NATIONAL DIABETES REPOSITORY RESEARCH GOVERNANCE FRAMEWORK AND GUIDELINES

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1. Overview

Diabetes Action Canada strives to ensure secure access to data for uses consistent with Diabetes Action Canada's mission, while maximizing opportunities for patient- and research-informed decision making. Since Diabetes Action Canada is a research entity at the University of Toronto, our guidelines adhere and comply with University of Toronto Policies. In addition, involving patients and providers in governance activities builds our capacity to perform patient-oriented research. This fulfills the Canadian Institute of Health Research (CIHR) Strategy for Patient Oriented Research (SPOR) principle that patients need to be involved in all aspects of the research to ensure questions and results are relevant and can be integrated into practice.

The **Research Governing Committee (RGC)** has been established to provide oversight for data requests involving secondary data analysis and to ensure that decisions made, pertaining to the National Diabetes Repository, are in the best interest of the patients.

What is Secondary Data Analysis?
Secondary Data Analysis is a term used to identify research that is done with data that was collected for another purpose. For Diabetes Action Canada, this is the analysis of data that was originally collected by physicians for direct patient care (primary purpose). This data was then made available for research use (secondary purpose). It is stored in the Repository.

What is the Difference between Data Governance and Information Governance?
Data Governance deals with how the data is stored and maintained whereas *Information Governance* deals with who gets access to the data and how it is used.

Our focus will be on **Information Governance.**

- **Who is requesting access to the data?**
- **What is their purpose for using the data?**
- **How will the data be used?**
- **Will the benefits of the research to those living with diabetes outweigh any concerns?**

To answer these questions, the RGC will review submitted applications and will draw upon any external advice it deems necessary.

Our overarching goals complement the 4 areas of focus indicated above and can be summarized in the following statement:

We will develop a process that permits use of the data in the National Diabetes Repository to enable research and discovery which will improve the lives of Canadians living with Diabetes. We will ensure that the right people will receive access to the data, and that all requests will be in line with legal, privacy and confidentiality obligations. We will align to the Governing Principles that are outlined in the following section. The guidelines will ensure consistency, transparency as well as accountability. We will earn and maintain the trust of patients, partners and the public.

2. Governing Principles

Our RGC governance process is guided by eight principles as summarized below:

1. **Transparency**

   All decisions, policies, and practices of the RGC are freely accessible to those affected by the decisions and to the public.

2. **Accountability**

   The RGC is accountable to those who will be affected by its decisions or actions.

3. **Following the rule of law**

   The RGC will ensure compliance with applicable laws, regulations and standards.

4. **Integrity**

   The committee will ensure that uses of the data have a clear patient/public interest consistent with the intended purpose of the repository, are of high scientific and ethical integrity; and are maintained in a secure and private manner.

5. **Participation and Inclusiveness**

   Patients and their families, health care professionals, and researchers should participate in governance over data.

6. **Impartiality and independence**

   The RGC will attempt to reach a broad consensus on what is in the best interest of those living with diabetes and their families. All members in the process must look beyond their personal interests as patients, health care providers, or researchers.

   In addition, the committee will operate in a zone of bounded independence from management, to ensure that its decisions are free from institutional conflicts of interest.

7. **Effectiveness, Efficiency and Responsiveness**

   Governance of the data should ensure the objectives of Diabetes Action Canada are met effectively and efficiently.

8. **Reflexivity and Continuous Quality Improvement**

   The RGC should allow research to proceed in the face of uncertainty; and incorporate continuous learning and quality improvement from prior experiences with data use.

3. Structure of the Research Governing Committee

Members will consist of:

a) **Six people with experience living with diabetes – both patients and their caregivers.**
b) **Two health care professionals who are contributing their electronic medical record data.**
c) **Two researchers with relevant expertise in database research and clinical trial design.**
d) **Two persons with relevant experience in Research Ethics, Privacy, and/or Law.**
e) **The data repository project manager or other administrative staff (non-voting).**

Members appointed to the RGC will hold the position for 3 years, nominally, and as far as possible turn-over will be staggered. There will be 2 co-chairs. One will be from among the patient representatives, the other from among the other members.

