

Bloorview Research Institute's Research Data Management Strategy

The Bloorview Research Institute (BRI) Research Data Management Strategy outlines the institutional commitment to responsible practices for the management of data created, collected and utilized throughout the research process within the auspices of the BRI. It was created in advance of the [Tri-Agency Research Data Management Policy](#), which promotes responsible use of research funds and the creation of [FAIR](#) (Findable, Accessible, Interoperable, and Reusable) data.

Importance of Research Data Management

Research Data Management (RDM) refers to the processes applied throughout the lifecycle of a research project to guide the collection, documentation, storage, sharing, and preservation of research data, and allows researchers to find, access, and use data. For the value of data to be fully realized, good RDM practices such as creating a data management plan and utilizing systems to organize and document datasets are needed throughout the course of research and beyond. Implementing good RDM practices is a shared responsibility between researchers (scientists, staff, students and collaborators), institutions, communities and funding agencies.

Accurate and reliable data that are made available to others promote study replication and data validation. Researchers should consider the value of making quality-controlled datasets available for reuse, and facilitating further reach and impact of the research investment. This supports research findings and can open new channels for discovery, contributing to global understanding, knowledge building, and innovation. However, this should be balanced with appropriate protections to ensure that ethical, legal, and regulatory responsibilities are met, as well as agreements with communities and partners.

Approaches

Bloorview Research Institute aims to develop a collaborative approach that enables a shared responsibility model where researchers adopt best research data management practices while ensuring good institutional data stewardship and maintaining compliance. Researchers are responsible for ensuring the safe handling and secure storage of data as per institutional guidance with appropriate security controls and restrictions around access to information. Research data also

needs to be managed in ways that adhere to all legal and ethical requirements and fulfill any sponsor obligations or research partner expectations.

It is recognized that what constitutes research data will differ by project and that different kinds of data or research methodologies will require distinct practices to make the data most useful. Data management decisions will also be impacted by the characteristics of the individual datasets. Likewise, disciplinary standards, ethical requirements and practices may influence the management of data, including approaches to workflows, required documentation, participant consent discussion, metadata selection, and repository selection for data deposit and sharing. Research involving confidential or sensitive data will need to adhere to additional legal and ethical frameworks to ensure information is protected and to reduce risks of harm. Researchers working with vulnerable or marginalized communities (eg. marginalized within territorial or organizational communities) should follow community-developed principles and engage with members to design research approaches in addition to all other requirements described. Data related to research by and with First Nations, Inuit, Métis or Urban Indigenous communities whose traditional and ancestral territories are in Canada must be managed in accordance with data management principles developed and approved by those communities, and on the basis of free, prior and informed consent. This includes, but is not limited to, considerations of Indigenous data sovereignty, as well as data collection, ownership, protection, use, and sharing.

Expectations for Research Data Management Practices

Institutional Practices

It is expected that research conducted at or under the auspices of Bloorview Research Institute will adhere to institutional policies, SOPs, guidelines, and recommendations for proper data handling (See [Appendix B](#)). Researchers should treat data with rigour, operate within institutional frameworks in an effective manner and abide by all ethical, legal and regulatory requirements, sponsor obligations, and partner expectations. Research data should also be managed in ways that align with disciplinary best practices and community-driven principles. When using third-party data, researchers must ensure that they abide by licenses and terms of use.

Researchers must ensure and/or support security requirements and guidelines that are implemented to prevent unauthorized access, loss and compromise. The appropriate selection and use of data management infrastructure should align with institutional policies/procedures and disciplinary best practices as well as project needs. First, consider the use of approved and vetted institutional resources. If considering the use of other resources, ensure compliance with relevant policies, procedures, security guidelines and institutional approval, when applicable. Researchers must justify the utilization of an additional resource (eg. data management infrastructure) not approved or vetted by the institution.

