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| **DATE RECEIVED** |  | **APPLICATION NUMBER** |  |
| *Office use only*  ***01.06.2021*** | | *Office use only*  ***2021-6, AK*** | |

**Application for access to research data from the**

**GLA:D© Back registry**

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| **Section 1 – Project details** |

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| **1.1** | **Title of project** |
| Investigating mechanisms of change in the GLA:D Back program. | |

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| **1.2** | **Researchers involved in the conduct of the project** | | | |
| **Primary Investigator** | | | | |
| **Job title: Dr** | | **Name**: Bernard Liew | | **Current qualifications** *(please include all)*: PhD |
| **Department, institution and full postal address**:  School of Sport, Rehabilitation and Exercise Sciences, University of Essex, Wivenhoe Park, Colchester, Essex, CO4 3SQ | | | | |
| **Phone 1**:+44 120 687 3522 | | | **Phone 2**: | **Fax:** |
| **Email**: [bl19622@essex.ac.uk](mailto:bl19622@essex.ac.uk) | | | | |
| **Role(s) in project:** Analysing data, reporting, interpretation of results, manuscript writing and reporting. | | | | |

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| **Co-investigator** | | | |
| **Job title: Professor** | **Name**: Alice Kongsted | | **Current qualifications** *(please include all)*PhD |
| **Department, institution and full postal address**:  Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Campusvej 55, 5230, Odense M, Denmark. | | | |
| **Phone 1**: | | **Phone 2**: | **Fax:** |
| **Email**: alicek@sdu.dk | | | |
| **Role(s) in project:** Reporting, interpretation of results, manuscript writing and reporting. | | | |

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| **Co-investigator** | | | |
| **Job title:** Professor | **Name**: Per Kjær | | **Current qualifications** *(please include all)*PhD |
| **Department, institution and full postal address**:  Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Campusvej 55, 5230, Odense M, Denmark | | | |
| **Phone 1**: | | **Phone 2**: | **Fax:** |
| **Email**: pkjaer@health.sdu.dk | | | |
| **Role(s) in project:** Reporting, interpretation of results, manuscript writing and reporting. | | | |

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| **Co-investigator** | | | |
| **Job title:** Professor | **Name**: Jan Hartvigsen | | **Current qualifications** *(please include all)*PhD |
| **Department, institution and full postal address**:  Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Campusvej 55, 5230, Odense M, Denmark | | | |
| **Phone 1**: | | **Phone 2**: | **Fax:** |
| **Email**: jhartvigsen@health.sdu.dk | | | |
| **Role(s) in project:** Reporting, interpretation of results, manuscript writing and reporting. | | | |

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| **Co-investigator** | | | |
| **Job title:** Professor | Inge Ris | | **Current qualifications** *(please include all)*PhD |
| **Department, institution and full postal address**:  Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Campusvej 55, 5230, Odense M, Denmark. | | | |
| **Phone 1**: | | **Phone 2**: | **Fax:** |
| **Email**: iris@health.sdu.dk | | | |
| **Role(s) in project:** Reporting, interpretation of results, manuscript writing and reporting. | | | |

Repeat for as many co-investigators involved in project.

If the contact details change, please advise the GLA:D Back Group as soon as possible.

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| **1.3** | **Proposed start and completion dates for this research project** | |
| What is your proposed start date? | | Aug 2021 |
| What is your proposed completion date? | | Work package one Dec 2021  Work package two June 2022 |

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| **1.4** | **Plain language description** |
| In plain language, give a succinct description of the background and potential significance of the research project *(250 words max)*  Low back pain (LBP) is one of the most common and burdensome global health problems. The GLAD program was conceived as an approach to increase translation of clinical guidelines to clinical practice. The primary aims of this project are to understand the mechanisms by which the GLAD program improved pain and disability, and to determine if mechanisms may differ between subgroups. The secondary aim is to use a data-driven approach to uncover alternate models, and compare whether the alternate or the theoretical models on which the GLAD program was developed provide a better statistical fit. Two work packages (WP) are proposed.  WP1  Cluster analysis will be used on baseline variables (demographic and health, pain, psychological, and functional characteristics) to identify homogenous clinical subgroups. The optimal number of clusters will be determined using a statistical threshold combined with expert opinion. A multi-group structural equation modelling (SEM) will be performed to test the statistical fit of the theoretical model (<https://doi.org/10.1186/s12891-018-2334-x>). The variables included into SEM will include the change scores of pain, function, physical performance, and psychological characteristics. The clusters will be used as the grouping variable in the SEM analysis, to understand if the path coefficients differ between clinical subgroups.  WP2  For each clinical subgroup identified, Bayesian Networks will be used to learn structural networks using the same variables in SEM. The data-driven network models will be refitted using SEM. A comparison will be made of whether the theory or data-driven models provide a better statistical fit to the observed data. | |

