UNIVERSITY OF OTTAWA HEART INSTITUTE
INSTITUT DE CARDIOLOGIE DE L'UNIVERSITÉ D'OTTAWA

McGill

INTERCONNECTOME
CŒUR-CERVEAU
BRAIN-HEART
INTERCONNECTOME

uOttawa

ARCHIMEDES

Data Governance Framework

Version 2.0

August 6, 2026

1. Introduction to ARCHIMEDES 4
1.1 ARCHIMEDES Core Values 4
1.2 ARCHIMEDES Collaborating Institutions 4
1.3 Reservations 6
1.4 Contact 6
2. Data Access 6
2.1 Tiered Access Data Release – Phased Implementation 6
3. Overview of Data Flow in ARCHIMEDES 6
4. Types of Data 7
5. Data Set Contribution Requirements and Process 7
5.1 Authorizations for Contribution 8
5.2 Informed Consent 9
5.3 Core Permissions 9
5.3.1 Core Permissions - Controlled Access Data 10
5.3.2 Core Permissions - Open Access Data 10
5.4 Data Contribution Agreement and Process 11
5.5 Data Contribution Form 12
5.6 Submission of Supporting Documentation 12
5.7 Evaluation of Proposed Data Contributions 13
5.8 Data Contribution 13
5.9 Ingestion into Private Environment 13
5.10 Preparing Data Sets for Release 14
5.11 Data Set Curation and Validation 14
5.12 Removing Select Identifiers (ARCHIMEDES Technical Team) 14
5.13 Data Quality (ARCHIMEDES Technical Team) 15
5.14 Pre-Release Verification and Validation 15
5.15 Institutional Data Contributor Credentialing and Authentication 16
5.16 Role Based Access Controls 16
6. Data Access Requirements and Process 17
6.1 Accessing Open Access Data 17
6.2 Accessing Controlled Access Data 17
7. Overview of Technical Elements of ARCHIMEDES 19
8. ARCHIMEDES Data Query Tool (DQT) 19

9. Data Analysis 19
9.1 Community Contribution of Analysis Tools 20
10. Data Protection 21
10.1 Re-identification Risk 21
10.2 Data Breach Notification 22
11. Data Set Backup and Disaster Recovery 22
11.1 Data Set Storage and Backup Strategy 22
11.2 Disaster Recovery and Business Continuity 23
11.3 Compliance and Data Retention 23
12. IT Security 23
13. Intellectual Property 24
14. Return of Individual Results, Material Incidental Findings, and Derived Data Sets 24
15. Data Set Withdrawal, Correction and Access 25
16. Database Decommissioning and Changes in Data Stewardship 25
17. Approval and Review 25
Appendix A – Glossary of Terms 26
Appendix B – ARCHIMEDES Governance Structure 30
Appendix C – TERMINOLOGY GUIDE 33

1. Introduction to ARCHIMEDES

Advanced **R**esearch **C**ollaboration for **H**ealth **I**ntegration, **Med**ical **E**xploration, and Data **S**ynthesis ("**ARCHIMEDES"**) is a digital health platform that Ingests, manages, and/or releases Data Sets for research purposes including: biostatistical analyses, predictive modelling, data visualization and artificial intelligence.

Our **vision** is to provide a bilingual national health data platform that provides centralized and flexible access to curated health research data, which can be analyzed using state-of-the-art distributed computing tools. ARCHIMEDES is equipped to Ingest all health data including multimodal health data (e.g., behavioural data, imaging data, wearables data).

A glossary for this Data Governance Framework ("**Framework**") is set out at Appendix "**A**."

1.1 ARCHIMEDES Core Values

Values and Principles	Commitments associated with these values and principles
Collaboration	We will promote interdisciplinary collaboration and partnerships within Canada and internationally.
Privacy, Confidentiality, and Security	We will embed privacy, confidentiality, and security considerations in all aspects of governance and development processes.
Integrity	We will uphold ethical and research integrity standards in data acquisition, management, sharing, and analytics.
Open Science and Equity	We will promote transparency and openness of research and all its outputs to favour equitable access and reuse.
Training	We will provide and promote education and training resources that encourage robust and ethical research data management and transparent data sharing that respects privacy and research security.

1.2 ARCHIMEDES Collaborating Institutions

ARCHIMEDES is a joint scientific effort of the University of Ottawa Heart Institute ("**UOHI**"), the University of Ottawa ("**uOttawa**"), and McGill University ("**McGill**").

Ottawa Heart Institute Research Corporation ("**OHIRC**"), the research and contracts arm of the UOHI, acts as the data steward for ARCHIMEDES Data Sets and implements and oversees ARCHIMEDES' data governance practices. It is the accountable entity, administering ARCHIMEDES' Data Set use, contribution and access requirements and approving Data Set release and access in a manner that is consistent with applicable law and this Framework.

McGill develops, operationalizes and maintains the technological infrastructure and technical elements of ARCHIMEDES. Its responsibilities include hosting and managing ARCHIMEDES Data Sets and implementing reasonable technical security measures for the platform. ARCHIMEDES builds upon the existing data-sharing infrastructure within LORIS, CBRAIN, NeuroHub, and C-BIG, with new features tailored for cardiac application within Brain-Heart Interconnectome ("**BHI**") Program.

ARCHIMEDES is an initiative of the University of Ottawa's BHI Program, funded through the Government of Canada's Canada First Research Excellence Fund ("**CFREF**") (2023–2030). As the lead institution accountable for the delivery of the BHI Program and its research objectives, uOttawa is responsible for ensuring that ARCHIMEDES is implemented in a manner consistent with the Program's vision, governance requirements, and funding obligations. Accordingly, uOttawa has an essential oversight role in relation to the funding of the ARCHIMEDES platform. However, uOttawa is not the accountable entity in respect of the Data Sets that are contributed by an institution, and in turn, Ingested and released by ARCHIMEDES. OHIRC is the legal entity responsible and accountable for the ARCHIMEDES platform.

While OHIRC, McGill, and uOttawa have distinct but complementary roles in developing and operating ARCHIMEDES, each institution ensures oversight of the overall governance and participates in defining the strategic direction of ARCHIMEDES through the governance structure of ARCHIMEDES (described at Appendix "**B**").

ARCHIMEDES enables Institutional Data Contributors to contribute either:

- Coded Data,
- De-identified Data, or
- Pre-clinical Data

Once the Data Set has been Ingested by ARCHIMEDES, it is maintained in the platform and ultimately released so that Principal Investigators and their Research Team and/or Open Access Users can use the Data Set for their own research.

ARCHIMEDES protects the privacy of individuals and is based on an express informed consent model (or other ethical and legal authorizations described in Section 5.1.) as follows:

1. Research participants' express informed consent is the primary legal authorization to contribute, use, and release Coded Data though other legal and ethical authorizations (such as an ethics waiver of informed consent requirements, De-identification, or other enabling law) are permitted in limited contexts.
2. Express informed consent is broad, as permitted under the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* ("**TCPS-2**") or local equivalent. Broad consent allows the Ingestion of Coded Data to maximize use amongst the research community for the advancement of health purposes. This approach must be clear to all research participants, ethics review bodies, Institutional Data Contributors, Institutional Data Users, and Principal Investigators and their Research Team. These groups must be informed (with risks disclosed in the Informed Consent Form) that ARCHIMEDES Data Sets:
    a. may be held indefinitely,
    b. will be used for commercial and non-commercial research purposes, and
    c. risks of re-identification exist now and, in the future, although steps have been taken technically and administratively to reduce (but not eliminate) that possibility.
3. The Data Access Compliance Office ("**DACO**") at OHIRC is responsible for reviewing express informed consents and ethics waivers of the informed consent requirement

against established criteria, and the ARCHIMEDES technical team at McGill performs limited automated verification of the Data Set Ingested into ARCHIMEDES against ARCHIMEDES standards (e.g., that standard identifiers have been removed).

4. Institutional Data Contributors are accountable for having the lawful authority to provide Data Sets to ARCHIMEDES.

1.3 Reservations

OHIRC and McGill reserve the right to cease hosting any contributed Data Set through ARCHIMEDES, or to cease making that Data Set available to Principal Investigators and their Research Teams and/or to Open Access Users.

OHIRC and McGill further reserve the right to revoke Institutional Data User access if the Institutional Data User and Principal Investigator are found to breach the conditions of access, or to ensure compliance with ethical, legal, or institutional obligations.

1.4 Contact

Institutional Data Contributors, Institutional Data Users, and Principal Investigators and their Research Teams may contact the ARCHIMEDES Ethics Helpdesk at OHIRC to obtain information about the data governance practices of ARCHIMEDES, the Data Set contribution and access processes, and the analytical tools available through ARCHIMEDES.

