NETWORK DATA ACCESS COMMITTEE (DAC)

Terms of Reference

Background

This Network Data Access Committee (DAC) Terms of Reference is a pilot and will be adapted through consultation and piloting of the Network data access procedures. The elements of this terms of reference are derived from the Global Alliance for Genomics and Health, Data Access Committee Guiding Principles and Procedural Standards Policy (2021), and informed by a review of best practices in access governance across Canada and internationally, as well as consultation with MOHCCN stakeholders.

1. Mandate

The Network DAC reviews and approves data access requests/Studies to ensure timely access to Network data (data made available for sharing across the Network) and compliance with Network policies and agreements.

2. Governance

The Network DAC is established by Terry Fox Research Institute (TFRI) in consultation with Network Council, with appropriate input from the broader Network. This responsibility includes establishing these Terms of Reference, as well as appointing the initial DAC Chair and members. The Terms of Reference shall be periodically reviewed and revised depending on the volume and complexity of requests.

3. Independence

The decisions of the Network DAC are generally binding on data-contributing institutions and researchers, who have agreed (through the Network Master Agreement and policies) to implement Network DAC approvals. Each data-contributing institution will be responsible for granting the corresponding user permissions for their data to the requesting institutions in a timely manner.

4. Principles for Reviewing Access Requests

The DAC will strive to make access decisions in a timely, consistent, transparent, and fair manner. Review criteria and timelines shall reflect the context of sharing coded genomic and related health data (no biospecimens). General review criteria include the following (which can be further specified for specific contexts in the **Data Access Procedures**).

General	The Study is compatible with the objectives of MOHCCN (to advance biomedical research and improve cancer prevention, diagnosis, and care)
PI bona fides	PI is a bona fide researcher (e.g., qualifications, affiliation, track record).
Scientific feasibility	The Study is scientifically sound. The Study is specific enough to constitute a single project. Access to Network Data is necessary to conduct the Study.
Ethics	Evidence of local REB approval for the Study, which should consider: - Compatibility of Study objectives with Network consent principles. - Minimal risk of privacy to individuals or stigmatization of communities.
Privacy/security	List of research team members (under PI responsibility) to have access to data.

5. Composition

The DAC shall consist of a minimum of **7** active members with different forms of expertise/experience (minimum 2 bioinformaticians, 2 clinical researchers, and 2 ethical/legal experts). Not all members need to attend each meeting/review each request (see Quorum below). This membership composition ensures alternative members are available to review requests at any given time. Membership should also reflect the regional diversity of the Network. The DAC may request input from (non-voting) invited experts (including patient representatives) to review particular Studies. Members will participate voluntarily as part of their Network participation; no funds are available to compensate members. The DAC may be expanded to include 1-2 patient representatives as (voting) members, conditional on appropriate training and support.

Individual DAC Member Responsibilities:

- To be familiar with the Network Data resource and the Network agreements and policies.
- To handle data access requests and communications confidentially.
- To carry out reviews and other responsibilities in a timely manner.
- To declare any real or perceived conflicts of interest, in recognition of the MOHCCN Code of Conduct, future Network policies, and community standards. Members will not participate in discussion or voting where they have conflicts.

a. **Appointment:** The DAC Chair and members will be appointed by TFRI with endorsement from Network Council for a term of 2 years (renewable). TFRI may request nominations from the Network, e.g., from the DAC, Steering Committee, Network Council, and/or Network leadership. An effort will be made to stagger terms so not all members are replaced at the same time. Regional representation shall be considered when making appointments.

b. **Membership Changes:** Any additions or changes in membership will be reflected on the table below and communicated to Network Council for endorsement.