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| **1.5** | **Clearly state the aims and/or hypotheses of the research project** |
| *250 words max*  WP1   * The theoretical model will provide a good statistical fit to the observed data using standard SEM fit indices. An acceptable model fit is expected to reach p > 0.05, RMSEA < 0.05, AGFI ≥ 0.90 and BCFI ≥ 0.95. * The SEM model with path coefficients free to vary between all subgroups will be significant different compared to the model with coefficients constrained to be equal. Significance will be determined using an Analysis of Variance.   WP2   * The theory-driven models in WP1 will provide a better SEM statistical fit compared to the data-drive models using SEM fit indices, across all clinical subgroups. | |

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| **1.6** | **Project funding** |
| Indicate whether funding for salary and project expenses has been obtained and if not where funding will come from.    None | |

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| **Section 2 – Details about applications to the Human Research Ethics Committee (HREC) and the Data Protection Agency** |

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| **2.1** | **Submission of this project to a Human Research Ethics Committee (HREC)** |
| **2.1a** | **Has this project been approved by a HREC?** |
|  | If **NO,** pleaseprovide evidence from the HREC that the study does not require HREC approval. |

*Please provide the following information regarding applying to the HRECs*

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|  | Name of authority | Is letter attached?  *Place x in appropriate box* | | |
| Yes | No | Comment |
| 1 | De Videnskabsetiske Komitéer for Region Syddanmark, projekt-id S-20172000-93  (Settlement by VEK common to the entire GLA:D Back Project) |  |  |  |

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|  | If **YES**, please complete tables below and attach approval letters. |

*Please provide the following information regarding applying to the HRECs*

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|  | Name of HREC | Is approval granted and letter attached?  *Place x in appropriate box* | | |
| Yes | No | Comment |
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| **2.2** | **What format do you require the data?** |
| **Anonymous** (In the supplied file, there will be no identifiers that could be matched to any individual participant, only a project-specific ID) | |
| **Pseudo-anonymised data \*** (The project-specific ID in the supplied file could potentially be rematched by the GLA:D Back registry Data Manager to specific individual participants, if required by you in the future) | |
| **Identified** \* Specify which identifying variables required in the file (CPR number, name, episode ID) | |
| \* Identifiable data may be used for research purposes only. Applicant assumes full responsibility as Data Controller according to the European General Data Protection Regulation (GPDR) upon receiving the data.  Only anonymous data may be accessed outside the European Union. | |

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| **Section 3 – Details about the data required for the proposed research project** | | |
| **3.1** | **Variables required from the GLA:D Back registry** | |
|  | Variables to be specified later (The GLA:D Back group can ask for a specification for their assessment of the application) | |
|  | List of variables attached (please indicate the variables requested in the form “GLA:D Back variable list”) | |
|  | Variables listed below (if only a few variables are needed) | |
| 1 |  |
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*Extend the table as necessary*

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| **3.2** | **Date range of the data required from the GLA:D Back registry** |
| **Sample size** | Specify the sample size required:  All collected samples to date. |
| **Sample size calculations** | Justify this sample size:  In WP1- part 2 of the proposal document, there are 8 variables, which mean the number of observations is = 36. Given that the proposed theoretical model will have 7 variance, 16 path coefficients, and 10 covariance parameters, the degrees of freedom of the model is 3. Sample size was estimated using the semTools package in R. with a null model root mean square approximation (RMSEA) of 0.03, and an alternate model RMSEA of 0.10, degrees of freedom of 3, a sample of 1203 is needed to achieve a statistical power 0.9, at an alpha of 0.05.  Due to the data-driven nature of WP2, machine learning techniques are known to be data-hungry. Hence, it is still recommended that all collected samples are used. |

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| **3.3** | **Does your project require a specific date range of the data required from the GLA:D Back registry** |
| **NO** | |
| **YES** | Specify the date range required: |

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| **3.4** | **What data file format do you require?** |
| **STATA  SPSS  Excel  csv** | |
| **Section 4 – GLA:D Back Ethical Code of Conduct for Data Access** | |

