

**GLA:DTM Canada**

**Data Access Request Manual**

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**INTRODUCTION**

The Data Access Request application form is used to request data from the GLA:DTM Canada database and is intended to be a stand-alone document. This manual provides supporting information that may be useful in completing the Data Access Request Form (note the section numbers in this manual do not always align with the numbering on the application form as some aspects of the form do not require explanatory information in the manual). It is also highly recommended that applicants familiarize themselves with the GLA:DTM Canada Data Access Policy.

**Planning and Completion of the Data Access Request**

Specific information is required about your project in order for the GLA:DTM Canada Data Access Committee to adjudicate it and to allow preparation of the data.

**Summary of the Data Access Process**

The data access request process and release of data are dependent on satisfactory completion of the Data Access Request Form, obtaining ethics approval for the process, and demonstration of funding or sufficient resources to complete the project. The approval process is not automatic and requires attention to detail in completing the request form. The GLA:DTM Canada data have been collected in compliance with ethics and privacy legislation (i.e. each provinces/territories’ legislation) governing each of the sites providing the GLA:DTM Canada program to individuals with hip and knee osteoarthritis. Each request for data is evaluated against the agreements under these ethics and privacy requirements.

To complete the Data Request Form:

* Become familiar with the data request form, available data including the population and data holdings and considerations for privacy
* Ensure ethics and any peer review requirements have been met
* Ensure the appropriate application, approvals and research agreements are sought (particularly if linkages to primary data collection or other health administration data)
* Submit a COMPLETE Data Access Request Form with all supporting documentation
* Work with the GLA:DTM Canada team to complete the study population description and any data linkages

The contact for queries about data access and all necessary documents are found on www.GLADCanada.ca.

Once the Data Access Request Form has been completed and the necessary approvals are in place, a research/data sharing agreement (hereafter research agreement) must be signed by the Principal Applicant and their institution and the data custodian(s). This agreement will be developed and finalized between the Principal Applicant’s institution and Research Contracts, University Health Network who are the current custodians of the data. This form will become an appendix to the research agreement.

**Completing the Data Access Request Form**

The form is a fillable Word document with the document text protected from inadvertent changes. Checkboxes may be checked by clicking the mouse or using the space bar.

The following sections provide explanatory information where necessary for completing the Data Access Form.

**Section 1: Application Details**

Please note that the application title cannot be changed once the application is submitted.

**Section 2: Principal Investigator, Co-applicants and Other Team Members**

This section contains information for completing the ‘Research Team Information’ on the Data Access Form.

The *principal investigator* assumes overall responsibility for the project using the GLA:DTM Canada data and is listed as the principal investigator or a co-investigator on the ethics approval. The principal investigator also enters into the research agreement. In the event of a breach, the principal investigator will be held personally and professionally accountable to the research agreement.

The principal investigator is an individual who has faculty appointment at a Canadian University or College or is deemed a principal investigator at an affiliated institute (e.g. a hospital-based research institute etc.). In addition to bearing overall responsibility for the project, including the activities of the co-investigators, who are assumed to be acting under the delegated authority of the principal investigator, the principal investigator is required to act within the requirement of the Tri-Council Policy Statement (TCPS).

The principal investigator can delegate *a study coordinator* as the primary contact for the duration of the study agreement.

*Co-investigator/co-applicant* name(s), position, institution and institutional email address must be provided on the Data Access Request Form and mirror the investigator list on the ethics certificate and the grant (if funding is in place).

*Trainees* cannot serve as the principal investigator. Rather they are considered a member of the research team and indicated as an individual who will have access to the raw dataset as necessary.

*Authorized Users or persons who will have access to the raw data* at any time must be identified. The name, position, institution and institutional email address of each individual is required. Each person will be required to sign a confidentiality pledge and demonstrate current completion of privacy training priori to release of data. It is recognized that institutions utilize various training entities (e.g. institutional modules that comply with TCPS, CITI etc.) and certification that meets the individual’s institutional requirements is acceptable.

The research team members and individuals with access to the data **MUST** be kept current with the GLA:DTM Canada team. This may require ethics amendment to reflect changes to the research team.

**Section 3: Previously Approved Data Request(s) Relevant to the Application**

If the current application is related to a previously approved data access request, please explain the relationship to the previously approved study in the ‘Research Project Description’ section of the form. An example might be: I have previously received approval for data under project number [insert project number]. I am now applying for permission to link these data to the Discharge Abstract Data (DAD) or Hospital Separation data. A copy of the prior data access approval needs to be attached to the current application.

