

**Application for GLA:DTM Canada Data for Research Purposes**

**NOTE:** The GLA:DTM Canada Data Access Committee holds the authority for approving release of and disclosure of the data for a specific research purpose.

This form should be completed by the applicant taking into consideration the GLA:DTM Canada Data Access Policy and using the GLA:DTM Canada Data Request Manual. Please ensure all attachments are included with the submission.

**Section 1: Application Details**

**Principal Investigator**

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**Project Title**

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**For GLA:DTM Canada Admin Use Only**

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| **Date project application first received (Day/Month/Year):** |
| **Project Number:** |
| **Date Application Submitted to DAC:** |
| **Date DAC approval (Day/Month/Year):** |
| **Data Request Version Date (e.g. V-1 2016-06-28):** |
| **Resubmission Date (Day/Month/Year):** |
| **Resubmission Version Date received (e.g. V-2 2016-07-12):** |
| **Date REB Certificates Received (Day/Month/Year):** |
| **Date Contract/Agreement Signatures Completed (Day/Month/Year):** |
| **Date Fee Received (Day/Month/Year):** |
| **Date Data Set Released (Day/Month/Year):** |

**Section 2: Research Team Information**

Please list all applicants including students and any other personnel who will be involved in the project (e.g.: advisor, statistician, research assistant, etc.). **Note: Anyone requiring access to data must use the email address of their affiliated institution. Email addresses containing domain names such as gmail, hotmail, etc. are not acceptable for anyone named on this application.**

**PRINCIPAL Investigator** (is the person listed as Principal Investigator in the Ethics Board Approval and cannot be a trainee)

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| LAST NAME | FIRST NAME | TITLE |

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| INSTITUTION NAME | POSITION |
| MAILING ADDRESS (including street address, room/unit number, city, province, country, postal code) |
| PHONE | FAX | EMAIL ADDRESS |

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**Project Coordinator/Manager** (primary contact for correspondence etc.)

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| MAILING ADDRESS (including street address, room/unit number, city, province, country, postal code) |
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**Co-applicants** (all additional members of the team)

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**Authorized Users** (people who will have access to the data at any time)

\*complete if not detailed in any personnel category above

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**Section 3: Funding**

1. **Who is funding this research?**

**External Funding:**

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| Agency Name or NA | Expiry Date |

**Internal Funding:**

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| --- | --- |
| Fund Name or NA | Expiry Date |

**No Project Funding:**

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| *If the project has received no dedicated funding, please indicate why, and how the work will be resourced.* |

**Section 4: Conflict of Interest**

All conflicts of interest (COI) must be declared and it is advisable to err on the side of reporting any potential perceived COI.

COI includes any association or connection, financial or non-financial, of the applicant, their spouse, domestic partner, parent or child with the sponsor of the project or the manufacturer or owner of any drug, device, program or method being evaluated in the project.

Examples of financial interests include ownership of stocks, patent or royalty interests, consulting fees or honoraria, speaking fees, salary, study participant accrual rewards, lectureships, membership on board of directors or scientific advisory boards. Non-financial COI examples include: previous research collaborations, student/teacher/mentor relationships, other personal or professional relationships, professional differences or any other connection that might be perceived to have influence on the project and its conduct and reporting.

Attach statement of any COI or indicate not applicable

**COI statement attached YES NO**

**Section 5: External Scientific Peer Review**

**Was the Project Peer-Reviewed? YES NO**

**If YES by what Group/Organization?**

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**If NO, why not?**

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**Section 6: Ethics Review**

*Attach a copy of the current ethics approval for the project and the current consent form for the research collected data (if applicable) or approval for linkage to external data (e.g. administrative data if applicable). This consent form must explicitly state the GLA:DTMCanada data will be linked with the researcher collected data.*

*Note that when the REB is in progress, provisional approval may be granted but REB certificates and all agreements must be received before data are abstracted and released.*

**REB Approval for Data Access: NO YES In Progress**

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| Organization(s) providing approval | Certificate Number (indicate pending if in progress) | Expiry Date |

 **REB approved Consent Form attached**

 **If NA, please specify why:**

**Researcher Collected Data REB Approval: NO YES In Progress NA**

**(if separate from above)**

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| Organization(s) providing approval | Certificate Number | Expiry Date |

 **Consent Form attached**

 **If NA, please specify why if will be required:**

**External data linkage: NO YES In Progress**

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| Organization(s) providing approval | Certificate Number | Expiry Date (If Applicable) |

 **Consent Form attached**

 **If NA, please specify why if will be required:**

**Section 7: Research Project Description**

**Project title**

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**Alternate title(s) if funding or ethics documents differ from above**

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**7.1 Project purpose and background including objectives/aims and hypotheses**

**(Maximum 500 words or one page)**

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**7.2 Summarize the study design and methodology**

**(Maximum 500 words or one page)**

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**7.3 Describe how these data are necessary, including any linkage to primary data, and are required to achieve the research objectives**

**(Maximum 350 words)**

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**7.4 How will confidentiality of individuals, program delivery sites, etc. be protected during analysis and reporting of results?**

**(Maximum 350 words)**

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**7.5 Defining Your Study Population**

This section needs to be completed with reference to the data description for the GLA:DTMCanada database (please use the hip and knee Excel spreadsheets to identify the variables to define your dataset below).

