SickKids Institutional Research Data Management Strategy

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Background

In March 2021, the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC) (the Tri-Agencies) released a [Research Data Management Policy](). The objective of this policy is to support Canadian research excellence by promoting sound research data management and data stewardship practices. Under this policy, all research hospitals and post-secondary institutions in Canada that are eligible to administer Tri-Agency funding are required to develop and publicly post an institutional Research Data Management strategy by March 1, 2023.

In response to this policy, Hospital for Sick Children (SickKids) has developed an **Institutional Research Data Management (RDM) Strategy**. This document outlines our institution's commitment to supporting best practices in RDM based on the [FAIR principles]() to make research data findable, accessible, interoperable, and reusable. This strategy will be used to inform future policy development and to guide the development of tools, resources, and infrastructure for our research community.

Research Data Management Principles

SickKids is Canada's most research-intensive hospital and largest pediatric academic health science centre dedicated to improving children's health. Researchers at SickKids Research Institute are working across the spectrum of child health, from basic science at the sub-molecular level, to advances in clinical diagnostics, treatments and prevention. As Canada's leading institution in active pediatric clinical trials, SickKids is committed to the ethical and responsible management of pediatric data in accordance with relevant laws, regulations, principles and standards.

A set of Research Data Management Principles have been established to ensure that all research data are managed optimally, including its governance, architecture, quality, master and meta data management. These principles have been adapted from the the Research Data Management Principles developed by the RDM Advisory Committee of the Toronto Academic Health Sciences Network (TAHSN).

These principles encompass the following values:

• Steward Data with a Child and Family Focus
• Promote Research Integrity and Excellence
• Recognize the Value of Data and Data Sharing
• Encourage the Implementation of Data Management Plans
• Facilitate Long-Term Access Through Data Deposit
• Reflect Institutional and Disciplinary Practices and Standards
• Honour Indigenous Community-Driven Principles

- Strengthen Partnership and Collaboration
- Integrate Excellence in All Disciplinary Approaches
- Treat All Human Subjects Data with Appropriate Respect and Safeguard Privacy
- Learn Through Ongoing Communication and Engagement Opportunities
- Provide Infrastructure that Supports Diverse and Complex Programs of Research
- Ensure Support Services are Available
- Commit to Advocacy and Support for Researchers' Needs

Detailed descriptions of these principles are provided in the [Appendix](#).

Importance of Research Data Management

Research Data Management involves the collection, documentation, storage, sharing, and preservation of research data. Good research data management practices ensure:

- Research data are stored securely and preserved following the completion of a study
- Data are accurate, complete, consistent, and documented
- Confidential data are managed appropriately to fulfill legal and ethical obligations
- Data are accessible for yourself and other researchers
- Compliance with requirements from funding agencies and publisher
- When data are shared, findings may be validated and replicated and may lead to valuable discoveries by other research teams

Stakeholders

The RDM strategy applies to all SickKids researchers, including trainees, students, and staff. SickKids will work to make resources available for all research staff to support good RDM practices, with an initial focus on Tri-Agency and NIH-funded researchers to ensure that existing RDM requirements are met.

Oversight and Review

The SickKids RDM Strategy is being developed and implemented under the guidance of the Chief Data Officer and the Executive Director of Research Operations.

Two committees were formed to oversee the development of the SickKids RDM strategy: the RDM Working group and the RDM Steering Committee. Both groups include representation from Research IT, Research Operations, Data Strategy, the Research Ethics Board, and Privacy and Risk Management. A current list of members on both committees is below.

RDM Steering Committee

- Sandeep Gill – Project Manager, Data Strategy
- Naveen Hassan – Director, Privacy and Risk Management
- Wayne Lee – Executive Director, Research Operations
- Avery MacLean – Director, Research IT
- Paula Murray – Senior Data Analyst, Data Strategy
- Treacey Sheehan – Manager, Clinical Research Services
- Rachel Solomon – Chief Data Officer
- Dr. Padmaja Subbarao – Associate Chief, Clinical Research
- Dr. Elizabeth Stevenson – Chair, Research Ethics Board

RDM Working Group

- Brendan Flynn – Research Applications Specialist, Research IT
- Lynne Howell – Senior Scientist, Program in Molecular Medicine
- David Kenney – Manager, Clinical Research Services
- Wayne Lee – Executive Director, Research Operations
- Paula Murray – Senior Data Analyst, Data Strategy

Relevant Strategies and Policies

The following is a list of some internal and external policies and guidelines that may be relevant to researchers as they are considering data management strategies for their research. Note that SickKids login credentials are required to view internal SickKids policies.