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| **4.1** | **Research projects that use data from the GLA:D Back registry must adhere to ethical research practices and observe European legislation regarding data protection. Do you agree to comply with the following data access rules:** |
| **YES**  **NO** | 1. Upon receiving the data, the Applicant assumes full legal responsibility as Data Controller according to the European General Data Protection Regulation (GDPR). 2. Ownership of the data remains with the organisation that collected the data and contributed it to the GLA:D Back registry. 3. Data will only be used for the research project that access was given. Reanalysis of the same data for a different research question requires a new application to the GLA:D Back registry steering group. 4. Access will only be granted for the specific part of the GLA:D Back registry required for the approved research project. 5. Only the researchers working on this project will have access to the data. Under no circumstances will the data be given by the researchers to any third party. 6. If access to the data is withdrawn by a committee, the recipient of the data will immediately erase or destroy the data they were supplied from the GLA:D Back registry. Grounds for withdrawal of access are noncompliance with this Code of Conduct. |

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| **Section 5 – Authorship Rules** |

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| **5.1** | **Research projects that use GLA:D Back registry must adhere to internationally accepted authorship rules. Do you agree to comply with the following authorship rules:** |
| **YES**  **NO** | * A member og the GLA:D Back Group is entitled to collaborate on each publication unless explicitly relinquished by the Group. The member concerned is included among the Co-investigators. * All persons designated as authors must qualify for authorship. Each author must have participated sufficiently in the work to take public responsibility for the content. * Authorship credit will be based only on substantial contributions to:   1) Conception and design, or analysis and interpretation of data; and to  2) Drafting the article or revising it critically for important intellectual content; and on  3) Final approval of the version to be published.  Conditions 1, 2, and 3 must all be met.   * Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of a research group or membership of a GLA:D Back registry steering group is not sufficient for authorship. * Any part of an article critical to its main conclusions must be the responsibility of at least one author. * All people who are named as authors, either in the authorship position below the title or in a footnote, should fully meet the above criteria for authorship. Research group members who do not meet these criteria will be listed, with their permission, in the Acknowledgments or in an appendix. * The order of authorship will be a joint decision of the co-authors. Authors may wish to explain the order of authorship in a footnote.   *(Uniform Requirements for Manuscripts Submitted to Biomedical Journals, International Committee of Medical Journal Editors, 5th Ed 1997)* |
| **Section 6 – Check list for the application** | |

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| **6.1** | **Check list for the application** |
| **YES** |  |
|  | I have read and agree to comply with the *GLA:D Back Ethical Code of Conduct for Data Access and the Authorship Rules (The Vancouver Protocol)* |
|  | The application is completed electronically, NOT handwritten |
|  | The application is the current version available from the committee |
|  | I have included signatures of the Chief Investigator and all co-Investigators |

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| **6.2** | **Attachments** |
| **Not**  **applicable** |  |
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| **YES** | **Name of attachment** |
|  | Protocol |
|  | List of variables |
|  | Other (please describe): |

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| **6.3** | **Are there any other aspects about the proposed project that you would like to communicate to the committee?** |
| *No* | |

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| **Section 7 – Declarations and Signatures** |

We, the undersigned, declare the following:

We accept responsibility for the conduct of the research detailed above in accordance with the principles outlined in the *GLA:D Back Ethical Code of Conduct for Data Access and the Authorship Rules*.

We will provide Annual and Final reports to the GLA:D Back Group.

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| **Signature of Primary Investigator/or Supervisor** | |
| Name :Bernard Liew | Date:26/05/2021 |
| Signature | |

*In addition to the above, I also take responsibility for the ethical conduct of the research project*

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| **Signature of Co-Investigator** | |
| Name: | Date: |
| Signature | |

*Repeat for as many co-investigators involved in project.*

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| **Section 8 – Approval**  *(Office use only)* |
| **WHEN SIGNED BY THE GLA:D BACK GROUP,**  **THE APPLICATION FORM ACTS AS CONTRACT BETWEEN APPLICANT AND THE GLA:D BACK REGISTRY** |

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| **Check list prior to approval**  *(Office use only)* | | |
|  | Compliance with 4.1, 5.1 and 6.1 | |
|  | List of variables received | |
|  | List of variables | |
|  | Received |
|  | To be specified later |

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| **APPROVAL: Signatures of GLA:D Back Group** | |
| Name: Alice Kongsted | Date: |
| Signature | |

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| Name: Jan Hartvigsen | Date: |
| Signature | |

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| Name: Per Kjær | Date: |
| Signature | |

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| Name: Inge Ris | Date: |
| Signature | |

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| **Check list after approval**  *(Office use only)* | |
|  | Copy of signed contract forwarded to applicant |
|  | Data set prepared and made available on SharePoint / Secure Server |

**GLA:D Back Registry contact information:**

GLA:D Back Registry

Att.: Orla Lund Nielsen

Nordic Institute of Chiropractic and Clinical Biomechanics

Campusvej 55

5230 Odense M

Denmark