

**DIABETES ACTION CANADA (DAC)**
**PROOF OF CONCEPT NATIONAL DIABETES RESPOSITORY**

Subject	Project Adjudication	SOP#	DACNDR-PA001.0
Document Number	001	Author	Conrad Pow
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## 1. GENERAL INFORMATION

The aim of this standard operating procedure (SOP) is to outline the eligibility criteria and the adjudication process for project requests.

## 2. SCOPE

This document is intended for all DAC staff and for DAC researchers wishing to conduct a secondary data analysis project using data housed in DAC's National Diabetes Repository.

## 3. ROLES AND RESPONSIBILITIES

**3.1 DAC Repository Manager (Conrad Pow):** Responsible for the overall operations (recruitment, developing policies and procedures, site relationship) and communication regarding the DAC Repository.

**3.2 DAC Repository Data Manager (Tao Chen):** Responsible for data extraction, processing, quality check, destruction, reports, transfer, secondary data usage, and managing the data dictionary; responsible for updating the DAC Repository Manager on changes or problems with the DAC Repository.

**3.3 DAC Repository Research Administrator (Aashka Bhatt):** Responsible for managing the participant database and facilitating meetings.

**3.4 DAC Researcher:** Responsible for ensuring that all project team members, including self, are familiar with the DAC Policies and Procedures pertaining to the National Diabetes Repository. Will be responsible for ensuring that all project team members have signed COI statement. Will be responsible for the management and oversight of the project.

**3.5 DAC Repository Scientific Advisory Committee (SAC):** The SAC is made up of 3 members. The SAC is responsible for reviewing projects proposing to access data in the DAC Repository. The SAC will review the scientific merit and methodology of the project.

**3.6 DAC Repository Research Governing Committee (RGC):** The RGC will ensure that the focus of the proposed project is aimed at what is in the best interest of the patient and that aligns with DAC's mission and values.

#### 4. SECONDARY DATA USAGE

Data in the DAC Repository will only be available to DAC researchers wishing to conduct secondary data analysis. Once approved, they will be given remote access to a specified data cut at the Centre for Advanced Computing Canada (CAC).

#### 5. ELIGIBILITY CRITERIA AND ADJUDICATION PROCESS

DAC Researchers will electronically fill and submit an Access Request Form as outlined in the project submission SOP: **NDR –PSAP001.00**. In order for the project to qualify to use the National Diabetes Repository, a number of conditions must be met.

- 1: Project Importance: The objectives of the project must be targeted to transform and enrich the lives of patients living with diabetes. This includes preventing complications, transforming diabetes care, improving outcomes and quality of life...)
- 2: Methodological Quality: A credible review (e.g. CIHR) will be required to ensure the methodology is sound. If a credible review has not been completed, the project **must** be reviewed by the Scientific Advisory Committee.
- 3: Project Feasibility: The project scope, timelines, REB and funding will be reviewed to ensure that the project can be completed as requested. Any findings will be provided to the Researcher.
- 4: Study Team: The Principle Investigator **must** be a DAC Researcher. All project team members must sign a Conflict of Interest Declaration.
- 6: Translation of Knowledge into Practice: The project should include a plan for integrated KT where patients, stakeholders and potential knowledge users are engaged in the entire research process. This also includes providing feedback to DAC and each participating PBRN.
- 7: Potential to Contribute to DAC’s Research Reputation: All work must be aligned with DAC’s Mission and Values. Any research should not provide a reputational risk for DAC, where direct, indirect or perceived.

#### 7. DEFINITIONS AND ABBREVIATIONS

<b><i>Organizations</i></b>	
<b>CAC</b> (Centre for Advanced Computing)	The Centre for Advanced Computing located at Queen's University, is a consortium comprised of Carleton University, University of Ottawa, the Royal Military College of Canada, and Queen's University. They provide high availability, secure, advanced computing resources and support for academic and medical researchers.
<b>CIHI</b> (Canadian Institute for Health Information)	CIHI is an independent, not-for-profit organization that houses a broad range of health system databases, on Canada’s health system and the health of Canadian. It conducts its own research and makes the data available for external researchers. For more information, visit: <a href="https://www.cihi.ca/en">https://www.cihi.ca/en</a>

<b><i>Organizations</i></b>	
<b>CIHR</b> (Canadian Institute for Health Research)	As the Government of Canada's health research investment agency, the Canadian Institutes of Health Research (CIHR) supports excellence across all four pillars of health research: biomedical; clinical; health systems services; and population health. Their mandate is to "excel, according to internationally accepted standards of scientific excellence, in the creation of new knowledge and its translation into improved health for Canadians, more effective health services and products and a strengthened Canadian health care system.
<b>DAC</b> (Diabetes Action Canada)	Diabetes Action Canada is a chronic disease network within SPOR focusing on diabetes and its related complications. More information may be found at: <a href="https://diabetesaction.ca/">https://diabetesaction.ca/</a>
<b>SPOR</b> (Strategy for Patient-Oriented Research)	Patient-oriented research refers to a continuum of research that engages patients as partners, focusses on patient-identified priorities and improves patient outcomes. The objective of SPOR is to foster evidence-informed health care by bringing innovative diagnostic and therapeutic approaches to the point of care, so as to ensure greater quality, accountability, and accessibility of care.
<b><i>Technical terms</i></b>	
<b>Data providers</b>	For our purposes, data providers are health care providers who participate in contributing their EMR data for our data safe haven. Currently, all our data providers are from primary care practices and mostly physicians. In future, data providers may extend to other groups that hold patient-level information that will reside in our data safe haven.
<b>PBRN</b> (Practice-Based Research Network)	A practice-based research network (PBRN) is a group of practices devoted principally to the care of patients and affiliated for the purpose of examining the health care processes that occur in practices.
<b>REB</b> (Research Ethics Board)	REB is an independent ethics committee created by organizations that helps ensure that all the proposed or ongoing research in their organization that involves human subjects meets the highest ethical standards and that safeguards are implemented to provide the greatest protection to human subjects.
<b>RGC</b> (Research Governing Committee)	Governance is a term that has no single agreed-upon universal definition. The Institute on Governance suggests: "Governance is how society or groups within it, organize to make decisions." Further, they (and others) suggest that there are three key issues: <ol style="list-style-type: none"> <li>1. Who has a voice in making decisions?</li> <li>2. How are decisions made?</li> <li>3. Who is accountable?</li> </ol> <p>The DAC Governance Committee is comprised of 50% patients and 50% professionals and Subject Experts.</p>