Internal Policies & Guidelines

- Research Computers, Servers, and Storage Media Policy and Procedures (link)
- Replacement of Computer Equipment for Research Operations Staff (link)
- Removal of Research Computer Equipment (link)
- Hardware Decommissioning (link)
- SickKids Information Technology Acceptable Use Policy (link)
- Remote Access Policy (link)
- SickKids Information Security Policy (link)
- Records Creation, Retention, and Destruction (link)
- Electronic Monitoring Policy (link)
- Privacy and Confidentiality of Information (link)
- Research Activities involving Human Participants in the PGCRL (link)

External Policies and Guidelines

Research data may be subject to policies from external organizations including requirements from funding agencies, government regulations, and guidelines from community organizations. Relevant external policies and guidelines may include, but are not limited to:

- Tri-Agency Research Data Management Policy (link)
- Tri-Agency Framework: Responsible Conduct of Research, 2021 (link)
- Tri-Agency Statement of Principles of Digital Data Management, 2016 (link)
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2018 (link)
- CIHR Health Research and Health-Related Data Framework and Action Plan, 2017 (link)
- SSHRC Research Data Archiving Policy (link)
- Tri-Agency Open-Access Policy on Publications (link)
- NIH Grants Policy Statement (link)

Institutional Support

SickKids is committed to supporting excellence in Research Data Management by providing policies, resources, infrastructure, and services related to RDM.

In December 2022, the SickKids Research Institute (RI) Scientific Staff were surveyed to better understand current RDM practices and areas where institutional support is needed. The results of this survey will be used to plan for future RDM support.

In the coming months, the SickKids RDM Working Group will focus on developing templates and materials to support researchers in developing data management plans (DMPs) to fulfill Tri-Agency, NIH, and other funding agency requirements.

The RI, in conjunction with the RDM Steering Committee, will provide ongoing opportunities for feedback from the research community to ensure that existing RDM supports continue to meet researcher needs.

Researchers with questions or comments regarding the SickKids RDM Strategy may contact researchdata.management@sickkids.ca.

Ethical Considerations

Researchers must ensure that human research data complies with ethical and scientific standards, national and international regulations, disciplinary norms, internal guidelines and policies, and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 (2018)).

The SickKids Research Ethics Handbook has detailed information regarding ethical considerations including the consent and assent process, privacy and confidentiality, participant recruitment, and conflicts of interest.

Researchers should consult with the SickKids Research Ethics Board (REB) and the Research Ethics and Regulatory Compliance Office (RERC) with other questions on study-related ethical obligations.

Indigenous Data Considerations

For research conducted by and with First Nations, Métis, or Inuit Peoples, data management plans (DMPs) must recognize Indigenous data sovereignty and incorporate principles of data management developed by and with these communities. Indigenous community organizations must also be consulted during all research study phases.

The First Nations principles of OCAP (Ownership, Control, Access, Possession) and the CARES (Collective Benefit, Authority to Control, Responsibility, Ethics) principles are two data governance frameworks developed for First Nations and Indigenous data, respectively. These frameworks guide how to collect, protect, use, and share data and complement the existing FAIR principles.

Researchers are required to consult the framework for the ethical conduct of research involving First Nations, Inuit, and Metis people described in [Chapter 9 of the Tri-Council Policy Statement: Ethical Conduct for Research (TCPS 2)](#).

Note that all research studies involving First Nations, Métis, and Indigenous participants must be vetted by the SickKids [Indigenous Health Council](#).

Researchers may also find helpful information and resources at the following links:

- [Ontario Federation of Indigenous Friendship Centres](#)
- [University of Manitoba – Indigenous Scholars and Research](#)
- [National Collaborating Centre for Indigenous Health – Indigenous Health Researchers Database](#)

Researcher Responsibilities

The Tri-Agency RDM Policy contains two requirements that pertain directly to individual researchers: Data Management Plans and Data Deposit.

Data Management Plans

For certain funding opportunities, the Tri-Agencies will require a Data Management Plan (DMP) to be submitted at the time of the funding application. DMPs contain details on how research data will be managed throughout the research life cycle.