Researchers will be made aware of the institutional support for various data management activities, when available. Researchers will also be provided opportunities to increase the understanding of RDM and utilize resources that aid in the implementation of responsible data management practices. BRI will strive to make these learning opportunities available internally, and when possible, will share external resources to the research community. All researchers, research team members, and students should be encouraged to build capacity and skills in data management activities and practices. RDM concepts will be integrated into institutional training, policies and procedures when possible.

Data Management Plans

Research at BRI should reflect best practices in the planning and execution of projects. The ideal state is for all research projects conducted at the BRI to be supported by a data management plan (DMP) or an equivalent document. DMPs help to conceptualize and develop consistent data management procedures across project stages and are living documents that can be modified to accommodate changes.

Documenting processes in the planning stage of a project maintains data integrity and project efficiencies and helps to prepare data in ways that enable preservation and data sharing.

Planning also helps to ensure the necessary supports and resources are in place and included in budgets. When creating a DMP, researchers should note all ethical, legal, regulatory, cultural, and intellectual property considerations and should adhere to institutional policies, best practices, research quality standards, disciplinary processes, and requirements or expectations outlined by sponsors, project partners, or publishers. DMPs in the context of Indigenous research must be co-developed and designed with those community members and in consideration of community-driven principles.

BRI will provide guidance to assist researchers in developing data management plans through available institutional tools and infrastructure that can be utilized in research projects of various disciplines.

Data Deposit

Data management practices should include considerations and mechanisms to appropriately and securely maintain data after project completion. Publications and research data should be prepared and packaged (along with any accompanying documentation, source code, software requirements, metadata, and supplementary materials) in a way that balances long-term access/reuse with ethical, legal, regulatory, privacy requirements and in accordance with external partner requirements and sub-contract agreements. Researchers should retain these data with a

designated custodian (as defined by PHIPA, institutional policies or study/project agreements) and archive for any defined period specified by a sponsor, project partner, or publisher requirements.

When applicable, researchers may deposit the data into an institutionally-approved repository and, when appropriate, made available to others. Additionally, all data deposit and sharing should follow REB-approved protocol and participants' signed consent forms. When depositing and sharing data, BRI will provide resources to enable researchers to prepare datasets that embody the FAIR Principles (making data Findable, Accessible, Interoperable, and Reusable) and are aligned with legal, ethical and regulatory requirements. Research publications and data management plans should include information about where and how to access supporting data and any conditions of use.

Data Retention

Data created, acquired, recorded and used within a research study must be maintained in accordance with the defined retention period based on institutional policies/records retention schedule, regulatory, legal and privacy requirements, and research standards (eg. ICH Good Clinical Practice).

Researchers, the designated custodian and external partners, when applicable, must adhere to the defined data retention schedule and ensure appropriate disposition of records is completed when all retention requirements are met. Procedures for disposition of records must meet institutional, regulatory, and legal requirements to ensure the privacy and confidentiality of research participants.

The data retention period must be clearly stated in the participant consent form and must be defined in the Data Management plan, or an equivalent document and any external partner agreements, when applicable.

Privacy Breaches and Privacy Complaints

Researchers are responsible for reporting privacy breaches and privacy complaints to the designated institutional channels. In tandem, researchers must also take any appropriate immediate action to mitigate the breach. Additionally, researchers must ensure that research participants are provided the necessary information to securely submit any privacy complaints to the institution.

BRI and Holland Bloorview will manage all reports of privacy breaches and complaints in accordance with the institutional policy, with a formal, comprehensive, methodical and client and family-centered approach.

Influencing Factors for Research Data Management

Indigenous Research

Researchers must respect Indigenous cultures and knowledge, as well as recognize Indigenous data sovereignty and jurisdiction over data about Indigenous communities. Any research involving Indigenous communities must adhere to all legal and ethical requirements and be conducted in accordance with community-driven principles (such as the CARE Principles and the OCAP Principles). Indigenous peoples, communities, and organizations must be engaged throughout the research lifecycle and be involved in all key decision-making. This includes co-developing the data management plan and creating written agreements to ensure the incorporation of holistic research approaches, defining responsibilities and expectations related to data, and outlining commitments to minimize harm to Indigenous communities. Outcomes of research should be shared and returned, and data should be used in ways that benefit the communities and promote capacity development and community empowerment.