Patient members will be drawn from recommendations of the Collective Patient Circle. The final choice will be made by the RGC maintaining or enhancing diversity in type of diabetes, age, sex and gender, geographic location, language, patient/caregiver, and co-morbidities.

Data provider members will be nominated by all organization who provide data to the RGC, then selected by the RGC, again ensuring diversity, especially geographic diversity.

Reporting Structure: The RGC provides and accepts input from the Diabetes Action Canada operations management and the Repository Project Manager. It operates at "arm's length" from management, reporting only to the Diabetes Action Canada Steering Council.

The RGC exchanges information with the Collective Circle, accepting direction from the patients and reporting on research activities. To do this the patient co-chair of the RGC is available to attend Collective Patient Circle meetings as required.

Similarly, RGC exchanges information with the Data Provider Advisory Group or the Data Provider source organizations.

Steering Council: The steering council oversees all aspects of the workings of the Diabetes Action Canada network. It ensures that the Vision and Mission of the SPOR Network are fulfilled. It monitors governance performance and manages conflicts.

Operations/Management: This committee is responsible for advising the Scientific Co-Leads and the SPOR Network Management on all activities of the Network. All research and management activities are brought forward to this committee which in turn reports to the Steering Council.

4. Data request and oversight process

Stage and description of activities

1. Researcher completes an online access request form outlining the project, data elements, methodology and timeframe. This is electronically submitted to the Repository Manager for review.
2. Repository Manager will review the application with the Data Manager to ensure that the data requested will be sufficient for the proposed analyses. Applications with any potential issues or concerns are flagged for further clarification with the Researcher.
3. An initial consultation (phone or in-person) will be held with the researcher to discuss how they will meet the purpose, scientific, and ethics integrity requirements and to describe their plans for Research Ethics Board (REB).
   Once the Repository Manager confirms the researcher meets the qualifications and requirements, the proposal will be reviewed by our Scientific Advisory Committee (SAC) to look into the scope of methodology and the scientific integrity. If the researcher has already received peer-review (such as CIHR), then it can skip the SAC stage and move to the next step, review by the RGC.
4. RGC members review all applications. This provides an opportunity for input from patient and provider members of the committee - chiefly to ensure that the project will be carried out with the best interests of the patients at the forefront.
5. The Committee members will aim for a consensus-based agreement, unless a contentious issue triggers need for consultation with the Steering Council. The Steering Council will be asked to provide guidance on how to proceed with an application or to seek general policy direction.
6. After the project has been approved, the Repository Manager will send the Researcher a Confirmation of Feasibility package which will include: a quote for services, Conflict of Interest Declaration (COI), Confidentiality Agreement (CA), letter of approval from the RGC and reiterating the requirement for REB approval.
7. The researcher will submit an application to a REB and will provide (if not already done), the approval letter from the REB along with the COI and CA.
8. Once the project has been approved, and all documents have been received, the Repository Data Manager will work with the Researcher to create a Data Set Creation Plan (DCP). The DCP will outline the data requirement, timeframe and any limitations. This will be acknowledged by the Researcher approving the data set.
9. A Research and Data Access Agreement will be prepared by the Data Manager and signed by the DAC Executive Director or designate, the Researcher, and the Researcher's Institutional Authority (if applicable)
10. All members of the project team will be required to sign a Confidentiality Statement and Conflict of Interest Declaration.
11. After all documents have been received, the Researcher will be provided a Username and Password with instructions on how to access their space on the secure analytic virtual environment.

12. Participatory approach to interpretation of findings: for those projects that were deemed contentious in (4-5) the Researcher shall provide the Research Governing Committee an opportunity to:
    a) Review results at this stage to ensure patient and provider representatives can add their insights into the findings and pose solutions that could make a difference in the lives of patients with diabetes, and;
    b) For Health Care Professionals, this review provides an opportunity to comment to any impacts of the research at the policy level.
13. Once the Researcher has created their manuscript-ready outputs, they will email the Repository Data Manager and request the output.
14. The Repository Data Manager will analyze the risk of re-identification, and once satisfied; the outputs will be emailed to the researcher.
15. Researcher prepares final report and will notify Diabetes Action Canada 30-days prior to publication.