Note: The variables used for dataset creation also need to be identified on the Excel data element checklists provided for those with hip and knee OA by variable label description as described in section 7.6.

Provide a textual description of the sample (inclusion and exclusion criteria) not exceeding 250 words.

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Indicate the rationale for the study sample in relation to the study questions. Do not exceed 250 words.

**7.6 GLA:DTMCanada Data Fields/Variables Requested**

Attach the list of data fields with the individual variables indicated using the Excel spreadsheets for hip and knee participant data that provides detail of the data collected. **Please check this very carefully as multiple revisions/requests cannot be accommodated and additional fees may be incurred.** Also, note that there are some differences by hip and knee (e.g. the HOOS vs the KOOS) hence there are two documents listing the variables that must be checked.

While the EQ5D is collected, it can only be accessed for a subsample of the data related to a specific research question where the PIs have received approval for the collection of the EQ5D from the EQ5D developers as part of their specific study. In some cases, a broader institution or health authority license may have been purchased. This approval must be included with the Data Access submission request or it will not be provided.

Finally, not all provinces have collected some of the patient-reported outcomes. For example, the International Physical Activity Questionnaire was mandatory for Ontario for the period Jan 2017 to Dec 2019 but was not collected by many other provinces.

**Section 8: Data Security**

**8.1 Physical Location and Data Security**

Indicate the research location(s) where the data will be used or accessed and storage sites (if different). Indicate the security measures in place at each location, including protection at workstations, hard copy and source media.

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| **SITE 1** | **ORGANIZATION NAME** |
| **MAILING ADDRESS** (including street address, room/unit number, city, province, country, postal code) |
| **PHYSICAL SECURITY MEASURES** **LOCKED FILE CABINETS DOOR LOCKS OTHER: SPECIFY** |

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| **SITE 2** | **ORGANIZATION NAME** |
| **MAILING ADDRESS** (including street address, room/unit number, city, province, country, postal code) |
| **PHYSICAL SECURITY MEASURES** **LOCKED FILE CABINETS DOOR LOCKS OTHER: SPECIFY** |

**8.2 Network Security and Back-up**

If data are stored on a network or a system where individuals other than the identified project personnel have access, or on a system connected to a public network (the internet), indicate and describe the security processes in place.

**Site 1: (Sites must coincide with those described in Section 8.1)**

 Firewall

 Password changed every \_\_\_\_\_\_\_\_\_ days

 Drives or folders with access restricted to a specific research group

 File encryption

 Other: specify

 Security audit process: describe

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 Access tracking process: describe

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Describe in 150 words or less, the frequency, storage and retention schedule for

network back-ups

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**Site 2:**

 Firewall

 Password changed every \_\_\_\_\_\_\_\_\_ days

 Drives or folders with access restricted to a specific research group

 File encryption

 Other: specify

 Security audit process: describe

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 Access tracking process: describe

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Describe in 150 words or less, the frequency, storage and retention schedule for

network back-ups

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**8.3 Personal Computer Security and Back-ups**

If data will be accessed or stored on the hard drive of a personal computer or laptop, identify all security measures taken to protect data residing on the PC.

Electronic locking system

Encryption

Logon Password

Removable drive

Individual file or folder passwords

Encryption

**Section 9: Data Destruction**

Describe the planned process of data destruction.

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**Section 10: Archival Data Storage**

Archival data related to a specified project will be stored for 7 years after project completion at the host of the GLA:DTMCanada database, which complies with Provincial privacy and confidentiality, and security measures necessary for protection of the data.

**Section 11: Data Request Checklist**

**Required documentation**

Electronic copies of all required supporting documents must be included in the application or it will be returned.

**Eligibility**

* The Principal Investigator meets the criteria for data access.

**Attachments**

* PI CV attached
* Copy of statement of COI(s) (or indicated NA in application section)
* Copy of ethics certificates (or indicate in progress or indicate NA in application section)
* Informed consent form(s) (or indicate in progress or indicate NA in application sections)
* Final funding letter for project if peer-reviewed or contract (removing financial information)
* Copy of population/sample and data variable check list document(s)
* Copy of approval for use of EQ5D (if applicable as indicated on the data checklist)

**Section 12: Signatures and Declaration**

Once this data request is approved, the Principal Investigator will need to enter into a Research Agreement for transfer of the data.

**Principal Investigator:**

By signing, I declare that all information provided in this application is complete and correct

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Principal Investigator Signature Print Name Date (dd/mm/year)

Create one compiled PDF document and submit to GLADCanada.info@gmail.com with the subject heading ‘GLAD Data Access Request’.