The Tri-Agencies have announced that they will pilot the inclusion of DMPs for the following funding opportunities:

CIHR

- Network Grants in Skin Health and Muscular Dystrophy (Anticipated launch fall 2022 or early winter 2023)
- Virtual Care/Digital Health Team Grants (Anticipated launch fall 2022 or early winter 2023)
- Data Science for Equity (Anticipated launch fall 2022 or early winter 2023)

NSERC

- Subatomic Physics Discovery Grants - Individual and Project (Anticipated launch summer 2023)

SSHRC

- Partnership Grants Stage 2 (Anticipated launch summer 2023)

This pilot stage is the first step towards a future state in which all DMPs will be required for most Tri-Agency funding applications.

Note that DMPs are already required by other funding agencies. As of January 25, 2023, Data Management and Sharing Plans are required for research, funded or conducted in whole or in part by NIH, that results in the generation of scientific data. Researchers should refer to the [NIH Data Management & Sharing (DMS) Policy](#) for more information.

Data Deposit

After reviewing the institutional strategies and in line with the readiness of the Canadian research community, the Tri-agencies will phase in the data deposit requirement.

Grant recipients will be 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.

Grant recipients will not be required to share their data. However, the agencies expect researchers to provide appropriate access to the data where ethical, cultural, legal, and commercial requirements allow, and in accordance with the FAIR principles and the standards of their disciplines.

Additional information regarding the Tri-Agency DMP and Data Deposit requirements will be communicated with the SickKids research community as more details become available.

Definitions

Data Deposit - Data deposit refers to when the research data collected as part of a research project are 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.

Ideally, data deposits will include accompanying documentation, source code, software, metadata, and any supplementary materials that provide additional information about the data, including the context in which it was collected and used to inform the research project. This additional information facilitates the curation, discoverability, accessibility, and reuse of the data. (Tri-Agency Research Data Management Policy, **Frequently Asked Questions**, Government of Canada 2021)

Data Management Plan (DMP) - 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 the course of a research project to reflect changes in project design, methods, or other considerations. DMPs guide researchers in articulating their plans for managing data; they do not necessarily compel researchers to manage data differently. (Tri-Agency Research Data Management Policy, **Frequently Asked Questions**, Government of Canada 2021)

Human Subjects Research – Research that involves humans (including living individuals, human biological materials and information from or about humans).

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. (Social Sciences and Humanities Research Council **Definition of Terms**, Government of Canada 2021)

Research Data - Research data are data that are used as primary sources to support technical or scientific inquiry, 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. (Tri-Agency Research Data Management Policy, **Frequently Asked Questions**, Government of Canada 2021)

Research Data Management (RDM) – RDM encompasses the processes applied through the lifecycle of a research project to guide the collection, documentation, storage, sharing, and preservation of research data. (Tri-Agency Research Data Management Policy, **Frequently Asked Questions**, Government of Canada 2021)

TAHSNr - Toronto Area Health Sciences Network Research

Appendix

Research Data Management Principles

Steward Data with a Child and Family Focus

SickKids is cognizant of the unique health needs and confidentiality considerations of pediatric research participants. With data becoming more accessible such as through open-access platforms, it is SickKids priority to ensure policies are in place to foster the inclusion of pediatric participants in research while protecting their rights and interests. The responsible sharing of pediatric data will consider the involvement of pediatric participants and their parents/legal guardians, consent, data confidentiality, privacy rights, data protection, and risks and benefits. Careful research planning will optimize the ability to share data. Specifically with regards to the assent/consent process in a pediatric population, this process can evolve throughout the research process. Safeguards will continue to be in place to respect the privacy of participants and to ensure the confidentiality of their information for all stages of the research life cycle including its collection, use, dissemination, retention and/or disposal.

Promote Research Integrity and Excellence

Providing support that promotes and integrates the responsible conduct of research is essential to building and maintaining an environment that fosters research and innovation excellence. Well-managed data is fundamental to the research process and advances discovery and knowledge mobilization. Responsible research data management actions align with the objectives of institutional, national, and international strategic directions for research. RDM practices should foster equity, diversity, and inclusiveness, and provide flexibility for distinction-based approaches. Research data managed with integrity and in an ethical and transparent manner strengthens outputs, facilitates excellence and innovation, and increases our global impact in both scholarship and society beyond academia.

Recognize the Value of Data and Data Sharing

Research data underpins institutional knowledge building, advances in scientific discovery, and improvements in the quality of healthcare for children, both in Canada and globally. Accordingly, there is value in data as a distinct research output. Proper documentation and stewardship of data results in the ability to validate results and the replication of studies to support research findings. Well-managed data enables data sharing and reuse, which increases access to results (including the reporting of negative results) and can lead to further discovery and greater reach and impact. In pursuit of research and scholarship, variation in the interpretation of data between researchers is expected.

