise to new inventions. *UHN Policy – Intellectual Property Protection & Commercialization and UHN’s [‘Commercialization Lives Here’](#)* Strategic plan will continue to provide a framework guiding the management of IP at UHN, supporting its further development through partnership, commercial investment, or other for the benefit of the public, UHN partners, and interested stakeholders.

Indigenous Data Considerations

At UHN we recognize that research data originating by and with First Nations, Métis, and Inuit communities should be managed in accordance with the principles developed and approved by their respective communities. We are committed to ensuring that research for and about Indigenous nations is collaborative, and that research data are utilized to advance Indigenous aspirations for collective and individual wellbeing. UHN Research will work towards aligning research data management activities with the principles of OCAP (ownership, control, access, and procession) and CARE (collective benefit, authority to control, responsibility, and ethics) to ensure data is not used harmfully and not de-contextualized. Adhering to the guidelines set out by the First Nations principles of OCAP and CARE will result in equitable outcomes for Indigenous community through inclusive development and innovation, improved oversight, and citizen engagement.

Oversight

Planning is underway to integrate research and RDM considerations into the systems and structures of UHNs evolving Indigenous Health Program. Working with leadership and the UHN Indigenous Council, we will establish oversight processes to align research data management with the interests of indigenous communities when collaborating, collecting, developing, analyzing, interpreting, and disseminating research data.

Priorities & Objectives

Our goal is to build upon existing infrastructure and services across our 4 priority areas that will inform investment in future RDM capacity at UHN:



Priority 1: Ensuring Research Integrity & Reproducibility through organizational policies, processes, training, and good research data management plans (DMPs) that adhere to Tri-Agency and other funding and regulatory agencies requirements and other best practice standards.



Priority 2: Preserving Data & Maintaining Security by providing digital solutions to enable data capture, preservation, and retention.



Priority 3: Federating data by providing a data deposit service and infrastructure with transparent oversight that enables access to a wide range of institutional data sources to researchers within and outside UHN to optimize usability and impact of research data.



Priority 4: Improve Collaboration by guiding and enabling researchers to follow the FAIR and CARE data principles that support discovery, sharing, and re-use of research data within the organization and with external partners, when possible, to reflect and optimize UHN's investment and stewardship in data resources.

Looking Ahead – Multi-year RDM Roadmap

UHN will continue to support researchers and enable good RDM practices by building upon current policy and processes and expanding training and tools offered in support of our identified priority areas.

Looking ahead, we are investing resources to implement an RDM strategy that puts practice to the FAIR/CARE principles, provides centralized RDM support services, organizational policies and training for researchers. The RDM Strategy Roadmap below outlines current strengths as well as ongoing and future data management initiatives in order to build capacity for RDM that is aligned with UHN’s RDM goals as well as the [UHN Research Strategic Plan 2019-2023](#).

Research Data Management (RDM) Strategy Map 2022 - 2025

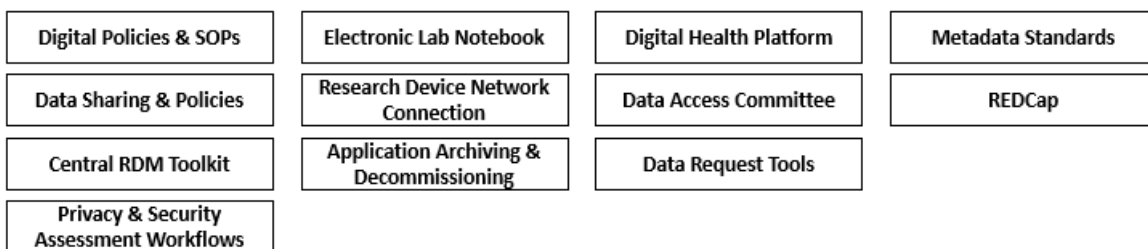
Strategic directions



RDM Goals



Project Initiatives





Priority 1: Ensuring Research Integrity & Reproducibility



Current Strengths

- UHN's **current policies** governing research data management include:

Responsible Conduct of Research Policy
UHN Privacy Policy and UHN's Standard for De-identification
UHN Intellectual Property Protection & Commercialization Policy

Data Ownership, Stewardship & Security of Health Information Policy
UHN Information Security Policy and Application Security Standard
UHN Appropriate Use of Information & Information Technology Policy

- UHN currently provides a centralized framework for the creation and approval of internal and external **research data registries** as well as large data sharing initiatives.



