

DIABETES ACTION CANADA

PROOF OF CONCEPT NATIONAL DIABETES RESPOSITORY

Subject	Record Retention	SOP#	Diabetes Action CanadaNDR-RR001.00
Document Number	001	Author	Conrad Pow
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1. GENERAL INFORMATION

This standard operating procedure (SOP) is to outline and define the responsibilities and processes regarding the Record Retention Policy.

2. SCOPE

This document is intended to outline the record retention process once a project has been formally closed. This SOP will provide an understanding for all Diabetes Action Canada Researchers, Diabetes Action Canada staff and Diabetes Action Canada Committee Members.

3. ROLES AND RESPONSIBILITIES

3.1 Diabetes Action Canada Repository Manager: Responsible for the overall operations (recruitment, developing policies and procedures, site relationship) and communication regarding the Diabetes Action Canada National Diabetes Repository.

3.2 Diabetes Action Canada Repository Data Manager: Responsible for data extraction, processing, quality check, destruction, reports, transfer, secondary data usage, managing the data dictionary and user account creation; responsible for updating the Diabetes Action Canada Repository Manager on changes or problems with the Diabetes Action Canada National Diabetes Repository.

3.3 Diabetes Action Canada Repository Research Administrator: Responsible for managing the participant database and the facilitation of meetings.

3.4 Diabetes Action Canada Researcher: Responsible for ensuring that all project team members, including self, are familiar with the Diabetes Action Canada 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.

4. PREREQUISITE

This SOP will take effect once the Project Closure process has taken effect. Please see SOP **Diabetes Action CanadaNDR-PC001.00**

5. RECORD RETENTION GUIDELINES

- 1: Approvals from Research Ethics Boards (REBs) include language regarding the limits of use, disclosure and retention of data. These guidelines must be adhered to. Additionally, some funders may have terms requiring researchers to retain data for a defined period of time. If there is any ambiguity, the maximum term should be used.
- 2: Our goal is to retain data before and after publication of research results, in order to respond to comments, rebuttals and/or allegations of research misconduct. At a minimum, data should be retained for a minimum of 5 years.

6. DEFINITIONS AND ABBREVIATIONS

<i>Organizations</i>	
CAC (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.
CIHI (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: https://www.cihi.ca/en
CIHR (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.
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: https://diabetesaction.ca/
SPOR (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.
<i>Technical terms</i>	
Data providers	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,

Technical terms	
	data providers may extend to other groups that hold patient-level information that will reside in our data safe haven.
DCP Dataset Creation Plan	This document outlines the specific requirements for the data needed for the study. It will list the data elements, timeframe and study cohort. This document will be created by the research in consultation with the Repository Data Manger.
Retention Period	This period defines the term of the project specific dataset. Usually this is outlined in the REB approval document. If not, it will be decided and agreed upon between the Researcher and Repository Manager, outlined in this SOP.
Secure Environment	Secure Environment is the term we use to represent the secure researchable database comprised of de-identified patient records extracted from electronic medical records (EMRs).
REB (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.
Research Governing Committee (RGC)	<p>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:</p> <ol style="list-style-type: none"> 1. Who has a voice in making decisions? 2. How are decisions made? 3. Who is accountable? <p>The Diabetes Action Canada Governance Committee is comprised of 50% patients and 50% professionals and Subject Experts.</p>