

DIABETES ACTION CANADA
NATIONAL DIABETES REPOSITORY

Subject	Decision Making Framework	SOP#	DACNDR-DMF002.0
Document Number	002	Author	Conrad Pow
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1. GENERAL INFORMATION

The aim of this standard operating procedure (SOP) is to define the framework for managing conflict of interest and bias regarding relationships with funders and external parties concerning the Diabetes Action Canada (DAC) National Diabetes Repository.

2. SCOPE

This document is intended for all DAC staff, DAC Committee Members and DAC researchers. It serves to describe the foundational ethical values and principles necessary for the evaluation of submitted projects.

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. CORE VALUES

- 1: Providing excellent and robust data and analytic tools in a secure analytical virtual environment (SAVE), where bias and conflict of interests are mitigated as much as possible.
- 2: Improving patient care and health service delivery with a particular focus on diabetes and its related complications.
- 3: Inclusiveness and collaborative relationships with patients, researchers, clinicians, and stakeholder groups whose mission, values, and practices are in alignment with DAC.
- 4: Transparency and accountability for the surveillance, quality improvement, and research produced.
- 5: Effective stewardship of the data repository created by participating PBRNs ensuring data quality, security and privacy practices are appropriate and meet or exceed local and national regulatory standards.
- 6: No identifiable data regarding healthcare practitioners or patients will be released to Researchers or third parties without REB approval and necessary consents in place.

5. SAFEGUARDING RESEARCH

Any decisions regarding publication and presentation of findings related to research outputs from the DAC National Diabetes Repository rest entirely with investigators. No partner organizations or individuals will be given authority to limit sharing of findings with the public assuming the information falls within the legislated privacy limitations and partnership agreements.

For-profit entities or charities whose mission, values or practices conflict with our values (e.g., companies that manufacture or sell products that are known to be harmful to human health, or that knowingly engage in practices that violate human rights will be excluded from partnerships with DAC’s National Diabetes Repository.

6. CONFLICT RESOLUTION

If conflicts arise or are discovered, the DAC National Diabetes Repository will reserve the right to terminate or reassess the project scope. In accordance with local and national REB standards all projects will be reviewed yearly to ensure compliance with all DAC National Diabetes Repository’s policies and SOPs.

7. DEFINITIONS AND ABBREVIATIONS

<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/

<i>Organizations</i>	
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, data providers may extend to other groups that hold patient-level information that will reside in our data safe haven.
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 Analytical 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.
Research Ethics Board (REB)	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.
RGC (Research Governing Committee)	<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 DAC Governance Committee is comprised of 50% patients and 50% professionals and Subject Experts.</p>

APPENDIX A

DAC National Diabetes Repository Core Values (Expanded)

Empowerment of practitioners and patients

DAC National Diabetes Repository recognizes that demonstrating integrity is essential for building trust among the organizations and people with whom it deals. It is critical for establishing and maintaining an excellent reputation with the Canadian public. We operate with professional integrity to maintain confidence in the organization itself, in its relationships, its data gathering, management and analysis services, its information and knowledge products.

Transparency

The DAC National Diabetes Repository practices being transparent about what it is doing, how and when it is doing it, with whom it is engaged, and what impact it believes the activity or product may or will have. Information is conveyed in timely and appropriate ways to relevant stakeholders and audiences in the spirit of intentional openness. Transparency is created by communicating regularly with participating Practice-based Research Networks (PBRNs), making information available on our website and reporting to our stakeholders. Transparency is a pre-condition for any form of accountability.

Accountability

We appreciate the importance of establishing a highly accountable organizational culture. Attaining and maintaining organizational accountability necessitates our willingness to accept full personal accountability for the assigned roles and responsibilities related to governance, management practices, the implementation of the DAC National Diabetes Repository's strategic plan, and to the delivery of value to internal and external stakeholders. It also requires risk and liability management which DAC National Diabetes Repository mitigates by complying with all ethical, legal, privacy and regulatory requirements and procedures.

Collaboration

Success is supported by our commitment to be a trusted and respected partner and collaborator. When appropriate, we share our skills, talents, knowledge and resources with others who hold a shared purpose and direction. As a pan-Canadian resource we nurture our unique capacity to contribute to the strengthening and advancement of primary healthcare (primary care and public health) research, practice and policy at regional, provincial and national levels through partnership and collaborative initiatives. In the spirit of collaboration, we may serve as a bridge or connector between information technology, healthcare and academia.

Stewardship

DAC National Diabetes Repository is a steward of a data repository containing clinical electronic medical record data from primary care, including Patient-Reported Experience Measures and Patient-Reported Outcome Measures. Referring to data and knowledge product accessibility, we support processes and agreements that enable timely access to accurate and quality data, data sharing, analysis, translation and interpretation, and the information exchange of such. We work to improve ease of use of the above.

DAC National Diabetes Repository remains flexible to enable positive, creative, organized and timely reaction to the needs of the organization, our partners, funders, investors, stakeholders, and the broader community. We endeavor to engage in regular knowledge exchanges at multiple levels to facilitate response to 'environmental' changes and emergent opportunities or concerns.