Partnerships and Collaborations

Research is strengthened by partnership and collaboration. Strong partnerships and collaborations require agreements between research partners with clearly articulated rights and responsibilities related to data. BRI will encourage and support researchers in establishing suitable agreements that are aligned with BRI policies prior to the execution of the project and actions related to data must abide by the terms. These agreements may articulate responsibilities, conditions of access, and data practices including licenses, ownership, data/material transfer, security, storage, retention, and sharing. When conducting research involving partnership or collaboration, any conflict of interest should be stated, and data collection and interpretation should not be influenced.

Disciplinary Approaches

Practices and standards for managing data vary greatly by discipline, data type, and research method. Researchers should learn from and utilize community-developed disciplinary methods, standards, and best practices and incorporate disciplinary approaches into projects so that the most value can be derived from the outputs. Researchers should engage with disciplinary communities of practice and contribute to the efforts that move disciplinary RDM approaches and knowledge discovery forward.

Institutional Supports

BRI is committed to providing supports to researchers that assist with establishing and implementing responsible RDM practices. To ensure effective supports, BRI will provide feedback mechanisms and actively engage with researchers and other stakeholders to identify new areas for development to reflect evolving practices and needs. Supports will respect the diverse and distinct approaches required for research data management activities across disciplines, type of data, and project partner requirements. BRI will represent and support the interest of researchers and will advocate to influence change on behalf of BRI researchers to hospital, TAHSN, provincial, federal, and other related committees.

A coordinated approach to supports includes providing guidance, platforms, tools, resources, and support services that are available across the institution. These supports include:

- Educational and training approaches to enhance capacity for research data management
- Communication channels to promote best practices and keep researchers informed on updates and changes
- Assisting researchers with developing sound DMPs
- Advising researchers on technical and security best practices
- Facilitating access to a range of infrastructure solutions, including systems and networks for storage, computing and processing resources, and software, tools, and applications
- Providing approved options for data deposit, preservation and sharing

Future Directions

Goals and Strategies

Bloorview Research Institute will regularly review and revise the strategy where appropriate, for instance, as RDM services, infrastructure and practices evolve.

Short-Term Goals:

- *Continue to raise awareness for RDM within the first year by:*
 - *Enabling better access to institutional and external policies and guidelines (e.g., via BRI's web-based Resource Portal)*
 - *Co-creating RDM solutions, documents, resources and templates based on disciplinary best practices with support and feedback from the BRI research community*
 - *Introducing a Data Management Plan template and the DMP Assistant platform to the research community as a resource*
- *Continue to assess and evaluate the current state of RDM practices in the institution via:*
 - *Feedback mechanisms (e.g., surveys, ongoing meetings with the BRI research*

- community)
- Observing research activity in the institution (approximate research volume, types of data produced and types of studies and partnerships involved)
- Identify existing RDM supports and services

Long-Term Goals:

- Provide learning and training opportunities for RDM best practices with educational workshops, webinars – led by internal BRI staff or external subject matter experts when applicable
- Co-creating RDM solutions, documents and resources based on disciplinary best practices with support and feedback from the BRI research community
- Expand RDM supports, services and/or infrastructure in terms of funding, availability, staffing and sustainability with consideration for institutional factors such as staffing and source/longevity of funding
- Ensure all new Clinical research studies have implemented a Data Management Plan or an equivalent section in the study protocol

Feedback Mechanism

Comments related to the Bloorview Research Institute Research Data Management Strategy can be submitted using [an online feedback form](#). Responses to the survey will be reviewed every 6 months from the date of publication of this document. Ongoing feedback received from this survey and other avenues will be used for further iterations of the institution’s strategy and to determine emerging needs of the research community.