5. Terms of reference for Research Governing Committee

In this section, we review the terms of reference for the Research Governing Committee

Parameter	Description
Type of committee	Standing
Purpose	– Receive updates and reports on research applications to ensure alignment with DAC mission, goals and principles. – Review and approve data access requests. – Refine data access policies as particular use-cases become clear. – Quality and continuous learning in governance process: o Ensure data access policies and processes are in place and working appropriately. o Review how well the services are able to accommodate the research questions being posed.
Scope	– Limited to publicly funded observational projects conducting Secondary Data Analysis.
Authority	– Decisions are subject only to review by the Steering Council. – Makes recommendations to Operations/Management Committee regarding revisions to policies.
Membership	– 12 members, including 2 co-chairs. o 6 people with experience of living with diabetes. They will represent 50% of the RGC members o 2 Physician or other data provider representatives, nominated by data provider organizations and selected by the RGC. o 2 Researchers with relevant experience in: database research and clinical trials design. o 2 persons with relevant experience in Research Ethics, Privacy, or law. – Subject matter experts may be called upon, as required to address specific issues when members do not have the expertise. – Members will be appointed for 3 years. – There will be 2 co-chairs. o One of these will be from among the patient representatives. The other from among the remainder of the members.

Parameter	Description
	○ After the first year, each co-chair will be required to have served one year on Committee before taking office.
Meeting arrangements	– Meetings of approximately 90 minutes will be held every 2 months (or as determined). Subsequent meetings will be conducted remotely (teleconference or web-based meeting). – Quorum will consist of: ○ at least three patient representatives ○ at least one data provider representative ○ at least one researcher ○ at least one legal, ethics, privacy representative ○ 50% of members +1 – Agendas and minutes ○ TBD
Reporting/ Accountability	– The RGC will be accountable to the Steering Council. It will Advise via the Repository Sr. Project Manager the Operations/Management Committee as required. – Individuals representing the patient advisory group will also have a liaison and reporting role with their respective advisory groups.
Deliverables	– Reporting to the Steering Council and Operations/Management Committee as needed.
Review frequency	– Annually at the beginning of academic year.

Application number

Appendix 1. Application form for data use and linkage only

Diabetes Action Canada Study Application Form For Secondary Analysis of Data

Important Please Note: Please complete *ALL* un-shaded fields.	
Study Title:	Long-form title: Working title:
Applicant:	
Title/Full Name:	
Address:	
Daytime Telephone Number:	
Email:	
Principle Investigator (if different from applicant):	
Title/Full Name:	
Address:	
Daytime Telephone Number:	
Email:	
Sponsor:	
Budget related to this request (with justification)	

Scientific and Ethics Review:	
Has there been external scientific review of this protocol?	☐ Yes, this protocol was part of a larger peer-reviewed grant. Please describe the reviewing organization.
	☐ Yes, this protocol specifically was peer-reviewed. Please describe the reviewing organization and attach reviewer's feedback.
	☐ No
Do you have research	☐ Yes – Which REBs have or will be reviewing this

ethics approval for this study?	protocol? Please include the REB correspondence with your application. If no revisions were required, please indicate.
	☐ In progress – Which REBs are reviewing this protocol?
	☐ Seeking REB review after DAC approval.
	☐ No – Please provide written correspondence with your REB indicating why not required.
Does this study have any proprietary or commercial element to it?	☐ Yes – Please describe:
	☐ No

Project Details (maximum 500 words):
Background: [Describe the underlying clinical scenario / issue.]
Research questions/Study aims:
Data fields required: Demographic (e.g. age range, gender) Diseases (List all relevant diseases) Medicines (List all relevant) Other
Please describe your sampling frame:
Patient outcomes being measured:

How will this research benefit people who are living with diabetes or the general public?
What are the potential research-related risks to this study? (Include policy or social implications.)
How will these risks be mitigated?
In what way(s) have patients or their families or caregivers been involved in the planning of the research?
How are sex and gender issues being addressed in this study? (See CIHR guidance: http://www.cihr-irsc.gc.ca/e/50836.html)
What are your plans for data linkage? ☐ No plans for data linkage ☐ Yes, plans for linkage. Please describe:

Form to be signed off by the P.I. and dated.

Signed _____

Date _____

Please attach Protocol, REB approval, scientific review feedback, and any other third-party feedback on the protocol.