2. Data Access

2.1 Tiered Access Data Release – Phased Implementation

For this initial phase, ARCHIMEDES is introducing two release tiers:

1. Controlled Access, and
2. Open Access

	Controlled Access	**Open Access**
Data Types Disclosed	Coded Data De-identified Data Pre-clinical Data	De-identified Data Pre-clinical Data

3. Overview of Data Flow in ARCHIMEDES

An overview of the Data Set flow mapped against legally accepted terminology is set out at Appendix "**C**." For the purposes of this Framework, all terminology is "researcher friendly."

The following figure summarizes the key components of Data Set flow in ARCHIMEDES, beginning with the:

- contribution of Data Sets by Institutional Data Contributors,
- Ingestion by ARCHIMEDES for processing, and
- release of Data Sets for access and use by the Principal Investigator and their Research Team.

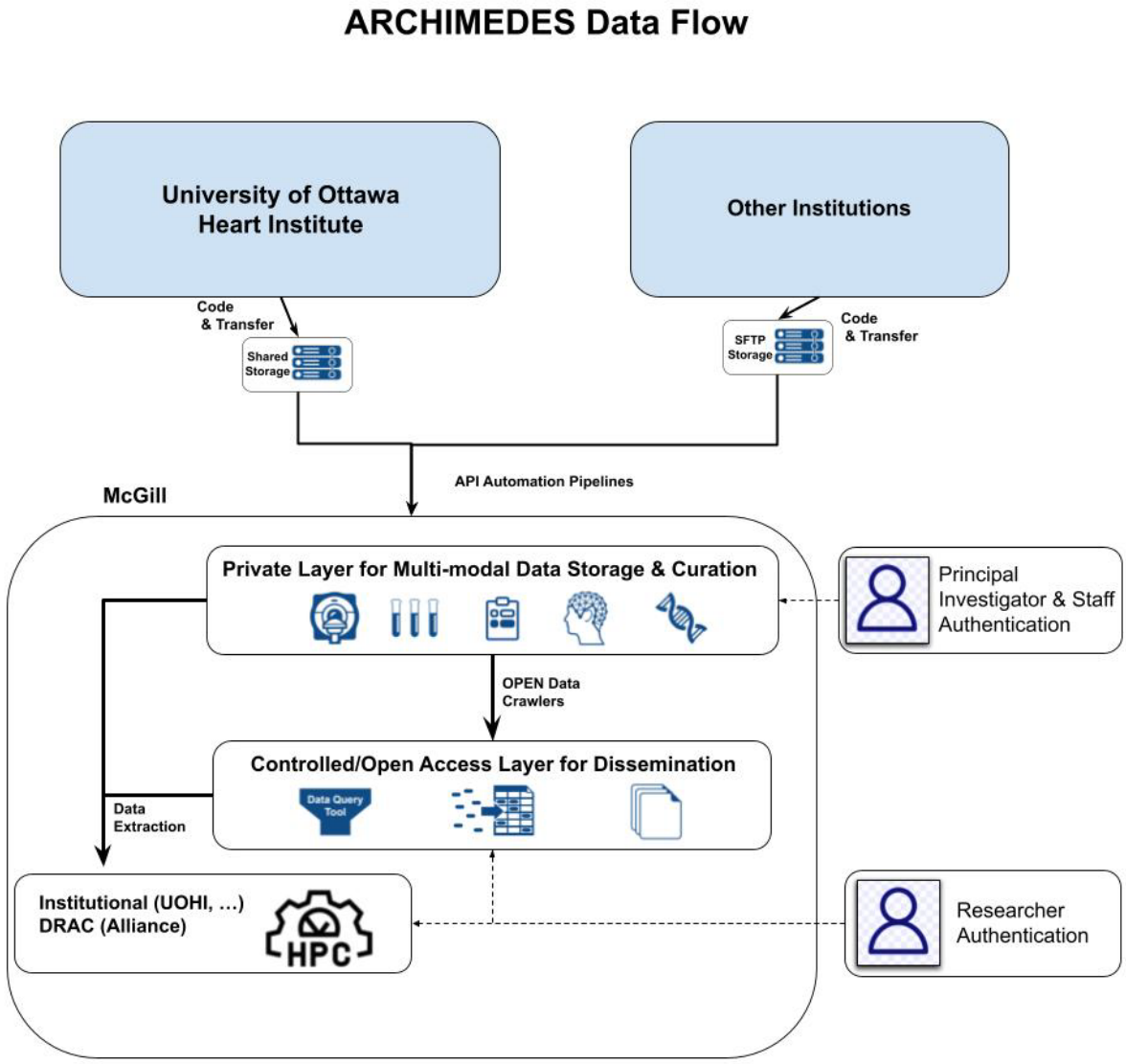

Figure 1: ARCHIMEDES Data Set Flow

4. Types of Data

Multimodal curated health data, including, but not limited to, behavioural data, wearable data, imaging data, and biomaterials data are available in ARCHIMEDES. This includes both data derived from human research participants, and data not derived from human research participants (i.e., Pre-clinical Data).

5. Data Set Contribution Requirements and Process

Prior to contributing Data Sets to ARCHIMEDES each Institutional Data Contributor must:

- have the institutional, ethical, and legal authorizations required to contribute the specific Data Set to ARCHIMEDES and release this Data Set through Controlled Access or Open Access; and

- enter into a Data Contribution Agreement ("**DCA**") with OHIRC. This enables authorized Principal Investigators from the Institutional Data Contributor to contribute the Data Sets to ARCHIMEDES by submitting a Data Contribution Form specific to a Research Project.

All Data Sets to be Ingested into ARCHIMEDES require review of the Data Contribution Form by the ARCHIMEDES DACO prior to being sent to the DAC for final approval.

5.1 Authorizations for Contribution

In contributing a Data Set to ARCHIMEDES, Institutional Data Contributors must confirm that they are authorized to release the Data Set in the chosen tier of release as described in the DCA, the Data Contribution Form, this Framework, and relevant ARCHIMEDES policies.

Each Institutional Data Contributor must ensure that one of the following ethical-legal authorizations supports each Data Set contribution and release through the Controlled Access or Open Access tiers of ARCHIMEDES:

A. **Informed consent and ethics approval:** the express informed consent of research participants, and a research ethics board approval (or local equivalent), authorize the Data Set to be released according to the Core Permissions of the chosen release tier.

B. **Ethics waiver of informed consent requirement**: A research ethics board (or local equivalent) has authorized the release of data, through an ethics waiver of the express informed consent requirement, that authorizes the Data Set to be released according to the Core Permissions of the chosen release tier.

C. **Enabling local law:** Local law allows the contribution of the Data Set to ARCHIMEDES according to the Core Permissions of the chosen release tier.

D. **Data is De-identified[1]:** The Data Set is De-identified in accordance with Ontario IPC De-identification Guidelines or comparable provincial or territorial de-identification standard. Such Data Sets can consequently be released through the chosen release tier.

E. **Data is not human research participants data (i.e., is Pre-clinical Data):** The Data Set does not, nor did it ever, constitute data relating to human research participants, or identifiable personal data, according to applicable research ethics requirements and data protection laws. This is reserved for Pre-clinical Data such as data derived from non-human cell cultures, from testing on animal models, or that relates to drugs and devices. Such Data Set can consequently be released through the chosen release tier.

Prior to authorizing the Data Set, the ARCHIMEDES DACO reviews the supporting documentation that justifies the Ingestion and the DAC approves the contribution.

The Institutional Data Contributor is ultimately responsible for ensuring such authorization complies with the applicable Core Permissions.

[1]Please note that de-identification as a separate authorization for contribution does not apply to Open Access. Consent must always be obtained for De-identified Data that is contributed to the Open Access tier.

Authorizations – Sign-Offs

- For Controlled Access, Principal Investigators act on behalf of the Institutional Data Contributor for authorizations A, B and E, while authorizations C and D require sign off from the Institutional Data Contributor's Institutional Signing Official ("**ISO**").
- For Open Access, ISO sign off is required for all authorizations.

The processes used by ARCHIMEDES DACO to review the authorizations and supporting materials are further detailed in ss. 5.7 and 5.8, below, and in the procedures followed by the DACO ("**DACO Procedures**"). Please see the DACO Procedures (Data Contribution).

5.2 Informed Consent

Institutional Data Contributors obtain express informed consent and an ethics approval, as well as anything required under local laws.

Consent forms used for Data Set contribution must, at a minimum, incorporate the Core Permissions detailed at s. 5.3.1 (Controlled) or 5.3.2 (Open Access) to enable Data Set contribution and sharing through ARCHIMEDES. Examples have been provided here.

Open Access Consent forms must use the template consent forms provided by OHIRC.

- **For Prospective Consent**: The ARCHIMEDES Consent Form Templates, provide template consent language to Principal Investigators to obtain consent to the future Ingestion and release of Data Sets through ARCHIMEDES (broad consent as permitted under TCPS-2).
- **For Retrospective Consent:** The ARCHIMEDES Consent Form Templates may also be used to obtain a new consent authorizing the sharing of research Data Sets Ingested as part of a prior study. The ARCHIMEDES Retrospective Consent Filter is a self-assessment tool that enables Institutional Data Contributors to determine whether the language of their existing Informed Consent Forms is suitable to allow the contribution of the Data Set to ARCHIMEDES and, if so, at what access tier and which steps, if any, should be taken prior to sharing Data Sets through ARCHIMEDES.

