

DIABETES ACTION CANADA
PROOF OF CONCEPT NATIONAL DIABETES RESPOSITORY

Subject	Researcher Account Creation	SOP#	DACNDR-RAC001.0
Document Number	002	Author	Tao Chen
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1. GENERAL INFORMATION

This standard operating procedure (SOP) is to define the key aspects involved in the creation of Researcher User Accounts for access to the secure analytical environment within Diabetes Action Canada's (DAC) National Diabetes Repository.

2. SCOPE

This document is intended to outline the process for providing access to DAC Researchers and to establish the guidelines for all DAC staff and committee members.

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, managing the data dictionary and user account creation; 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, troubleshooting user problems and delegating appropriately 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 the COI statement. Will be responsible for the management and oversight of the project. Will be responsible for reporting data anomalies encountered during data analysis to the DAC Repository Data Manager

4. PREREQUISITES

Authorized DAC Researchers must have entered into a Researcher Agreement with Diabetes Action Canada and have completed (along with all project team members) a Conflict of Interest Declaration (as outlined in SOP **DACNRD SPO-PSAP 001.0**)

5. USER ACCOUNT CREATION PROCESS

- STEP 1:** The DAC Repository Data Manager will contact the Researcher to create unique login credentials. This will be used by the Researcher to gain access to the secure analytical virtual environment (SAVE) through an SSL Connection.
- STEP 2:** The Researcher will provide the DAC Repository Data manager with an institutional email address and a cellphone number to receive the access credentials.
- STEP 2:** The DAC Repository Data Manager will contact CAC and Indoc in email, copying the Researcher to set up the account.
- STEP 3:** CAC will create a VPN account for the Researcher. They will provide the VPN profile via email, to the Researcher’s institutional email address. They will send the VPN password to the Researcher’s cellphone via text messaging.
- STEP 4:** Indoc will create a login account of the SAVE for the Researcher. They will provide the login username to the Researcher via email, to the Researcher’s institutional email address. They will send the login password to the Researcher’s cellphone via text messaging.
- STEP 5:** The DAC Repository Data Manager will email the Researcher with instructions on how to install, set up and connect to the VPN and how to connect to the SAVE.
- STEP 6:** The Researcher will log into the SAVE and will send an email to the DAC Repository Data Manager confirming access.
- STEP 7:** The DAC Repository Data Manager will move the project-specific dataset to the Researcher(s)’ data folder. The dataset will be provided to the Researcher as specified in the data creation plan (DCP).
- STEP 8:** The Researcher will be notified via email that the dataset has been posted to SAVE for their analyses.
- STEP 9:** The data will remain on the Researcher’s secure desktop for a predefined period of time, as outlined in the REB approval or as discussed and agreed upon with the DAC Repository Data Manager. Following this, the Project Closure procedures will commence, as per SOP **DACNDR-PC-001.00**

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.
Indoc (Indoc Research)	Indoc Research is a not-for-profit organization that provision of technical solutions for health informatics research. They provide technical support to assist DAC in managing the secure analytic environment.

<i>Organizations</i>	
DAC (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>	
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, as applicable by law.
Secure Analytic Virtual Environment (SAVE)	SAVE is the term we use to represent the secure environment where the Researcher and the analyst can remotely access the agreed-upon data set of the National diabetes repository and conduct analysis on the data set with the data analytic tools provided in the environment. The environment has no internet access and is under strict control that no data come in or leave the environment without the permission of the data manager.
SSL Connection	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.
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.