

DIABETES ACTION CANADA

PROOF OF CONCEPT NATIONAL DIABETES RESPOSITORY

Subject	Project Closure	SOP#	Diabetes Action CanadaNDR-PC001.00
Document Number	001	Author	Conrad Pow
Version Number	1.0	Reviewer	
Superseded Version	Draft	Reviewer Date	
Effective Date	05/07/2018	Status	

## 1. GENERAL INFORMATION

This standard operating procedure (SOP) is to define the key aspects involved in the Project Closure process.

## 2. SCOPE

This document is intended to outline the process to formally close a research project. This applies to Diabetes Action Canada Researchers and provide an understanding for all 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. PROJECT CLOSURE PROCESS

**STEP 1:** The Researcher will provide written notice to the Diabetes Action Canada National Diabetes Repository Data Manager to confirm that he/she has completed the analyses in the secure virtual environment and will formally request the research outputs.

**STEP 2:** The Diabetes Action Canada Repository Data Manager will send an acknowledgement email to the Researcher confirming that the notice was received and will email the Researcher the requested outputs.

**STEP 3:** The Diabetes Action Canada Repository Data Manager will:

- A:** Disable the login credentials of the Researcher and for the Analyst (if applicable)
- B:** Archive the project specific dataset as per Record Retention SOP **Diabetes Action CanadaNDR-RR-001.00**
- C:** Verify with the Diabetes Action Canada Repository Manager that no existing financial reconciliation is required.
- D:** Send an email to the Researcher and the Repository Manger once all the steps have been completed.

## 5. 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>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>Diabetes Action Canada</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,

<b>Technical terms</b>	
	data providers may extend to other groups that hold patient-level information that will reside in our data safe haven.
<b>CSV</b>	CSV is a simple file format used to store table style data such as database. Files in the CSV format can be imported to and exported from programs that store data in tables, such as Microsoft Excel. CSV stands for "comma-separated values".
<b>DCP Dataset Creation Plan</b>	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.
<b>Retention Period</b>	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, as applicable by law.
<b>Secure Environment</b>	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).
<b>SSL Connection</b>	SSL (Secure Sockets Layer) is the standard security technology for establishing an encrypted link between a web server and a browser. This link ensures that all data passed between the web server and browsers remain private and integral.
<b>Inclusion criteria</b>	This refers to the clinical (e.g. diabetes, hypertension, etc.) or demographic characteristics (e.g. age, sex) that people or their records must have if they are to be included in the research study.
<b>Exclusion criteria</b>	These are the characteristics that disqualify people or their data from being included in the study.
<b>REB (Research Ethics Board)</b>	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>Research Governing Committee (RGC)</b>	<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"> <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 Diabetes Action Canada Governance Committee is comprised of 50% patients and 50% professionals and Subject Experts.</p>