5.3 Core Permissions

The institutional, ethical, and legal authorizations supporting Data Set contribution and release through ARCHIMEDES must, at a minimum, permit the uses and processing described as Core Permissions below.

5.3.1 Core Permissions - Controlled Access Data

ARCHIMEDES permits the following Controlled Access model subject to the following requirements:

To contribute Data Sets to **ARCHIMEDES (Controlled)**, Institutional Data Contributors must first have documented Research Ethics Board (REB) approval on file, along with the following permissions from research participants through a "broad" express informed consent to research participation (or other mechanism, e.g. an ethics waiver of informed consent requirement).
1. Collection of the study Data Sets from research participants
2. Sharing of Coded or De-identified study Data Sets through a Controlled Access mechanism
3. International sharing of study Data Sets, if applicable
4. Future research on a relevant scientific research questions within the broad approvals set out in the Informed Consent Form
5. Use of the study Data Sets for commercial and non-commercial research purposes (this allows both the commercialization of downstream research outputs and research by private sector bodies)
6. Public sharing of anonymized Data Sets (optional, but recommended)
7. Indefinite storage of the study Data Sets contributed
8. Withdrawal of study Data Sets is not always possible if already used or published
9. A residual risk that the participant may be re-identified remains
10. Option to transfer Data Sets to the stewardship of a different data steward, and a different data repository (optional but recommended)

5.3.2 Core Permissions - Open Access Data

ARCHIMEDES permits the following Open Access model, subject to the following requirements. In very limited instances, OHIRC may permit exceptions to the template consent form on a case-by-case basis, as determined and approved by the DAC.

To contribute Data Sets to **ARCHIMEDES (Open)**, Institutional Data Contributors must have documented Research Ethics Board approval on file, along with ARCHIMEDES approved Informed Consent Forms, along with the following permissions through an express informed consent to research participation where required (or other mechanism, e.g. an ethics waiver of informed consent requirement).
1. Collection of study Data Sets from research participants
2. Sharing of De-identified Data through an Open Access mechanism
3. International sharing of study Data Sets
4. Future research on a relevant scientific research questions within the broad approvals set out in the Informed Consent Form
5. Use of the study Data Set for commercial and non-commercial research purposes (this allows both the commercialization of downstream research outputs and research by private sector bodies)

6. Indefinite storage of the study Data Sets contributed
7. Withdrawal of study Data Sets is not always possible if already used or published
8. A residual risk that the participant may be re-identified remains

5.3.3. Removal of Select Identifiers

Institutional Data Contributors are required to remove all Direct Identifiers from submitted Data Sets prior to contributing Data Sets to ARCHIMEDES and must adhere to ARCHIMEDES policies and applicable legal, ethical and institutional requirements.

- For Coded Data, ARCHIMEDES may also remove Indirect Identifiers that create a significant-re-identification risk, including those that do not contribute to the scientific utility of the data.
    - The ARCHIMEDES technical team works with Principal Investigators to detect and remove common identifiers using the tools and controls detailed below but does not assume responsibility for the adequacy or completeness of this verification and removal.
    - These are limited administrative oversight measures that may further reduce the risk of individual re-identification occurring in practice.
    - ARCHIMEDES does not assume any liability for any residual re-identification risk that may remain in the data.
- For De-identified Data, the Institutional Data Contributor is responsible for De-identifying the Data Set in accordance with Ontario IPC De-identification Guidelines or a comparable provincial or territorial de-identification standard.
- For Pre-clinical Data, the Institutional Data Contributor is responsible for ensuring that the Data Set does not, and never did, relate to human research participants or identifiable natural persons, and that it is out of scope of research ethics requirements and data protection laws.

Final decision as to the adequacy or completeness of the removal of identifiers rests with the Institutional Data Contributor.

Final responsibility for this removal and assessing and managing re-identification risk and ensuring research participants are adequately informed rests with the Institutional Data Contributor and its Principal Investigator.

5.4 Data Contribution Agreement and Process

Data contribution to ARCHIMEDES follows the process set out below:

1. Institutional Data Contributor enters into a DCA with OHIRC.
2. Principal Investigators seeking to contribute a Data Set to ARCHIMEDES submit a Data Contribution Form specific to that Data Set, with supporting documentation, to the DACO for approval by the DAC.
3. Institutional Data Contributors submit a list of its authorized Principal Investigators to the DACO and update the DACO each time it wishes to add or a remove a Principal

Investigator. Once the DACO approves them, Principal Investigators on the master list can initiate a new contribution, or amend an existing one, through the submission of a Data Contribution Form that is specific to that Data Set.

4. Principal Investigators must sign terms of use and then can upload, curate, and conduct analysis of the Data Set through ARCHIMEDES, and authorize the Data Set and release in Controlled Access or Open Access. They can also assign permissions to members of their Research Team at their institution. Such listed individuals can perform supporting activities that facilitate the upload, curation, and analysis of the Data Set in the Private Research Environment but cannot authorize the contribution and release of the Data Set to ARCHIMEDES' Controlled Access or Open Access tier. Any other individual at the Institutional Data Contributor's institution who requires access must be designated as a member of a Principal Investigator's Research Team or otherwise authorized by the Institutional Data Contributor.
5. The ISOs (or relevant intuitional representative) as designated and authorized by the Institutional Data Contributor (see s. 5.1.) have access to a list of the Principal Investigators' Data Sets (and the associated Data Contribution Forms) and are notified each time a new Data Set is created and/or is authorized for release in Controlled or Open Access.
6. The ISOs (or relevant institutional representative) are also notified each time a Principal Investigator is added or removed. The notification further describes their associated account permissions. The DACO operationalizes the changes to each Institutional Data Contributor's list of Principal Investigators in collaboration with the ARCHIMEDES technical team.

5.5 Data Contribution Form

To create a new Data Set, a Principal Investigator submits a Data Contribution Form that describes:

- the nature of the Data Set,
- the Data Sets that will fall within each tier of data release, and
- the ethical-legal authorization for the Data Set contribution to ARCHIMEDES and the release of such Data Sets through ARCHIMEDES.

The Data Contribution Form is signed by the ISO for all authorizations in the Open Access release tier and certain authorizations in the Controlled Access release tier.

5.6 Submission of Supporting Documentation

Before uploading the Data Set, the Institutional Data Contributor must provide supporting documentation that enables the ARCHIMEDES DACO to confirm the appropriateness of Ingestion into ARCHIMEDES and the proposed Data Set release (see. s. 5.1, Authorizations, above).

The Institutional Data Contributor specifies its legal authorities and uploads supporting materials relevant thereto, as follows:

A. **Informed consent and ethics approval** (Provide copy of express informed consent materials and ethics approval letter, for DACO evaluation).

B. **Ethics waiver of informed consent requirement** (Provide waiver letter, or other relevant document from the research ethics board, for DACO evaluation).

C. **Enabling local law** (Provide copy of enabling legal instrument, e.g., legislation, regulation, local ethics guidance, for DACO evaluation. The ISO must approve any Data Sets for contribution).

D. **Data Set is De-identified** (The ISO must approve that the Data Set is De-identified in accordance with Ontario IPC De-identification Guidelines or a comparable provincial or territorial de-identification standard. Provide ethics approval letter when required).

E. **Data Set does not include human research participants data (i.e., is Pre-clinical Data)** (Confirm that the Data Set does not include/constitute human research participants data. This requires them to confirm that the Data Set is not subject to *Personal Health Information Protection Act, 2004* ("**PHIPA**"), TCPS-2, or local data protection laws and biomedical research ethics requirements, and that it is not derived from human research participants.)

5.7 Evaluation of Proposed Data Contributions

The ARCHIMEDES DACO conducts a review of the Data Contribution Form and supporting documentation. Following completion of the review, the ARCHIMEDES DACO may require that additional steps or the request is submitted to ARCHIMEDES DAC for approval. The outcome of this review depends on whether the materials submitted align with the Core Permissions associated to the chosen tier of data release.

Only Data Sets from Institutional Data Contributors approved for contribution by the DAC will be integrated into ARCHIMEDES.

5.8 Data Contribution

Data Set contribution can occur once the Institutional Data Contributor and their Principal Investigator have obtained all necessary approvals for the contribution of the Data Set into ARCHIMEDES. The submissions process is described below:

5.9 Ingestion into Private Environment

Data Sets are Ingested into the Private Environment of ARCHIMEDES through two secure channels:

1. SSL-encrypted transfer through the platform's web-browser interface. This method uses the RESTful API to transfer the Data Set from the Institutional Data Contributor's servers to McGill servers.
2. Encrypted Data Set transfer through the Secure Shell File Transfer Protocol (SFTP or SSH), which enables bulk file transfer from the Institutional Data Contributor's servers to McGill servers.