Encourage the Implementation of Data Management Plans

A data management plan (DMP) is an essential part of designing and executing effective research approaches, from the inception to completion of a project. Proper planning improves data stewardship. A DMP provides direction and guidance for consistent actions across a project, increasing the reproducibility, visibility, and reuse of the research outputs. The creation and maintenance of DMPs should reflect best practices for managing data, improving project efficiencies, and mitigating risk.

Facilitate Long-Term Access Through Data Deposit

There is value in maintaining long-term access to data which supports research findings and serves as the basis for further inquiry. Data should be properly prepared, documented, and retained with assigned custodianship and, when possible, under the care of a designated repository. This facilitates the availability of results, and that data should be 'as open as possible, and as closed as necessary'.

Reflect Institutional and Disciplinary Practices and Standards

It is essential that data practices abide by legal and ethical frameworks, adhere to institutional policies and procedures, and consider expectations of sponsors and research partners. Approaches to RDM will be diverse and should reflect the distinct needs and practices required for different types of data and projects. This involves reflecting institutional guidance, ethical standards, community principles, disciplinary standards, and established best practices in RDM decisions.

Honour Indigenous Community-Driven Principles

Meaningful and respectful research honours Indigenous cultures and knowledge and data should be managed in a way that leads to beneficial change and the rebuilding of trust. All research developed and conducted should support Indigenous data sovereignty and be in alignment with community-driven principles (such as CARE and OCAP principles). There is recognition that each community is distinct, and relationships and research approaches will reflect these differences. Approaches should promote Indigenous perspectives, incorporate more holistic Indigenous methodologies, and minimize bias stemming from other cultural frameworks. The outcomes of such research should enable capacity development and community empowerment. Developing institutional direction and guidance requires engagement with Indigenous leaders, researchers, and communities.

Strengthen Partnership and Collaboration

Tremendous value is placed in fostering meaningful collaborations and research partnerships. Research is strengthened through relationships and engagement with communities, not-for-profits, government entities, the private sector, and academic researchers, local and global. Mutually beneficial research relationships outline the division of responsibilities related to data actions and ownership.

Treat All Human Subjects Data with Appropriate Respect and Safeguard Privacy

Confidential and sensitive data are subject to specific ethical, legal, and contractual obligations. Research conducted must be aligned with the Tri-Council Responsible Conduct of Research (RCR) and the Policy Statement on Ethical Conduct for Research Involving Human (TCPS 2) including core principles of respect for persons, concern for welfare, and justice. There must be adequate levels of infrastructure, security, and guidance in place to assist in mitigating any risk of harm and ensure the ethical treatment of data.

Integrate Excellence in All Disciplinary Approaches

Scholars engage in diverse research and scholarly endeavours which represent a variety of subject areas and research methodologies. Decisions around the treatment of data should reflect the best practices and standards appropriate for the types of data that a project includes. Flexibility in distinct approaches to data should be recognized and supported, and that research both benefits from and contributes to disciplinary communities of practice.

Learn Through Ongoing Communication and Engagement Opportunities

The research data landscape is dynamic and constantly evolving. There is a commitment to continuous engagement and communication with both our research community and external stakeholders. Ongoing learning from research communities will inform supports that are representative of diverse needs and practices. It is a priority to raise awareness and increase researcher knowledge of the evolving expectations of research data management practices.

Provide Infrastructure that Supports Diverse and Complex Programs of Research

Robust and coordinated infrastructure is vital to practices throughout the research data lifecycle and should be secure and bring consistency, interoperability, and equitable access. Infrastructure resources should be reflective of needs, scalable to meeting growth efficiently, and evolve in response to engagement with stakeholders.

Ensure Support Services are Available

There is a commitment to provide comprehensive and coordinated support services for data management. These services aim to increase the implementation of best practices for conducting effective research by engaging researchers and enhancing organizational expertise.

Commit to Advocacy and Support for Researchers' Needs

The institution should be a voice representing the needs and values of the research community as well as advocating to protect the rights of individual researchers and those participating in research. This involves a commitment to the betterment of research practices through continuous reflection, acting as leaders to influence change, and building mechanisms to assist researchers to practice standards and meet obligations.