**Section 4: Required Documentation Checklist**

This section serves to assist the principal investigator in submitting a complete application and to assist the GLA:DTM Canada team in assessing the content and completion of the application.

Please ensure consistency across all submission documents and the Data Access Form. All attachments should include the project title and principal investigator in the header.

All listed attachments are required. The exception is peer review documentation. If the project has not been peer reviewed, an explanation must be provided in the ‘External Peer Review’ section of the form.

Applications will be reviewed for completeness. Incomplete applications will be returned to the principal investigator and will not be submitted to the Data Access Committee for review.

**Section 5: Funding, Affiliations and Reviews**

1. **Funding:** The principal investigator must identify all funding sources and if funded by a for-profit organization, the principal investigator must guarantee that the funder will not influence the analysis or be given access to the data except in the final aggregated published results. Receiving funding that is considered in conflict of interest may result in the access to GLA:DTM Canada data being denied.

 If external funding is not secured, the principal investigator must demonstrate sufficient resources to complete the work in the ‘Funding’ section of the form.

1. **External Peer Review:** Applicants must indicate if external peer review has occurred and by which organization. It is acknowledged that peer review will not occur in all cases.
2. **Ethics Review:** Applicants must indicate the organization(s), certificate number(s) and expiry date(s) of ethical review by a REB and provide the supporting documentation (see the ‘Ethics Review’ section of the form). If the project has not been approved by the REB, the application will only be approved in principle by the Data Access Committee (DAC). Final DAC approval and any release of data will occur only when confirmation of REB approval and the documents are received.

 Ethics reviews are updated periodically and it is the obligation of the principal investigator to ensure the updated ethics information is forwarded to the GLA:DTM Canada team. Any projects that are in progress with ethics expiring or that have outdated documentation will be terminated and the principal investigator must destroy the data file.

**Section 6: Research Project Description**

1. **Project Title:** The same project title should be used on ALL supporting documents and reflect the title in the application form. If there is a discrepancy in the title on the application form and any supporting document, the principal investigator must indicate the reason for this on the form.
2. **Small Cell Size and Confidentiality:** Any cell sizes less than five will be suppressed or combined to avoid potential identification of a participant even though the data set provided will contain de-identified data. This would include, for example, suppression of a health region, if there are less than 5 sites offering the program in that region.

Only aggregate data may be reported at publication.

1. **Project Description:** Privacy legislation stipulates a ‘need to know’ basis. As such, the project must be sufficiently described, including its relation to any other relevant project(s), to justify the project, objectives and data requested.
2. **Research Questions, Objectives and Hypotheses:** The research question(s) will be assessed in accordance with provincial and national laws, regulations and ethical standards, and are also reviewed for public interest value and compliance with privacy legislation and the Tri-Council Policy Statement for guidelines involving ethical research on humans.

 ***Important:*** All analyses should be restricted to answer the specified research questions **ONLY** in the Data Access Application. Any change in direction or scope of the questions needs to be brought back to the Data Access Committee for review and approval. Depending on the scope of the changes, a new project application and new data abstraction may be required.

1. **Methodology:** The study design and methodology including all statistical procedures must be summarized. The description must clearly describe the connection among the research questions, the methods and the data requested as only the data required to address the question(s) can be released.

**Section 7: Study Population**

The study population is the group of subjects that the researcher wants to include in their analyses. It may include multiple cohorts and one or more comparison groups. For example, the study population may include all women who participated in the GLA:DTM Canada program and provided data in the year 2017. The cohort might be those with hip OA and the comparison group might be those with knee OA. The data extraction will be for the entire population and will include the variables specified by the applicant based on the detailed variable list provided.

The study population must be clearly defined using the data fields from the checklist outlining the available data and Applicants are advised that any changes to the study population post-approval will incur a fee in addition to any previous estimate or costs paid. A new review by the Data Access Committee will also be required.

**Section 8: Data Extracted**

1. **GLA:DTM Canada:** The principal investigator must download and complete the appropriate file checklist and indicate the data fields (variables) to be used for analyses. Note that the data fields/variables will be cross referenced to the methods and analyses to determine that each variable pertains to the study objective(s)/research question(s).

The onus is on the principal investigator to ensure all variables are selected and clearly indicated. Any omissions will be the responsibility of the applicant and will incur additional costs for data extraction.