Data Sets contributed to ARCHIMEDES reside in servers located at McGill. If using DRAC HPC, Data Sets may also be temporarily hosted on the DRAC infrastructure. A small number of the ARCHIMEDES technical team that perform data management, data curation, and platform administration can access them.

5.10 Preparing Data Sets for Release

1. After uploading a Data Set to ARCHIMEDES, Principal Investigators and their Research Team can analyze and manipulate the uploaded Data Set in the Private Environment.
2. Principal Investigators can then initiate the release process through a formal written request that outlines the components of the Data Set (e.g., specific instruments, visits, modalities, or cohorts) to be shared.
3. Data Sets to be released are then prepared in a secure staging environment, with or without assistance of the ARCHIMEDES technical team (as described below).
4. A final written sign-off from the Principal Investigator to the DACO confirms that the curated Data Set is accurate and ready for release through the chosen tier.
5. The DACO then instructs the ARCHIMEDES technical team to release the Data Set.

This two-step confirmation process—initial request and final sign-off—ensures alignment with consents and ethics approvals applicable to the Data Set, and the Data Contribution Form.

5.11 Data Set Curation and Validation

There are two main approaches to preparing Data Sets in the staging environment:

1. **Full Curation with ARCHIMEDES**
   In this model, the Principal Investigator and their Research Team, with the assistance of ARCHIMEDES technical team, test and review the Data Set within staging environments to ensure the Data Set is properly curated, validated, and prepared for release through the chosen tier.

2. **Handoff of Pre-curated Data**
   Alternatively, the Principal Investigator and their Research Team may provide fully curated Data Sets. In this case, the ARCHIMEDES technical team verifies that the Data Set is structured and annotated according to ARCHIMEDES standards for release through the chosen tier.

5.12 Removing Select Identifiers (ARCHIMEDES Technical Team)

Institutional Data Contributors and their Principal Investigators possess domain-specific knowledge and expertise that is fundamental to the effective removal of identifiers. They are responsible for determining the measures and controls required to adequately mitigate the residual risk of re-identification in the chosen tier of release.

ARCHIMEDES tools and controls, administered by the ARCHIMEDES technical team, and described below, detect and remove common identifiers from predefined standard fields but cannot comprehensively identify all potential identifiers across diverse data structures and contexts.

- **Double-coding and GUID assignment**: For Coded Data, project-level research participant codes are assigned a GUID (or are double-coded), ensuring that Data Sets are dissociated from their original sources. For Data Sets that Institutional Data Contributors describe as De-identified, no GUID is generated.

- **Removal of Indirect Identifiers for imaging data**: For certain data types, such as MRI, 'de-facing' algorithms are applied to remove facial features while maintaining anatomical integrity for downstream analyses. This is mandatory and is implemented without impacting core research workflows. Other bespoke workflows will be developed in the future for commonplace data types.

- **Temporal removal of Indirect Identifiers**: Dates tied to hospital visits, assessments, or research participant birthdates are stripped or shifted.

- **Metadata sanitization**: All potentially identifying metadata fields, such as DICOM headers, are systematically scrubbed or overwritten using standardized tools like DICAT (DICOM-anonymization tool). Fields such as StudyDate, and BirthDate are reformatted or removed to comply with ARCHIMEDES policies and standards.

Following this processing, Institutional Data Contributors and their Principal Investigators are solely responsible for determining whether supplementary measures are required to adequately mitigate the residual risk of re-identification in the chosen tier of release.

OHIRC and McGill are not responsible for monitoring whether there is an increased risk of re-identification in respect of the De-identified Data that has been combined with other data. OHIRC and McGill, however, may conduct spot audits or engage a third party to ensure that De-identified Data continues to be sufficiently De-identified.

5.13 Data Quality (ARCHIMEDES Technical Team)

Institutional Data Contributors and their Principal Investigators are responsible for the accuracy, completeness, and quality of contributed Data Set. ARCHIMEDES quality review is conducted solely to ensure the Data Set meets ARCHIMEDES standards.

- **Quality control and curation**: The Data Set undergoes automated and manual validation to identify inconsistencies, missing values, or outliers, but accuracy is not guaranteed. This includes logic checks, adherence to expected value ranges, and metadata consistency across instruments and time points.

- **Review compliance with standards**: Ensure adherence to ARCHIMEDES naming conventions, and standardized schemas.

5.14 Pre-Release Verification and Validation

Prior to making the Data Set available for release through the chosen release tier, verification and validation is performed to ensure that the Data Set is appropriately permissioned according to the release tier chosen by the Institutional Data Contributor, is double-coded (or assigned a GUID) for Coded Data, and is of sufficient quality meeting ARCHIMEDES standards. This is an administrative oversight process that the ARCHIMEDES technical team performs that may help Institutional Data Contributors reduce the risk of an unauthorized Data Set release or re-identification.

However, this process does not confirm the adequacy of the chosen release tier, or the adequacy or completeness of the removal of identifiers or De-identification of the data. Ultimate responsibility for ensuring that data is Coded, De-identified, or is Pre-clinical Data, in accordance with applicable laws and for selecting the appropriate release tier remains with the Institutional Data Contributor.

5.15 Institutional Data Contributor Credentialing and Authentication

When creating a new Data Set for contribution, authorized Principal Investigators ascribe the permissions defined in the table below to Research Team members at their institution.

The ARCHIMEDES user management module allows Principal Investigators to create accounts that are associated to their Data Sets in the ARCHIMEDES Private Environment. These accounts carry distinct privileges, ranging from permission to view a specific Data Set, to the ability to create releases and upload the Data Set to them to the ARCHIMEDES Private Environment, to creating additional new users and credentials with specific privileges. Contribution and Data Set release privileges are restricted to Principal Investigators alone. All logins, contributions, entry, uploads, and other interactions with ARCHIMEDES are logged and are tied to the account that performs these operations.

5.16 Role Based Access Controls

Once the DAC approves the contribution of the Data Set from the Institutional Data Contributor, Principal Investigators can assign members of their Research Team one or more roles, provided that the DACO has authenticated the Institutional Data Contributor and ensured all requisite contracts and forms have been completed. Each role has defined privileges at the site and/or project level. Roles are configurable in the system and mapped as follows:

Role	Key Permissions
Viewer	View catalog metadata and non-sensitive Data Set previews.
Contributor	Upload Data Sets, submit data dictionaries, view own Data Sets.
Manager	Add/remove project members, approve Research Team member accounts, manage data dictionaries.
Analyst	Execute queries, submit analysis jobs, access analysis pipelines.
Principal Investigator	Ability to create new Data Sets and release Data Sets through ARCHIMEDES and assign privileges in the Private Environment to their Research Team, relative to their created Data Sets.
Institutional Signing Official	Ability to view all activity associated with the institution, including creation of new Data Sets and release through ARCHIMEDES, and privileges granted in the Private Environment.

Access is further restricted to:

- Data Sets from specified Research Projects; and
- Data Sets from specified institutions (e.g., only McGill-affiliated Data Sets).

6. Data Access Requirements and Process

Data Sets contributed to ARCHIMEDES will be made available to Principal Investigators and their Research Team through Controlled Access and Open Access tiers. The authorization attributed to Data Sets informs the Institutional Data Contributor's selection of the appropriate release tier (i.e., an ethical and legal justification that supports its sharing and use, such as research participant consent, an ethics waiver of informed consent requirement, or other legal authority for Data Set release, as described at s. 5.1).

6.1 Accessing Open Access Data

Open Access data on ARCHIMEDES are made available through a public website that Open Access Users can access, to perform research on all relevant scientific research questions. Open Access Users are able to perform the analysis of Data Sets either using their own local hardware and computing capabilities (i.e., through download access to data). Open Access Users must respect ARCHIMEDES Open Access terms of use, which precludes non-research uses of Data Sets and those that could harm research participants. The DACO has little capability to monitor compliance with the governance rules applicable to Open Access data.

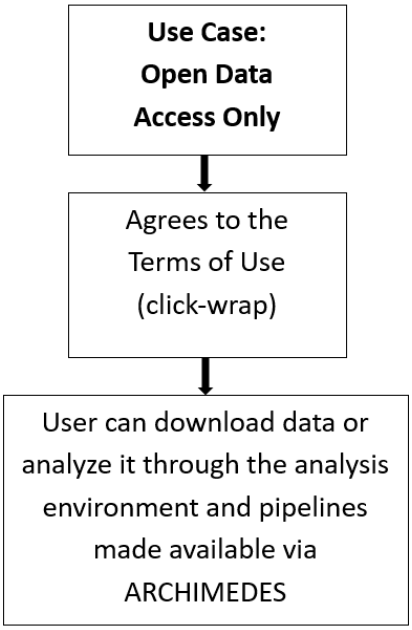

Figure 2: Open Access Workflow

6.2 Accessing Controlled Access Data

Controlled Access data are made available through ARCHIMEDES to authorized Principal Investigators and their Research Team to download Data Sets for an approved research purpose.

