Diabetes Action Canada

DIABETES ACTTION CANADA (DAC)

PROOF OF CONCEPT NATIONAL DIABETES RESPOSITORY

Subject	Project Submission and Approval Process	SOP#	DACNDR-PSAP001.0
Document Number	001	Author	Conrad Pow
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Superseded Version	Draft	Reviewer Date	
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1. GENERAL INFORMATION

The aim of this standard operating procedure (SOP) is to define all key aspects involved in the Submission and Approval of projects requesting to access to data held within DAC's National Diabetes Repository.

2. SCOPE

This document is intended for all projects that have been submitted to the DAC National Diabetes Repository. This applies to DAC staff, DAC Committee Members and DAC researchers wishing to conduct a secondary data analysis project.

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 (RCG): The RCG will ensure 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. SUBMISSION AND APPROVAL PROCESS

STEP 1: DAC Researcher will electronically fill and submit an Access Request Form (Appendix 1) through the Researcher portal at https://repository.diabetesaction.ca. The form outlines the purpose, methodology, requested data elements and timeframe. It also requires a copy of the full research proposal and whether there are any identified or perceived risks.

STEP 2: The Repository Manager and the Repository Data Manager will review the Access Request Form to assess the feasibility of the project based on the data elements requested. This may include a meeting with the Researcher to discuss the data elements requested, project objectives and overall budget.

STEP 3: If the project has been peer-reviewed (eg. CIHR has reviewed and reviewed the submitted protocol) then proceed to Step 4, if not, the Access Request Form and full research proposal will be reviewed by the DAC Scientific Advisory Committee (SAC) to assess the scientific merit and methodology of the project. The researcher will be updated on the scientific assessment by the SAC, if any concerns are raised, the Researcher will be requested to address them prior to the project moving any further.

STEP 4: The Repository Manager will provide the RGC a copy of the Access Request Form to advise on, but not limited to: (1) The project is in the best interest of the patients; (2) The project goals align with institutional mission and values. Once approval has been received from the RGC, the Repository Manager will provide the Researcher with written confirmation that the proposed project is feasible. The Confirmation of Feasibility (COF) letter will also identify the estimated costs for conducting the project.

STEP 5: If the project is not part of a larger REB approval, the Researcher will be required to apply for REB approval. The COF letter can be provided to the REB as supporting documentation assuring DAC supports the project. In addition, the Researcher must submit confirmation of funding (Peer Reviewed Grant, Institutional Funds, Investigator Funds…)

STEP 6: Once REB approval has been obtained, the Researcher will upload the REB approval letter through the Researcher portal on DAC repository website.

STEP 7: The Repository Manager will review the Access Request Form to ensure it aligns with the REB approval.

STEP 8: Upon RGC approval, the Repository Manager will provide the Researcher a DAC Repository Researcher Agreement (Appendix B) and Confidentiality Agreement (CA) (Appendix C).

STEP 9: After both Agreements have been fully executed, the Repository Manager and the Repository Data Manager will work with the Researcher to finalize the required data elements to create a Dataset Creation Plan (DCP). The DCP will be used to create a project specific dataset.

STEP 10: The dataset will be uploaded to the secure workspace for the researcher.

STEP 11: The Repository Data Manager will provide the Researcher the login credentials to remotely access the secure environment.

7. DEFINITIONS AND ABBREVIATIONS

Organizations	
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.
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.
Technical terms	
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, 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.

Technical terms	
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 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).
Inclusion criteria	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.
Exclusion criteria	These are the characteristics that disqualify people or their data from being included in the study.
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)	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: 1. Who has a voice in making decisions? 2. How are decisions made? 3. Who is accountable? The DAC Governance Committee is comprised of 50% patients and 50% professionals and Subject Experts.

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APPENDIX A

ACCESS REQUEST FORM

Application number

Diabetes Action Canada Study Application Form
For studies involving data use and linkage only

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 ethics approval for this study?	☐ Yes – Which REBs have or will be reviewing this 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.

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APPENDIX B

DAC RESEARCHER AGREEMENT

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APPENDIX C

DAC CONFIDENTIALITY AGREEMENT

Confidentiality Agreement
Diabetes Action Canada – National Diabetes Repository

All research assistants, coordinators, data managers and PIs who have access to electronic medical records (EMRs) and are accessing Diabetes Action Canada's National Diabetes Repository shall respect and preserve the privacy and confidentiality of patient and personal information. In particular they shall with respect to any data that it receives from the other Party:

i. comply with all applicable laws to such data and to the Parties, including as applicable the *Personal Information Protection and Electronic Documents Act* (Canada), the *Personal Health Information Protection Act* (Ontario), and any other relevant provincial or territorial laws or regulations;

ii. provide the DAC Repository Manager with a copy of all final research results, and any resulting publications, that are based upon such data;

iii. not attempt to learn the identity of any identifiable individual associated with any Information exchanged between the Parties.

Violation of this policy may result in loss of data access privileges. Unauthorized release of confidential information may also have personal, civil, and/or criminal liabilities and legal penalties attached.

I have read and agree to comply with the terms of the above statement.

Print name	Signature	Date (YY/DD/MM)
_____	_____	_____

Contact information of signee:

address _____

city / Province / postal code _____/_____/_____

phone ( )_____-_____

e-mail address _____

witness (print name)	witness (signature)	Date (YY/DD/MM)
_____	_____	_____