Future Direction

- Align UHN Digital policies and SOPs** and develop a **Master Validation Plan** that supports validation and integrity of select electronic platforms for essential research data collection and use in accordance with Health Canada and U.S. FDA requirements and other funding agencies.
- Revise **e-learning** and provide research and administrative teams with **asynchronous, case-based learning opportunities** in responsible conduct of research and good RDM practices.
- Develop UHN **data sharing policy and standards** that promote data sharing while considering other legal obligations, protecting intellectual property and pursuing UHN commercialization objectives.
- Improve the **privacy impact and security assessment workflows** for assessing new technologies.
- Consolidate communication, policy, guidance, and services into a **central RDM Toolkit** to enable access to best practices and data management plan (DMP) templates.



Priority 2: Preserving Data & Maintaining Security



Current Strengths

- Full-service **Bioinformatics Core** facility providing infrastructure and service to enable high performance computing and advanced data analysis including high-throughput sequencing data.
- Access to centrally managed and data collection platforms such as **REDCap, MediData Rave, and DADOS**. REDCap and MediData Rave are validated and conform to Health Canada and U.S. FDA regulatory requirements.
- **Enterprise Web Solutions and other tools** for securely sharing data with collaborators including UHN File Share, MS SharePoint.
- **Digital Security framework** that provides oversight and security tools designed to monitor activity and threats to data and other information hosted within our networks.



Future Direction

- Explore **electronic lab notes** solution for researchers to document their research data electronically to support data quality, sharing, and intellectual property protection.
- Provision **long-term storage options** for researchers who need to store data for infrequent use and or legal retention purposes.
- Devise clear **policies guiding data retention** timelines based on risk and value.
- Streamline and rollout **standard and secure connectivity of research devices** to the UHN-managed network improve research data management and security and oversee provision of administrative privileges.
- Implement **application archiving & decommissioning** solutions to retire legacy applications while preserving the databases and federating them within the enterprise Digital Health Platform for ongoing clinical, research, audit, and legal purposes.
- Develop and implement processes and training to **enhance research partnership and data security**.



Priority 3: Federating data



Current Strengths

- UHN's **Digital Health Platform (DHP)** integrates UHN clinical, research, and other operational data sources within an enterprise-wide framework. The platform enables management and utilization of big data in support of data-driven research, predictive analytics (including Artificial Intelligence (AI) and Machine Learning (ML)), precision medicine, and population health.



Future Direction

- Seek to leverage existing research data deposit infrastructure already in existence, including internal registries, external repositories, or the UHN Digital Health Platform (DHP).
- Work with the UHN Data Access Committee to develop and promote data deposit guidelines that support researchers in identifying appropriate data repositories that meet their respective funder and journal requirements as well as UHN data sharing policies.



Priority 4: Improve Collaboration



Current Strengths

- Expand and promote UHN's **Digital Health Platform (DHP)** to integrate and share research and other data sources to optimize reuse and data impact. This includes providing review and approval of research data requests as well as the creation and use of research registries.



Future Direction

- **Metadata standards** to be defined for the research community so researchers are able to organize their data in a meaningful way where datasets are searchable, easily locatable and easily understood.
- Enable opportunities for recognition of **excellence in data sharing** to encourage research without shared authorship or collaboration both within UHN and externally.
- Expansion of centralized oversight of data deposited into external registries and databases which will take the burden away from individual researchers.
- To engage specifically and significantly, to proactively maximize the full potential of results generated by our data and data infrastructure, where applicable, to impact health care for patients globally.
- To re-invest those successful results to power additional future discoveries and allow UHN to remain on the global cutting edge of better patient outcomes, research, training, and innovations.

Definitions

Research Data: Research data is anything that forms the basis of your research output. Any primary sources supporting research which may take the form of experimental data, observational data, operational data, third party data, public sector data, monitoring data, processed data, or repurposed data.

Research Data Management (RDM): making decisions about how you will collect and look after your digital and physical research data and putting those decisions into action.

FAIR Data Principles: FAIR principles are guidelines to support the discovery and reuse of research data, and metadata. The principles state that research data should be Findable, Accessible, Interoperable and Reusable (FAIR) for machines and for people.

CARE Data Principles: CARE principles stand for Collective Benefit, Authority to Control, Responsibility, and Ethics. The principles are focused on people and purpose, and on appropriate use and re-use of indigenous data.

Version History

Version	Date
1.0	March 1 st , 2023