Only Principal Investigators can request access to Controlled Access data. To do so, they must:

1. Create an account on ARCHIMEDES using an institutional e-mail address that is associated to the institution that hosts them; and

2. Submit a purpose-specific Data Access Request to the ARCHIMEDES DACO, specifying the requested Data Sets and the intended purposes of their research use, and identifying members of their Research Team.
3. Obtain an approval from the ARCHIMEDES DAC.

The Institutional Data User must further enter into:

- an Institutional Data Access Agreement (I-DAA) (if not already entered into); or
- Data Access Agreement (DAA) with OHIRC, confirming their appropriate use of the Data Set released to them.

Types of agreement

Two options are available:

- **(I-DAA) –** an overarching agreement signed by the Institutional Data User's ISO with OHIRC that establishes the obligations, responsibilities, and commitments of Principal Investigators and their Research Team members in using ARCHIMEDES Controlled Access data. Once the I-DAA has been signed and a Principal Investigator has created an account on the ARCHIMEDES, an ISO (or their agent) can allocate permissions to specific Principal Investigators at their institution. This enables those Principal Investigators to submit Data Access Requests ("**DARs**") through ARCHIMEDES.
- **Single-shot DAA –** Signed by an ISO with OHIRC, the Single-shot DAA governs a singular data access request. These are easier for Principal Investigators to manage but must be replicated for each access request.

The I-DAA can be concluded before the DAR is submitted.

The DAA is always submitted by the applicant but is countersigned after DAC approval.

Submission and approval of DAR

To submit a DAR, a Principal Investigator must first select the Data Sets they wish to access and add them to their cart on the ARCHIMEDES. They must then complete the DAR through ARCHIMEDES.

DARs are first reviewed by the ARCHIMEDES DACO for pertinence and completeness. Incomplete DARs are returned to applicants for completion prior to DAC evaluation. Once completed, the DACO sends the DARs to the DAC for approval. See the DACO Procedures (Data Access).

On receiving a DAR, the DAC convenes to review the application, during which it considers:

1. Whether the applicant is affiliated with a *bona fide* research organization and has sufficient research expertise to perform the proposed research;
2. Whether the proposed research activities fall within-scope of the informed consents, Data Set use conditions, and policies applicable to the Data Set; and
3. Whether the necessary supporting documentation has been provided (e.g., ethics board approvals, lists of Authorized Users). See the full DAC Evaluation Criteria.

The DACO communicates the decision of the DAC to the applicant. The possible outcomes are:

- acceptance,
- conditional acceptance, or
- refusal.

The decision-making process of the DAC is further detailed in the DAC terms of reference.

Duration of authorization

Once an applicant has received DAC approval to use the Data Sets, this authorization remains valid for a period of **three years**, after which point it is necessary to amend the DAR to obtain continued authorization to access and use the Data Sets. In some cases, such as when the supporting ethics approval is not valid for the full access period, the period of authorization will be shorter.

7. Overview of Technical Elements of ARCHIMEDES

ARCHIMEDES is composed of the following major technical elements:

- **Data contribution tools**, which enable Principal Investigators and their Research Teams to submit Data Sets to ARCHIMEDES for Controlled Access, or Open Access sharing.
- **Data Query Tool (DQT)**, which enables Data Sets to be searched according to data dictionaries that are made available to Principal Investigators and their Research Teams, and Open Access Users. This helps users find Data Sets that are useful to them.
- **User authentication and access request tools**, which enable prospective users to apply to use Controlled Access Data Sets.
- **High-performance computing capabilities**, which are made available through supercomputing facilities.

The functioning of these elements is further detailed below.

8. ARCHIMEDES Data Query Tool (DQT)

The ARCHIMEDES DQT is a data discovery tool that enables Principal Investigators and Open Access Users to search for Data Sets that are useful for their research. This helps Principal Investigators determine whether a Data Set that is useful for their purposes and is available for use with Controlled Access Data Sets.

9. Data Analysis

ARCHIMEDES enables Principal Investigators and their Research Teams to perform the analysis of Data Sets using their own local hardware and computing capabilities (i.e., through download access to data). Alternatively, it enables Principal Investigators and their Research Teams to perform the analysis of Data Sets using dedicated third-party high-performance computing ("**HPC**") infrastructure (i.e., supercomputing), and to analyze the Data Set using a collection of software tools, pipelines, and APIs. The details of each method of analysis are further outlined below.

Local analysis	ARCHIMEDES HPC
Computing capabilities: Principal Investigators can download Data Sets available to them to their local hardware.	**Computing capabilities:** Where Principal Investigators instead require greater computing power, ARCHIMEDES supports data processing across HPC. This allows Principal Investigators to access significant computing power and storage that would not otherwise be available to them The Digital Research Alliance of Canada (DRAC) HPC allocation of ARCHIMEDES is available to Principal Investigators, subject to the agreement with the DRAC. Use of DRAC HPC involves securely transferring Data Sets from ARCHIMEDES to DRAC's supercomputing facilities (i.e. distributed storage).
Analysis tools: This retrieval allows a researcher to analyze Data Sets with their preferred tools and hardware, so long as this analysis continues to respect the applicable data governance commitments.	**Analysis tools:** ARCHIMEDES supplies Principal Investigators with analysis tools (i.e., software, algorithms, and pipelines) created by the scientific community. Users can leverage these tools when they analyze Data Sets through HPC. The ARCHIMEDES technical team receives analysis tools from community contributors and performs a reasonable information security assessment and basic verifications of their functioning and fitness. It provides no guarantees regarding their non-infringement of intellectual property rights, nor their serviceability or good functioning. Principal Investigators will agree through click-wrap terms of service that these tools are provided without warranties nor guarantees. ARCHIMEDES integrates with other open-source tools, e.g., Jupyter Notebooks, DataLad, and Zenodo. These tools enable Principal Investigators to analyze Data Sets through HPC using their own code, or that of third parties.

9.1 Community Contribution of Analysis Tools

ARCHIMEDES enables members of the wider research community to contribute data analysis tools to its library of analysis tools. Principal Investigators and their Research Teams can analyze ARCHIMEDES Data Sets using these community-contributed tools, when analyzing the Data Sets through supercomputing facilities.

Community members that contribute a tool to ARCHIMEDES are required to provide information used to validate its appropriateness and agree to abide by a Tool Contributor Code of Conduct.

10. Data Protection

Identifiable Information

Each Institutional Data Contributor must ensure compliance with the data protection laws applicable, including PHIPA, that govern their Data Set contribution, use, and release and TCPS-2 requirements, in particular, in relation to "broad consent."

In the context of data protection laws, OHIRC is Ingesting (collecting) personal information for ARCHIMEDES under an express (broad) informed consent model as permitted under TCPS-2 or other ethical and legal authorizations described in Section 5.1. Data protection and governance responsibilities are shared among OHIRC and McGill in accordance with this Governance Framework and the agreements between the organizations:

- OHIRC performs administrative oversight and is responsible for discharging the data stewardship functions detailed in this Governance Framework, the DCA, and the I-DAA or DAA. OHIRC Ingests personal information pursuant to the applicable DCA's and releases personal information pursuant to applicable DAAs. OHIRC is the accountability entity in respect of the personal information ingested.
- McGill provides the technical operations and data management functions central to ARCHIMEDES and described in this Governance Framework.

Prior to releasing the Data Set based on the express informed consent or other authorization as set out above, it remains the sole obligation of Institutional Data Contributors, to ensure their Principal Investigators and their Research Teams respect privacy and data protection laws and related laws applicable to their activities and comply with the I-DAA or DAA.

UOHI Privacy Office is responsible for overseeing privacy compliance in connection with OHIRC's data stewardship functions under this Governance Framework and providing privacy guidance and support to the ARCHIMEDES governance bodies, as appropriate.

A note on: Multi-jurisdictional Data

All Canadian applicants are required to obtain REB review prior to accessing and using data because secondary use of Coded or De-identified Data stored in research data repositories for future research purposes does not qualify for an exemption from REB review. Therefore, there is no exemption from REB review in respect of the secondary use of Coded or De-Identified Data stored in the ARCHIMEDES platform.

However, applicants from other jurisdictions can either state that they are REB approved (and provide a supporting ethics approval); or can state that they are exempt from such obligation where this is the case, supported by supporting documentation (e.g. an exemption letter; or letter from an ISO for applicants not eligible to obtain an exemption letter).

10.1 Re-identification Risk

Principal Investigators contributing Data Sets to ARCHIMEDES do so in accordance with their local ethical and legal requirements and ARCHIMEDES standards, primarily based on express informed consent or an ethics waiver of express informed consent requirement to release the Data Set that has been treated to remove all Direct Identifiers, and may include the removal of some (but not all) Indirect Identifiers. While this reduces the risk of individual re-identification, it does not eliminate it. Such Data Sets are often still identifiable. This approach was chosen to achieve an

optimal balance between research participant privacy and maintaining the scientific utility of the data.

