

Research Data Management Strategy

Department of Academics



The newly integrated Academics program at Women's College Hospital (WCH) brings together education, research, and innovation to become the first hospital in Canada to truly integrate a learning health system. A central goal of WCH's strategy, [Build Back Better Strategic Road Map 2022-2024](#), pledges to drive excellence in health science and health services research, innovation and education; and enhance and align clinical and academic quality improvement infrastructure. Specifically, we strive to transform health for women and population well-being by building on our strengths and optimizing our blended academic environment to further establish our leadership and reputation in women and gender inclusive health.

Recognizing that data is a core component of research, and that good data management and stewardship is a pre-condition to supporting knowledge discovery and innovation, WCH will be prepared to implement the FAIR Data Guiding Principles for scientific data management and stewardship¹. These guiding principles will improve the Findability, Accessibility, Interoperability, and Reuse of research data.

In response to the Tri-Agencies Research Data Management (RDM) Policy, WCH is committed to research excellence by fostering a robust environment for data management that supports and develops researchers to be well-positioned to contribute and capitalize on data-intensive science and scholarship. This strategy will outline how WCH will **support, promote, and guide** researchers on research data management.

How WCH supports ethical, legal, and tri-agency requirements

Education

All staff, trainees and investigators who wish to conduct research involving human participants under the auspices of Women's College Hospital are required to complete training on:

1. Good Clinical Practice (GCP)
2. Responsible conduct of Research (RCR)
3. Basic Biomedical Research Ethics
4. Health Canada Division 5 – this training is mandatory for those involved in conducting research activities for Health Canada-regulated clinical trials.

Institutional authorization to proceed with new or ongoing studies is tied to course completion. These courses are offered and completed through the Collaborative Institutional

¹ Wilkinson, M. D. et al. The FAIR Guiding Principles for scientific data management and stewardship. Sci. Data 3:160018 doi: 10.1038/sdata.2016.18 (2016).

Training Initiative (CITI), with access through WCH's membership with the Network of Networks (N2). N2 is an alliance of Canadian research networks and organizations working to enhance national clinical research capability and capacity. WCH's partnership and participation in N2 supports our efforts to bolster our researchers understanding their obligations and foster an environment of ongoing learning and improvement.

WCH promotes the importance of confidentiality and data management as part of its onboarding process. All new staff, trainees, and physicians are required to complete privacy courses, as well as to review and sign a confidentiality agreement.

Review Processes and Resources

The Research Ethics Board (REB) of Women's College Hospital exists to ensure that all research activities involving human participants or human materials, being conducted within or on behalf of Women's College Hospital, meet current scientific, regulatory and ethical standards for the protection of human research participants in accordance with the Tri-Council Policy Statement: Guidelines on Research Involving Human Subjects (TCPS2). Ethics are principles of right conduct that guide 'what ought to be done'.

In the context of the Tri-Council Policy Statement, Women's College Hospital REB subscribes to the following ethical principles that are commonly held, valued by diverse research disciplines and express common standards, values, and aspirations of our research community:

- Respect for human dignity
- Respect for free and informed consent
- Respect for vulnerable persons
- Respect for privacy and confidentiality
- Respect for justice and inclusiveness
- Balancing harms and benefits

All research activities taking place at WCH are reviewed by the WCH REB, which has the authority and responsibility to independently approve, reject, propose modifications, put on hold, or terminate any proposed or ongoing research involving human participants being carried out within, or on behalf of WCH.

Researchers at WCH have access to the WCH ethics office for support and guidance, as well as templates and tools to support their work. This includes the appropriate collection, use, and protection of any and all research data collected as part of the project.

WCH also supports an Assessment Process for Quality Improvement Projects (APQIP) which reviews projects focused on healthcare quality improvement, project design, and evaluation. Researchers and clinicians undertaking work that does not require formal REB review have the opportunity to access this process to ensure their projects meet the highest standards, including safeguards and protection of all data collected as part of the project.

Research Operations at WCH focuses on the tasks of enhancing research by providing the roles, tools and processes needed to support researchers in achieving their research goals. Some of these resources include a Research Grants Office to support and review all pieces of research grant applications, including data management plans and mitigating risks from usage of data during and after a research project; Research Contracts to help draft and/or review contracts to govern the transfer of data, materials, confidential information, and funding with research institutions and service providers ensuring compliance.

REDCap Resource

REDCap (Research Electronic Data Capture) is a secure web application to support data capture for research studies, primarily by building and managing online surveys and databases.

REDCap allows for:

- validation (conforms to established requirements for completeness, accuracy, reliability, and consistent intended performance)
- audit trails and logs
- security of data
- back-up of data
- quality and data management (through data management tools, required variables, min/max values, branching logic, data dictionaries, among other features)

WCH offers the REDCap platform to all researchers and teams with different support models available. Tools and resources such as drop-in sessions, user guides, forms, and templates are available to support researchers and acts as an excellent resource for the management of research data.

The institution is committed to this resource and will continue to develop this platform and promote its use at WCH.