Chair	Institutions	From	Until
PM2C			
BC2C			
MOH-Q			
PR2C			
ACC			
Secretariat			

Membership Table Last Updated: January 2024

6. Management and Administration

Quorum – Meeting quorum will be **3** members attending online or submitting written recommendations in advance and should generally include at least 1 expert of each type above (clinical research, bioinformatician, and ethical/legal). This permits the DAC to divide up requests to multiple sub-committees. The DAC Chair shall ensure that a sufficient number and diversity of reviewers are assigned to a particular request. A meeting Chair may be appointed by the DAC Chair if the Chair cannot attend.

Time commitment - The DAC will meet at a minimum on a monthly basis (by web conference or similar means) to respect a maximum review timeline of 1 month. Members unable to attend a meeting in person may participate in advance by reporting their recommendations and comments in writing. Data access requests will be circulated to the Committee in advance to facilitate off-line review. The Chair will facilitate declaration and handling real or perceived conflicts of interest. Decisions will be made by consensus (or in case consensus can't be

reached by the Chair). Decisions may range from approval, refusal (with written reasons), or request for more information.

Data Access Secretariat – The DAC will receive appropriate administrative support from a Data Access Committee Secretariat e.g., with handling requests and managing meetings. This Secretariat role may be fulfilled by TFRI staff or may be delegated to a separate organization at TFRI's discretion.

7. Standard Operating Procedures

The DAC will follow the **Data Access Procedures** developed by the Data Policy and Standards Committee (DPSC), covering the receipt and review of access requests, communication, and implementation of access decisions, as well as the tracking of access approvals.

8. Periodic Reporting

The DAC will report metrics quarterly to TFRI to support Health Canada reporting, and annually to Network Council to support periodic review (e.g., number of requests/approvals/refusals; average time of review; common reasons for refusal; Study outputs). Reports may also be used to develop guidance for requestors (e.g., most common reasons for refusal).

9. Appeals

Where an application is rejected by the DAC, the requestor may request a review by the DAC, providing appropriate details. If further review is required, the DAC may consult TFRI and Network Council, who may recommend additional resources or external reviews.

10. Terms will be Updated and Reviewed

Terms will be modified and reviewed as needed, to reflect the evolution of the project. They will be reviewed annually and approved by the Network Council.

MOHCCN Data Access Procedures (January 31, 2024)

Introduction

This document describes the Marathon of Hope Cancer Centres Network (MOHCCN) procedures to ensure data access is provided in a timely manner in compliance with Network agreements and policies. This "Pilot" version focuses on access currently permitted under the Network Master Agreement/Joinder – Phase I, in order to support the launch of initial Network data-sharing activities.[1] This version is limited to organizational procedures, which will be piloted and linked to technical infrastructure development as part of Pathfinder activities. These data access procedures are maintained by the MOHCCN Data Policy and Standards Committee.

<table>
<tr><th colspan="2">Pilot Procedure to Access Network Data</th></tr>
<tr><td colspan="2">Scope: These pilot access procedures only apply to:
Studies led by an Investigator who is based at a "Network Institution" (i.e., institution that is a signatory to the Network Master Agreement/Joinder).
Investigators who are individual members of the Network (see Individual Membership Policy).
Access to data no longer subject to the Team Access Embargo period of 0-6 months (see Data Access and Use Policy).
Access to controlled-access data (see Data Privacy Policy).</td></tr>
<tr><th colspan="2">Data-requesting Institution</th></tr>
<tr><td colspan="2">Data-requesting Institution joins as Network Institution by signing Network Master Agreement/Joinder. This constitutes institutional acceptance of the "Terms of Data Access and Use", a global legal agreement enabling data sharing for all approved Studies.</td></tr>
<tr><th colspan="2">Data-requesting Researcher(s)</th></tr>
<tr><th>Single PI-led Study</th><th>Collaborative Study (Multiple PIs, institutions, and/or provinces)</th></tr>
<tr><td>Designs Study and drafts Protocol (using Platform metadata, open access data, data discovery).</td><td>Designs Study and drafts Protocol (using Platform metadata, open access data, data discovery).</td></tr>
<tr><td>Obtains local REB approval for Study.[2]</td><td>DAC may accept a single REB of record (if permitted by institutional policy).</td></tr>
<tr><td>Submits Data Access Request form to Network DAC.</td><td>May submit a single Data Access Request form with multiple lead applicants. Each</td></tr>
</table>

[1] The access procedures will be expanded to cover the broader types of access envisaged by the Network in future phases of MOHCCN.