In some cases, Institutional Data Contributors will contribute a Data Set based on another suitable authorization (i.e., enabling local law), on the grounds that the Data Set is De-identified in accordance with Ontario IPC De-identification Guidelines or a comparable provincial or territorial de-identification standard or on the grounds that the Data Sets are Pre-clinical Data.

ARCHIMEDES nonetheless treats all ARCHIMEDES-hosted Data Sets accessed in the Controlled Access environment as though they were personal information:

- In hosting the Data Sets, ARCHIMEDES applies security safeguards and access controls that are reasonable to the storage of personal information.
- Research participants provide broad express informed consent in alignment with TCPS-2 (where consent is the authorization for data disclosure).

10.2 Data Breach Notification

Institutional Data Contributors and Principal Investigators must provide a written notice to the UOHI Privacy Office of any potential, suspected or actual data breaches which may affect ARCHIMEDES Data Sets.

UOHI Privacy Office is responsible for providing notice of data breaches to regulatory authorities, affected individuals, and other third parties, as might be required by applicable law to mitigate the harms and other consequences that such breaches cause to affected individuals. It also is responsible to provide notice to Institutional Data Contributors of data breaches that are known or suspected to have affected their contributed Data Set(s). In practice, the original Institutional Data Contributor is responsible for informing affected individuals and ensure compliance with applicable data protection laws. Confirmed and material security or privacy incidents affecting ARCHIMEDES or its Data Sets, along with remedial actions taken, will be promptly reported to the Leadership Committee.

OHIRC and McGill will reasonably cooperate with the affected Institutional Data Contributor, and the breaching Principal Investigator (including their Research Team), to enact measures required to mitigate the harms that the data breach has caused, which can include providing notice to relevant privacy regulators as permitted or required by law.

11. Data Set Backup and Disaster Recovery

Institutional Data Contributors are responsible for backing up and safely storing their Data Sets. Routine backups are implemented by ARCHIMEDES technical team but due to the distributed nature of the ARCHIMEDES platform, we cannot guarantee that lost Data Sets can always be recovered.

11.1 Data Set Storage and Backup Strategy

Central Data Set storage and backup operations for ARCHIMEDES are managed by the ARCHIMEDES technical team within a secure virtual infrastructure. Access to Data Sets is strictly controlled and limited to designated ARCHIMEDES technical team users authenticated through secure credentials and operating within approved Virtual Machines ("**VMs**").

A multi-tiered backup strategy ensures high availability, Data Set integrity, and long-term recoverability.

All backup operations are logged and routinely validated to ensure Data Set fidelity.

11.2 Disaster Recovery and Business Continuity

A disaster recovery plan defines protocols for rapid response and restoration in the event of hardware failures, software corruption, security incidents, or natural disasters.

11.3 Compliance and Data Retention

Backup and recovery procedures align with McGill policies and applicable laws. All retained backups are subject to encryption-at-rest, audit controls, and retention schedules defined in DCA's or ethics protocols.

Future enhancements include the integration of immutable storage layers, cloud-based replication (as appropriate), and expanded automation for faster disaster response.

12. IT Security

The ARCHIMEDES platform adopts a layered and proportionate security strategy to mitigate risks of unauthorized access, Data Set loss, and misuse. These measures are aligned with McGill's IT policies and informed by leading practices in biomedical research data governance. Access to sensitive systems and Data Sets is controlled through granular permission settings, allowing administrators to manage roles at the level of individual collections, data modalities, workflows, and modules. Data Set-based access control lists (ACLs) are actively being developed to further enhance user-level segmentation and data protection.

Security measures are enforced at both the application and infrastructure levels. All network traffic to ARCHIMEDES is encrypted using SSL/TLS, and access to servers is restricted via closed ports, firewall rules (including Firewall), and IP-level blocking tools such as Fail2Ban. User authentication practices include strong password enforcement, credential rotation, and optional two-factor authentication (2FA). Regular credential verification ensures that only appropriate persons retain access. Server infrastructure is hosted in physically secure, access-controlled environments at the McGill Centre for Integrative Neuroscience (MCIN), protected with clear protocols, response timelines, and around-the-clock automated monitoring using Nagios.

Codebase security is maintained through continuous integration testing, routine audits, and manual reviews of any changes that involve Data Set access, storage, or user input. McGill personnel conduct ongoing security research and log any findings in a shared vulnerability database to ensure rapid mitigation of potential threats. Application-level protections include input sanitization, CSP headers, and role-based content filtering to reduce the risk of XSS, CSRF, and injection attacks.

A robust backup and recovery strategy further safeguards ARCHIMEDES Data Sets (implemented through McGill), which includes:

- Daily incremental and weekly full offsite backups of both virtual machines and databases, retained for up to six months to ensure recoverability;

- Restoration procedures are clearly defined in the event of hardware, storage, or system failure, and are tested routinely;
- ARCHIMEDES enforces a multi-layered security model designed to support sensitive Data Sets processing across DRAC's HPC infrastructure;
- The platform leverages containerized workflows that isolate user processes and ensure reproducibility while limiting system exposure;
- All user access is authenticated and controlled through role-based permissions, with support for secure login protocols and credential expiration policies;
- Data Set transfers to and from ARCHIMEDES are encrypted and staged in secure, access-controlled environments;
- DRAC centers implement their own rigorous physical and network security measures, including firewall protection, system auditing, and intrusion detection;
- The platform maintains audit trails for all Data Sets and job activity, ensuring traceability and compliance with institutional and national data protection policies; and
- While full automation of data pipelines is still under development, ARCHIMEDES's flexible API design supports secure, modular integration with external systems and tools without compromising its strict compliance posture.

13. Intellectual Property

ARCHIMEDES has adopted an open science strategy that maximizes the availability of a Data Set hosted through ARCHIMEDES, and that of derived Data Sets, for future research use where appropriate and in accordance with research participant consent and applicable privacy laws.

Principal Investigators, Institutional Data Users, and Open Access Users must refrain from asserting intellectual property rights in a manner that could preclude researchers from using or accessing Data Sets and other outputs hosted on ARCHIMEDES, or that could restrict ARCHIMEDES from sharing those outputs openly, as permitted by the respective Institutional Data Contributor.

OHIRC and McGill do not exercise the intellectual property rights associated with the Data Sets hosted on ARCHIMEDES, nor to Data Sets derived the hosted Data Set, except as is required to preserve the openness of Data Sets and of the other research outputs that are hosted on ARCHIMEDES.

14. Return of Individual Results, Material Incidental Findings, and Derived Data Sets

The Institutional Data Contributor is responsible for discharging its ethical-legal obligations to return individual results and/or material incidental findings to research participants, where applicable.

Principal Investigators and Open Access Users that access Data Sets on ARCHIMEDES are neither required, nor expected, to return individual-level research results or MIFs to OHIRC, nor to the original Institutional Data Contributors or research participants. OHIRC will not process the return of research results, or MIFs, to the Institutional Data Contributor or research participants.

OHIRC accepts the contribution of derived Data Sets to ARCHIMEDES according to the same conditions as other forms of Data Contribution. However, the choice whether to release derived Data Sets to ARCHIMEDES is left to the discretion of Principal Investigators and Open Access Users that generate such derived Data Sets.

15. Data Set Withdrawal, Correction and Access

The ARCHIMEDES DACO accepts Data Set withdrawal requests from the Institutional Data Contributors that first contributed the Data Set to ARCHIMEDES. Requests to withdraw Data Sets can be made at the level of the Data Set (i.e., requesting the withdrawal of the entire Data Set) or at the level of the individual record.

The Institutional Data Contributor is solely responsible for retaining any linkage logs that may be necessary to enable research participants to request data withdrawal, correction and access at the level of the individual record. In the case of withdrawal, absent a linkage log, it will only be possible to request the removal of entire Data Sets. Data Sets that have already been released through ARCHIMEDES to an Institutional Data User or an Open Access User cannot be removed or destroyed to preserve the scientific integrity of the analysis.

Research participants have the right to withdraw their consent, to make a request to correct and to access their data in ARCHIMEDES. However, ARCHIMEDES DACO cannot accept data withdrawal, corrections and access requests directly from research participants that disclosed their data to Research Projects hosted through ARCHIMEDES. Research participants must instead make their request with the original Institutional Data Contributor, who is responsible to respond to research participants and to explain any limitations on their rights of withdrawal.

16. Database Decommissioning and Changes in Data Stewardship

Data Sets housed in ARCHIMEDES is under the data stewardship of OHIRC, which exercises custody and control over the Data Set in accordance with this Governance Framework and the applicable agreements between the organizations. The technological infrastructure to support ARCHIMEDES is developed and implemented by McGill.

If ARCHIMEDES were to be discontinued at any time in the future, the ARCHIMEDES Leadership Committee will decide on the transfer or closure of the database in accordance with the applicable agreements among OHIRC, McGill and uOttawa.