Privacy and IMIT Resources

At WCH we respect the confidentiality and sensitivity of our patients' personal health information (PHI). We are committed to protecting PHI under the custody or control of WCH in accordance with the Ontario [*Personal Health Information Protection Act \(PHIPA\)*](#), the guiding privacy principles set out by the Canadian Standards Association's Model Code for the Protection of Personal Information, and privacy best practices.

As a provider of healthcare services to the residents of Toronto and the Greater Toronto region, WCH collects, uses, discloses, retains and safeguards PHI and is a health information custodian under PHIPA. Access to PHI is provided to only those that require access to provide or assist in providing care to a patient or as permitted by law. Access to PHI for research purposes is obtained only after appropriate ethical review and when appropriate consents are in place.

To guard against any unauthorized collection, use, or disclosure of PHI, it is appropriately protected through several measures including data encryption, regular monitoring / auditing of our electronic systems, investigating complaints, and mandatory annual privacy training for all research staff and clinician researchers.

WCH is a member of the Toronto Academic Health Science Network (TAHSN), which is working to develop guidelines and resources related to:

- cloud file sharing
- back-up for data on non-institutional resources
- self-management of equipment and services as they relate to data-access and security

WCH will continue to work in partnership with TAHSN to develop these tools, and to disseminate the resources to our researchers and teams.

WCH ensures that the research data collected and used through the use of public funds will be responsibly and securely managed by the promotion of the following:

- Supports available via the grants office for data management plans
- A research environment that is compliant with world class data stewardship practices
- Educational events hosted by WCH, UofT, and our TAHSN partners on the importance of data management through institutional educational events in addition to UofT's educational events:
 - <https://guides.library.utoronto.ca/RDM-intro>

- <https://onsearch.library.utoronto.ca/researchdata/training>
- An institutional data management policy that reflects FAIR Data Guiding Principles for scientific data management and stewardship

WCH is committed to the adoption of established best practices when developing institutional standards and policies for data management plans.

WCH Academics will hold a workshop entitled “**Building a research roadmap for cultural inclusion and accountability**” in March 2023. The workshop will be a full-day, fully in-person session, and will bring together a diverse set of health care leaders from within and outside of WCH to:

- share valuable insights and experiences with a focus on cultural inclusion and accountability for Black and Indigenous participants
- highlight and establish culturally relevant research frameworks that support accountability for equity
- identify areas of interest, including, but not limited to:
 - data management and governance
 - patient and community engagement
 - ethics and consent

Sessions will be led by experts in the fields of data governance and data sovereignty principles, patient and community engagement, and ethics and consent, and involve members of Academics, the WCH REB, the WCH Office of Equity, the Centre for Wise Practice, among others.

In preparation for the “**Building a research roadmap for cultural inclusion and accountability**” Workshop, WCH staff invitees will be strongly encouraged to undergo training on the First Nations principles of ownership, control, access and possession (OCAP training). The workshop will be led by Academics, and also involve input from the Centre for Wise Practices at WCH, as well as the WCH Office of Equity. The workshop will focus on building a framework on cultural inclusion and accountability, specifically for Black and Indigenous participants. Specifically, regarding Data Management and Governance, the workshop will touch on the need to address data sovereignty for both Indigenous and Black Communities, the consideration of community data ownership practices, and also address data collection, storage, access, destruction

WCH is moving towards a Learning Health System (LHS) framework. An LHS is defined as a system in which “science, informatics, incentives, and culture are aligned for **continuous improvement and innovation**, with best practices seamlessly embedded in the delivery process and **new knowledge captured as an integral by-product of the delivery experience.**”

(United States Institute of Medicine (IoM)). In other words, it is a model in which all involved are continuously asking questions about current processes, delivery, and outcomes, to determine if value is being added and assessing how/where it can be improved.

An LHS, to a large degree, will entail the leveraging of patient-centered outcomes through using real-time data to make improvements to patient care immediately, as opposed to years from now. As such, the systematic generation and collection of data stipulates that the data be accessible, manageable, and stored safely and securely. These activities will need to be carried out and governed with data stewardship, ownership, policies standards around data sharing (internally and externally), enabling technologies for data management, and other key elements in mind.

The Research Data Management Strategy at WCH is evolving and developing, and this is intended as a living document.

At the present time, WCH is committed to:

- Developing standards and guidelines for naming conventions for use in projects
- Identifying and providing guidelines on common data elements (CDEs) for researchers and their teams
- Working with our TAHSN partners to ensure researchers have access to data storage, back-up, and security resources
- Sustaining and enhancing the current WCH REDCap resource
- Developing a framework for cultural inclusion to guide the collection and use of data
- Providing educational resources and opportunities for staff with regards to data from underrepresented populations and data from Indigenous communities
- Developing resources and tools to support best practices for protecting participant privacy
- Working across the institution to develop a broad framework for data governance
- Formalizing an institutional data management policy that reflects FAIR Data Guiding Principles for scientific data management and stewardship