[2] "MOHCCN guidance for local REB review" to be developed. Local REB can be directed to consider alignment of the Study with MOHCCN Consent principles.

	institution requiring data access must list a lead applicant.

Network DAC Secretariat Review (expected timeline: 3-5 business days)
Conducts an initial administrative review confirming the following: • Completeness and consistency of **Data Access Request** form and supporting documents. • Institution of requesting researcher is a Network Institution. • Lead applicant is employed or affiliated with a Network Institution. • Lead applicant is a PI able to take responsibility for research and supervision activities. • All accessing team members (e.g., supervised students and technical staff) are individually listed, affiliated with the same institution as the lead applicant, and under the lead applicant's responsibility. [After Study approval, members can be added on request to Secretariat.]
Circulates compliant requests to Network DAC members for review.

Network DAC Review (expected timeline: 2 weeks-1 month).	
Members review access requests according to **review criteria** below. *Note: these are 'expedited' criteria specific to the context of the initial pilot phase and may need to be adapted for subsequent phases (e.g., access outside the Network; commercial access).*	
Study is "non-commercial academic research"	No production or manufacture of products for general sale. No commercial exploitation of data. No data access by for-profit organizations/sponsors (except aggregate results). May be industry-sponsored.
Scientific Feasibility	Study is scientifically sound. Study is specific enough to constitute a single project. Access to Network Data is necessary to conduct the Study.
Purpose / Ethics	Study aims are compatible with MOHCCN (to advance biomedical research). Study does not aim to present risks to the reputations of care-providing Sites (e.g., comparative performance research across Sites based on outcomes or quality of care) without express written permission of each Site. Evidence/applicability of local REB approval.
The Network DAC convenes at least monthly and issues a decision (approval, request for clarification, refusal with written reasons).	
For approvals, the Network DAC or Secretariat sends an **Implementing Email** (TBD) to the relevant parties. In light of the existing contractual framework (see above), Network Members are not required to negotiate and execute new data access and use agreements for each specific Study.	

Data-Contributing Institution(s) Implement Approvals (expected timeline: 3-5 business days)
Implements permissions for approved user(s) and provides data access.[3]
Approved and Authenticated Data User
If data is still subject to Network Access Period (6-18 months), Data User shall post a description of a proposed cross-cohort analysis to the Network mailing list 1 week in advance. Data User is expected to give Data-contributing teams notice of planned cross-cohort data analyses.
Tracking
Network DAC and Data-Contributing Institution(s) shall track duration of access and terminate access (or request data destruction/return) after 2 years (with 30-day notification and potential for renewal). Data Receiving Institution and researcher will also be obligated to cease access / destroy or return data at the end of the Study (see **Data Access and Use terms).**
Approved Data User will immediately inform DAC Secretariat of any changes to the Study.
Lay summaries of approved Studies are published on the MOHCCN website.
Amendments
Administrative amendments can be approved directly by DAC Secretariat. Minor amendments may be subject to expedited approval by the DAC Chair (as determined by the discretion of the Chair). Significant amendments (e.g., Study aims) may require full DAC review.
Periodic Reporting
DAC periodically reports access metrics to Network Council (e.g., # of requests/approvals/refusals; average time of review; common reasons for refusal; Study outputs).

[3] Exceptionally, a Data-Contributing Institution has a right to refuse access or transfer of Network Data on reasonable grounds, such as a conflict with legislation, REB, or consent terms (see **Network Master Agreement, Data Access and Use Terms**), though such refusals are expected to be rare. The refusal and supporting reasons and documentation must be reported to the Network DAC and the Requestor (expected timeline: 3-5 business days).