Should it be decided that the Data Sets are to be transferred to a third party that contractually agrees to respect the same conditions as ARCHIMEDES the Institutional Data Contributors will be notified, as will the OHSN-REB. Institutional Data Contributors will have the choice to withdraw their Data Sets.

17. Approval and Review

The Leadership Committee approved this Framework on August 6, 2026, and will ensure its continuing review on a yearly basis. A thorough revision of this Framework will be undertaken every 5 years. In addition, any revision and/or amendment made to this Framework must be approved by the Leadership Committee and the OHSN-REB prior to implementation. Changes will be prospective, will be communicated to Institutional Data Contributors and Institutional Data Users on the ARCHIMEDES website and will not, except in exceptional circumstances, require individual re-consenting or amendments to signed agreements.

APPENDIX A – GLOSSARY OF TERMS

Authorized User: The employees, agents, Principal Investigators and their Research Teams, or trainees of the Institutional Data User, to whom Data Set use privileges are assigned relative to one or more Research Projects.

Coded/Coded Data: Direct Identifiers are removed from the data and replaced with a code. It may be possible to re-identify specific participants (i.e., the Principal Investigator retains a list that links the research participants' code names with their actual names so data can be re-linked if necessary).[2] ARCHIMEDES treats Coded Data like personal information, to which data protection laws continue to apply.

Controlled Access: Coded Data released in Controlled Access is exclusively made available to Authorized Users, for an approved research purpose if: there is approval from the ARCHIMEDES Data Access Committee (DAC) and have host institution has concluded an I-DAA or DAA before being able to access data. De-identified Data and Pre-clinical Data may also be released through the Controlled Access tier where the Institutional Data Contributor selects this tier of release.

Core Permissions: To release data through ARCHIMEDES, the Institutional Data Contributor must demonstrate that it has obtained the permissions described at s. 5.3.1 for release in Controlled Access and 5.3.2 for Open Access through an express broad informed consent to research participation and ethics approval, an ethics waiver of informed consent requirement, or other legal authorization.

Data Access Agreement (DAA): A contractual agreement between an Institutional Data User and OHIRC that governs a singular Data Set access request and Research Project.

Data Access Committee (DAC): The ARCHIMEDES DAC at OHIRC approves requests to the contribution and of all ARCHIMEDES data and the use Controlled Access ARCHIMEDES data. The ARCHIMEDES Data Access Committee (DAC) Terms of Reference.

Data Access Compliance Office (DACO): ARCHIMEDES Data Access Compliance Office at OHIRC (DACO) reviews Data Contribution Forms and if applicable associated Informed Consent Forms against established criteria and makes a recommendation to the DAC as well as reviews Data Access Requests and associated documentation against established criteria and makes a recommendation to the DAC.

Data Access Request (DAR): This request specifies the requested Data Sets, the intended purposes of their research use, and the identities of the Authorized Users that are members of the Research Team.

Data Contribution Agreement (DCA): A contractual agreement between OHIRC and the Institutional Data Contributor that authorizes the Institutional Data Contributor and its Principal Investigators to contribute Data Sets to ARCHIMEDES.

Data Contribution Form: To create a new Data Set a Principal Investigator submits a Data Contribution Form that describes the nature of the Data Set, the data in the Data Set that will fall

[2]Government of Canada. (2022). *TCPS 2 (2022) – Glossary*. Panel on Research Ethics. https://ethics.gc.ca/eng/tcps2-eptc2_2022_glossary-glossaire.html

within each tier of data release, and the ethical-legal authorization for contribution to ARCHIMEDES and the release of such a Data Set through ARCHIMEDES.

Data Set: means a group or list of data elements, that are subject to common oversight and permissions, generated with the intent of being analyzed by researchers, shared to the appropriate tier of access, and used together, generally at the direction of one Institutional Data Contributor's Principal Investigators.

Data Query Tool (DQT): The ARCHIMEDES DQT is a data discovery tool that enables Institutional Data Users and Open Access Users to search for Data Sets that are useful for their research. This helps Institutional Data Users determine whether a Data Set that is useful for their purposes is available in Controlled Access, before undertaking the procedures required to request access thereto.

De-identified/De-identified Data: Information that identifies an individual as well as information that could be used, either alone or with other information, to identify an individual based on what is reasonably foreseeable in the circumstances is removed. (Verb: to de-identify; outcome De-identified Data). In practice, De-identified Data Sets are De-Identified in accordance with Ontario IPC De-identification Guidelines or a comparable provincial or territorial de-identification standard.

Direct Identifier: Variables that can be used to uniquely identify an individual, with or without the use of external information (e.g., name, civic address, social insurance number).

Indirect Identifier: Variables that can be used, often in combination with each other, to identify an individual and that are reasonably known by an adversary (e.g., age, profession, gender, ethnicity).

Informed Consent Forms (ICFs): The document through which research participants provide their express informed consent to participate in a research study, including consent to the contribution and release of their Data Set through ARCHIMEDES. For Controlled Access data, the Informed Consent Form must, at a minimum, incorporate the Core Permissions detailed at s. 5.3.1. For Open Access data, the Informed Consent Form must use the ARCHIMEDES Consent Form Templates provided by OHIRC.

Ingestion: in relation to information, means to gather, acquire, receive, or obtain the information by ARCHIMEDES. Information Ingested by ARCHIMEDES from Institutional Data Contributors will be released pursuant to the appropriate tier of access set out in the Data Contribution Form.

Institutional Data Access Agreement (I-DAA): A master contractual agreement that establishes the obligations, responsibilities, and commitments of Institutional Data Users and their Principal Investigators and Authorized Users in using ARCHIMEDES Controlled Access data. This allows specific named, authorized Principal Investigators to submit requests without requiring institutional sign off from the Institutional Data User at each instance.

Institutional Data Contributor: An institution that contributes a Data Set to ARCHIMEDES. The Institutional Data Contributor:

- obtains required legal authority to contribute the Data Sets (e.g., informed consent or other),

- selects a tier of data release (Open Access or Controlled Access),
- ensures the Data Set is Coded or De-identified, and
- signs a DCA.

Institutional Data Contributors are responsible for ensuring that their authorized Principal Investigators comply with applicable laws, ethics requirements and technical standards, and the terms of the DCA.

Institutional Data User: An institution that receives Controlled Access Data Sets from OHIRC through ARCHIMEDES. Institutional Data Users are responsible for ensuring that their usage, and that of their Authorized Users, complies with applicable laws, ethics requirements, technical standards, and the terms of the I-DAA or DAA.

Institutional Signing Official (ISO): The authorized representative identified by an Institutional Data Contributor or Institutional Data User with both the capacity and the authorization to bind that institution to contractual agreements which pertain to research, e.g. CEO, VP Research. An Institutional Signing Official signs contractual agreements that enable contribution or access on behalf of the Institutional Data Contributor or Institutional Data User.

IPC De-identification Guidelines: Information and Privacy Commissioner of Ontario's De-Identification Guidelines for Structured Data.[3]

Open Access: Data Sets released in Open Access is made openly available through a public website that anyone can access. To use Open Access data, Open Access Users must first agree to a click-wrap terms of use that requires them to use the Data Set exclusively for research purposes, and to respect the applicable ethical and legal restrictions on use.

Open Access User: Individual who agrees to the Open Access terms of use and accesses Open Access data.

Pre-clinical Data: Data that does not, and never did, relate to human research participants. To be considered Pre-clinical Data, data must not be subject to the TCPS-2 (or equivalent local research ethics requirement) nor to the PHIPA (or local data protection laws). E.g. Data Sets about non-human cell cultures, animal models data, or data about drugs or devices.

Principal Investigator (PI): The lead researcher responsible for the design, execution, and overall management of a Research Project. This role is central to ensuring the scientific integrity, regulatory compliance, and ethical conduct of the study. The Principal Investigator is affiliated with an Institutional Data User or Institutional Data Contributor and authorized to act as an agent of the Institutional Data Contributor for the purpose of Data Set contribution and/or access.

Private Environment: The private environment refers to the portion of ARCHIMEDES through which Institutional Data Contributors can store, analyze, and curate data related to a Data Set

[3]De-Identification Guidelines for Structured Data | Information and Privacy Commissioner of Ontario, October 2025. Accessed October 17, 2025. De-identification Guidelines for Structured Data | Information and Privacy Commissioner of Ontario

that they have uploaded, prior to releasing it for others to use through the Open Access or Controlled Access tiers.

Research Project: A self-contained research effort, with defined aims, methods, and outputs, carried out by a Principal Investigator and their Research Team in accordance with institutional requirements. Each Research Project is described in a Data Access Request (DAR) and must obtain approval from the ARCHIMEDES Data Access Committee (DAC). Rights to use Controlled Access ARCHIMEDES data are allocated relative to a specific Research Project.

Research Team: For each of their Research Projects, the Principal Investigator supplies a list of members of their Research Team (all from the same institution) to the DACO. Many obligations to ensure responsible use that are detailed in applicable contracts, and ARCHIMEDES policies apply to each Research Team and are assessed relative to each of their approved Research Projects. For example, Data Sets released as part of a Research Project can only be used by members of the associated Research Team, relative to the approved Research Project.

