

Appendix 3. Application process for research use of the data in the research repository

DIABETES ACTION CANADA

PROOF OF CONCEPT NATIONAL DIABETES RESPOSITORY

Subject	Project Submission and Approval Process	SOP#	Diabetes Action CanadaNDR-PSAP001.0
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Version Number	1.0	Reviewer	
Superseded Version	Draft	Reviewer Date	
Effective Date	05/01/2018	Status	

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 the Diabetes Action Canada National Diabetes Repository.

2. SCOPE

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

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, and managing the data dictionary; 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 facilitating 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.

3.5 Diabetes Action Canada 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 Diabetes Action Canada National Diabetes Repository. The SAC will review the scientific merit and methodology of the project.

3.6 Diabetes Action Canada 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 Diabetes Action Canada's mission and values.

4. SECONDARY DATA USAGE

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

5. SUBMISSION AND APPROVAL PROCESS

STEP 1: Diabetes Action Canada 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 is 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 National Diabetes Repository 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 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 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 Diabetes Action Canada 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 along with the REB submission.

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

STEP 8: After confirmation of REB alignment, the Repository Manager will provide the Researcher Diabetes Action Canada 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 Repository Data Manager will upload the project specific dataset to the secure workspace for the researcher to conduct analysis.

STEP 11: Once all agreements are in place, the Repository Data Manager will provide the Researcher the login credentials to remotely access the secure environment.



ACCESS TO DATA FOR SECONDARY USE FOR RESEARCH