The forms specifying the variables can be downloaded from the GLADTMCanada website <http://gladcanada.ca/> and must be appended to the Data Access Request Application. Please clearly indicate each variable required. Take care to indicate the variables across the time points (baseline, 3 and 12 months follow-up), if necessary.

The start and end date should also be clearly indicated for the population and applicants are encouraged to use calendar or fiscal year wherever possible.

1. **External Data:** If GLA:DTM Canada data are to be linked to external administrative data, the principal investigator needs to provide a copy of the approval for such linkage. Additionally, the consent form forwarded to GLA:DTM Canada needs to indicate that the subjects have consented to providing their health card number and such linkage.
2. **Researcher-Collected Data:** GLA:DTM Canada data can be linked to researcher-collected data through a third unique identifier that maintains the de-identification of the GLA:DTM Canada data. The principal investigator needs to ensure that their collected data can be transferred to the GLA:DTM Canada team for linkage and creation of this third identifier. This will require consent of participants and the applicant should append the consent form for the researcher-collected data. If for some reason, consent has not been obtained or consent has been waived, the applicant needs to provide justification including indicating that this justification was part of the REB approval in the ‘Ethics Review’ section of the form.

Additionally, the research project should clearly indicate through the objectives, methods and data analyses the rationale and logic for this linkage.

**Section 9: Data Security and Access**

1. **Privacy Risk Considerations:** The electronic collection of GLA:DTM Canada data has undergone the necessary privacy impact assessment and meets standards across the provinces and territories. However, some projects may require a Privacy Impact Assessment and the principal investigator assumes overall responsibility for obtaining such. The GLA:DTM Canada team will work with the applicant to supply information related to the GLA:DTM Canada data.

 The applicants must indicate how data will be protected once the data file is received as per the ‘Data Security’ section of the application form.

1. **Data Transfer:** GLA:DTM Canada data will be transferred by a secure web-portal once all necessary approvals are received (REB approval for the study, data application approval etc.). This portal meets the standards for transfer of patient-level data and hence for transferring de-identified GLA:DTM Canada data.

 At no time can any data be transferred among investigators by email, fax or regular mail. Any data transfer must occur in person, by secured courier or a secure file portal. Failure to comply will be considered a breech, will be reported to the relevant privacy office and the applicant(s)’ data access approval will be rescinded.

1. **Data Destruction Security:** All data and related materials containing data from GLA:DTM Canada or linked records generated from GLA:DTM Canada data, such as derived data, duplicated data, analysis tables, working files, back-up files, data on a server, temporary files etc. need to be destroyed at the completion of the project in accordance with the institution policies as outlined in the ‘Data Destruction’ section of the form.

Any paper files need to be destroyed in manner that leaves no possibility for reconstruction of information (e.g. cross-cutting shredding).

The principal investigator will be responsible for notifying GLA:DTM Canada that the data have been destroyed.

**Section 10: Project Communications**

All GLA:DTM Canada data access applications will be assigned a number for tracking purposes once received. **All applications will be reviewed initially by the GLA:DTM Canada staff for completeness; but, only complete applications will be forwarded to the Data Access Committee for review. Incomplete applications or those with inconsistencies will be returned to the applicant and will not be processed until a complete application package is received.** Not every application will necessarily be approved.

**Section 11: Cost Recovery for Data Access Requests and Data Extraction**

Currently the charge for partial cost recovery for retrieval and preparation of a dataset (i.e. one-time data cut only) based on data from the GLA:DTM Canada cohort is $3,000. Extra charges will apply for recurring data cuts and will be determined on a case-by-case basis as fees will vary depending on the frequency of data cuts. Additional fees may also be applied for data access requests that require more complex customization of datasets. If data linkage is required, the additional costs will be determined on a case-by-case basis for the linkage component as this will be dependent on the data and datasets to be linked. These fees are in line with other agencies.

The principal investigator will be responsible for the costs associated with the data request application and data extraction and all fees must be paid to the Canadian Orthopaedic Foundation prior to data abstraction. These fees can be paid through the online payment system at www.GLADCanada.ca

**Section 12: Questions and Help**

The GLA:DTM Canada team are available to help researchers with questions related to the available data and data elements but it must be recognized that time is a finite resource and applicants should ensure they have carefully reviewed all the materials prior to contacting the GLA:DTM Canada team.