APPENDIX B – ARCHIMEDES GOVERNANCE STRUCTURE

The ARCHIDEMES Leadership Committee, Joint Liaison Committee, and Community Partners Committee perform portfolio-specific decision-making and advisory functions as detailed below.

The Data Access Committee (DAC) oversees requests from prospective Institutional Data Contributors to contribute Controlled Access Data and Institutional Data Users to access Controlled Access data with the administrative support of the Data Access Compliance Office (DACO).

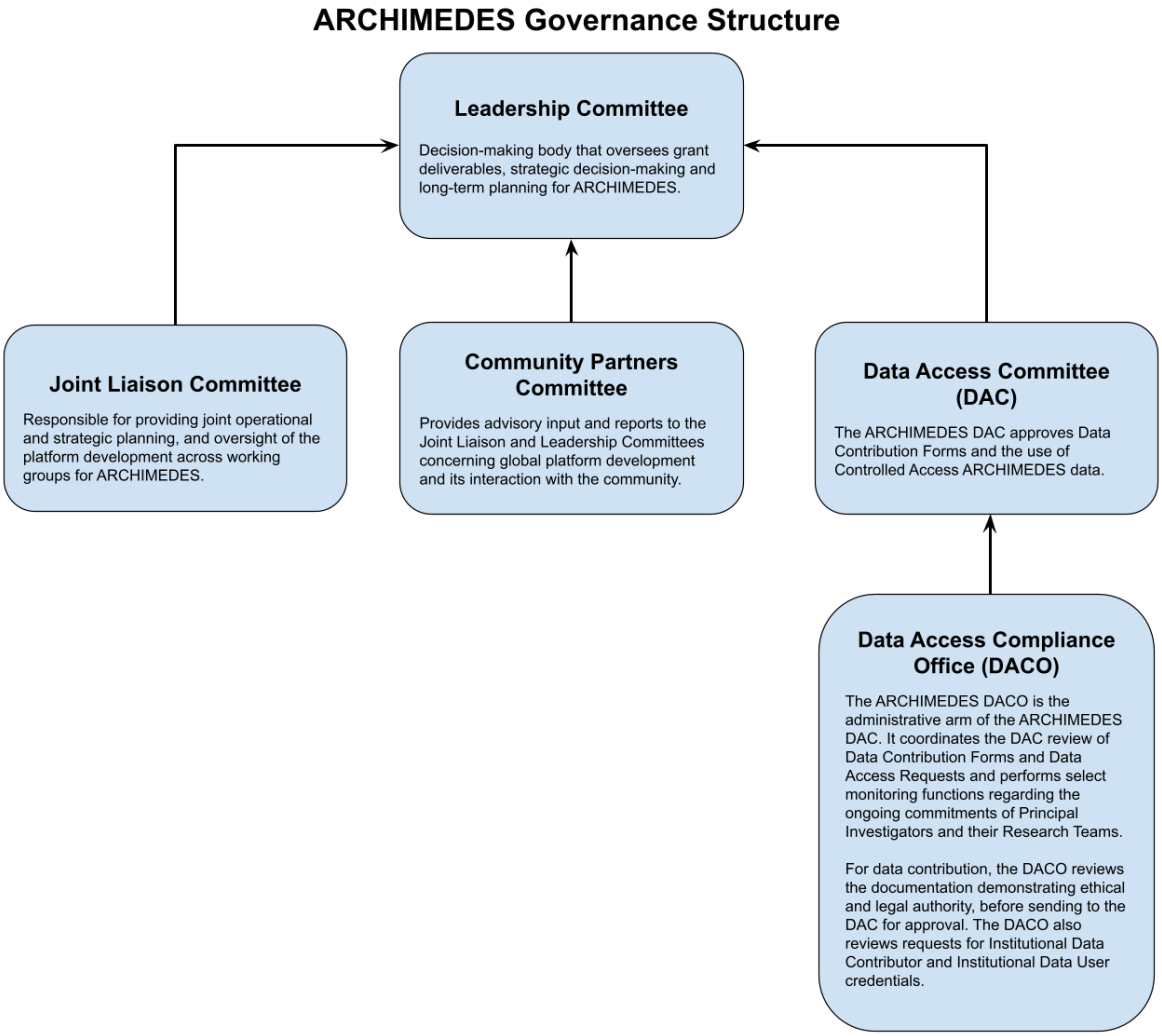

Figure 3: ARCHIMEDES Governance Structure

ARCHIMEDES Leadership Committee

The ARCHIMEDES Leadership Committee is the decision-making body of ARCHIMEDES and reports bi-annually to the BHI Executive Committee. It is responsible for oversight of ARCHIMEDES, strategic decision-making and long-term planning. Committee membership includes the scientific leads and senior representatives from each of uOttawa, OHIRC and McGill. Committee terms of reference can be found here.

ARCHIMEDES Joint Liaison Committee

The ARCHIMEDES Joint Liaison Committee ensures that the development and implementation of ARCHIMEDES will achieve the scientific goals of the BHI program. It will ensure full transparency, accountability, alignment, and continuity between collaborating institutions. The Joint Liaison Committee oversees the day-to-day operational management of all platform activities, with the oversight of the ARCHIMEDES Leadership Committee. Committee terms of reference can be found here.

ARCHIMEDES Community Partners Committee

The ARCHIMEDES Community Partners Committee includes stakeholders with expertise in topics that influence the successful implementation of ARCHIMEDES and its interaction with the community. The Community Partners Committee will provide advice to the Leadership Committee and to the Joint Liaison Committee, as applicable and required, on key areas that affect ARCHIMEDES, including commercialization, Indigenous community engagement, knowledge mobilization, open science, patient engagement, and training. This Committee reports to the ARCHIMEDES Leadership Committee. The Community Partners Committee terms of reference can be found here.

ARCHIMEDES Data Access Committee (DAC)

The ARCHIMEDES DAC approves requests to the Ingestion of ARCHIMEDES data and the use Controlled Access ARCHIMEDES data.

The ARCHIMEDES DACO is the administrative arm of the ARCHIMEDES DAC. It coordinates the DAC review of Data Contribution Forms and Data Access Requests and performs select monitoring functions regarding the ongoing commitments of Principal Investigators and their Research Teams. For data contribution, the DACO reviews the documentation demonstrating ethical and legal authority, including informed consent materials and ethics approvals, provided by Institutional Data Contributors for compatibility with ARCHIMEDES policies before sending to the DAC for approval. The DACO also reviews requests for Institutional Data Contributor and Institutional Data User credentials.

Ethical oversight

Ethics approval for the contribution of research participants' data in ARCHIMEDES is sought by Institutional Data Contributors to the local REB responsible for ethics oversight of each Data Set, and information on the contribution to ARCHIMEDES should be provided in the research participant Informed Consent Forms, when required.

Ethics approval for the creation of ARCHIMEDES was obtained from Ottawa Health Science Network Research Ethics Board (OHSN-REB) Protocol ID #20250418-01H.

Management

ARCHIMEDES OHIRC operations, staffing and finances are managed by the ARCHIMEDES Co-Chairs. ARCHIMEDES McGill operations, staffing and finances are managed by the ARCHIMEDES McGill lead. uOttawa manages the BHI funds contributed to ARCHIMEDES and is responsible for ensuring that ARCHIMEDES is implemented in a manner consistent with the Program's vision, governance requirements, and funding obligations.

Financing

ARCHIMEDES is undertaken thanks in part to funding from uOttawa awarded by the Government of Canada's Canada First Research Excellence Fund (CFREF) for the BHI Program as well as partnership matching funds from OHIRC and in-kind data-infrastructure contributions from McGill.

Ongoing funding sources will be sought to ensure the financial sustainability of ARCHIMEDES.

APPENDIX C – TERMINOLOGY GUIDE

COMPARISON BETWEEN PRIVACY TERMINOLOGY SET OUT IN LAWS AND THE RESEARCHER FRIENDLY TERMS SET OUT IN THIS FRAMEWORK

Legal / Statutory Terms	Equivalent Term	Equivalent Form of Agreement
Institutional Data Contributor **discloses** data	Institutional Data Contributor **contributes** data	Data Sharing Agreement = Data Contribution Agreement
PI **discloses** data on behalf of the Institutional Data Contributor	PI **contributes** data	Data Contribution Form
OHIRC (ARCHIMEDES) **collects** data	OHIRC (ARCHIMEDES) **ingests** data	Data Sharing Agreement = Data Contribution Agreement
OHIRC (ARCHIMEDES) **discloses** data to Institution	ARCHIMEDES r**eleases** data to Institution	Data Disclosure/Research Agreement = Institutional Data Access Agreement
OHIRC (ARCHIMEDES) **discloses** data to PI/researchers	ARCHIMEDES **releases** data to PI/researchers	Data Access Request Form