Version Information

Date	Version Code	Description
01 Mar 2023	1.0	Original version

Appendix – Policies and Guidelines

Holland Bloorview Policies and Guidelines

Data must be managed in accordance with applicable Holland Bloorview policies and guidelines, including, but not limited to:

- [Responsible Conduct of Research Policy](#), Bloorview Research Institute
- [Invention Policy](#), Bloorview Research Institute – Commercialization
- [Use of Information Technology](#), Holland Bloorview
- [Information Governance](#), Holland Bloorview
- [Freedom of Information and Protection of Privacy Act](#), Holland Bloorview
- [Organizational Commitment to the Privacy of Personal Health Information](#), Holland Bloorview
- [Summary of Contract Types Guide](#), Bloorview Research Institute – Grants, Contracts & Awards
- [Privacy Breaches and Privacy Complaints](#), Holland Bloorview
- [Document Management Policy](#), Holland Bloorview

Bloorview Research Institute Standard Operating Procedures:

Research data management procedures must be in compliance with Bloorview Research Institute Standard Operating Procedures, including but not limited to:

- [BRI SOP 004 Good Documentation Practice](#)
- [N2 SOP 014 Clinical Data Management](#)
- [N2 SOP 015 Investigator Study Files and Essential Documents](#)
- [N2 SOP 019 Confidentiality & Privacy](#)
- [N2 SOP 100 CRF Design](#)
- [N2 SOP 101 Study Analysis and Reporting](#)
- [N2 SOP 103 Data Management Plan](#)
- [N2 SOP 104 Database Setup](#)
- [N2 SOP 105 Database Maintenance and Management](#)
- [N2 SOP 106 File Transfer](#)
- [N2 SOP 107 Database Lock and Archiving](#)
- [N2 SOP 108 System Setup, Maintenance & Security](#)
- [N2 SOP 109 System Backup and Recovery Planning](#)

External Policies and Guidelines

Data may be subject to policies and guidelines from a variety of external sources, such as applicable laws and regulations, requirements from sponsors, or community-developed standards. Examples include:

- [Bill C-15: An Act respecting the United Nations Declaration on the Rights of Indigenous](#)

- [Peoples](#), Government of Canada
- [CARE Principles for Indigenous Data Governance](#), Global Indigenous Data Alliance
- [CIHR Publication-related Research Data, Tri-Agency Open Access Policy on Publications](#) Government of Canada
- [FAIR Principles](#), GO FAIR Implementation Networks
- [The First Nations Principles of OCAP](#), First Nations Information Governance Centre
- [Freedom of Information and Protection of Privacy Act \(FIPPA\)](#), Government of Ontario
- [The Government of Canada's National Security Guidelines for Research Partnerships](#), Government of Canada
- [National Inuit Strategy on Research](#), Inuit Tapiriit Kanatami
- [NIH Data Management & Sharing Policy \(2023\)](#), National Institutes of Health, USA
- [NSF Data Management Plan Requirements](#), National Science Foundation, USA
- [Personal Health Information Protection Act \(PHIPA\)](#), Government of Ontario
- [Principles of Ethical Métis Research](#), National Aboriginal Health Organization Métis Centre
- [Safeguarding Your Research](#), Government of Canada
- [SSHRC Research Data Archiving Policy](#), Government of Canada
- [Tri-Agency Research Data Management Policy](#), Government of Canada
- [Tri-Agency FAQs RDM Policy](#), Government of Canada
- [Tri-Agency Framework: Responsible Conduct of Research \(2021\)](#), Government of Canada
- [Tri-Agency Statement of Principles on Digital Data Management](#), Government of Canada
- [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS 2\)](#), Government of Canada
- [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans \(TCPS 2\), Chapter 9: Research Involving the First Nations, Inuit and Métis Peoples of Canada](#), Government of Canada