**Research Application Form LROI**

**Application to use data from the Dutch Arthroplasty Register (Landelijke Registratie Orthopedische Interventies; LROI) for research purposes**

|  |
| --- |
| **Study title**  |
| The study title should contain the study’s design, the type of data used, the geographic region and the timeframe within which the study will take place. If linkage between databases is to be conducted for the study, this should be clearly stated in the title ([RECORD 2019](https://www.record-statement.org/checklist.php)). |

**General information chief investigator**

|  |  |
| --- | --- |
| Title |  |
| Initials |  |
| Name |  |
| Position |  |
| Institute/organisation |  |
| Contact address |  |
| Contact email |  |
| Contact telephone |  |

|  |
| --- |
| **Other project members involved in the data handling** |
| **1.** | NamePositionInstitute |  |
| **2.** | NamePositionInstitute |  |
| **3.** | NamePositionInstitute |  |
| **4.** | NamePositionInstitute |  |
| **5.** | NamePositionInstitute |  |

**Please add the Curriculum Vitae of chief investigator to the research application**

**Research:**

|  |
| --- |
| 1. **Short summary of the study (maximum 200 words; this summary will be included on the LROI website after approval of the application)**
 |
| The summary should ([RECORD 2019](https://www.record-statement.org/checklist.php)): * Indicate the study’s design with a commonly used term in the abstract
* Provide in the abstract an informative and balanced summary of what will be done
* Specify the type of data used. The name of the databases used should be included. If linkage between databases is to be conducted for the study, this should be clearly stated in the abstract
* Specify the geographic region and timeframe within which the study will take place
 |
| 1. **List of 5 key words**
 |
| 1. |
| 2. |
| 3. |
| 4. |
| 5. |
| 1. **Background of research question (including goal, relevance and hypothesis)**
 |
| The background should ([RECORD 2019](https://www.record-statement.org/checklist.php)):* Explain the scientific background and rationale for the research question
* State specific objectives, including any prespecified hypotheses

Describe [previous and current LROI projects](https://www.lroi.nl/media/40ehsfet/overzicht-lroi-onderzoeksprojecten.xlsx) on this topic if applicable and state how your project is adding to this research. |
| 1. **Research question**
 |
| The research question should follow the PICO strategy, containing:* Patient or problem
* Intervention of interest
* Control or comparison
* Outcome or expected result
 |
| 1. **Study population (persons, implants, time period, exclusion and inclusion criteria)**
 |
| Give the selection criteria, and the sources and methods of selection of implants or participants. Describe time period of follow-up. For matched studies, give matching criteria ([RECORD 2019](https://www.record-statement.org/checklist.php)).  |
| 1. **Selection of comparison group(s) or controls, if applicable**
 |
| Give the selection criteria, and the sources and methods of selection of implants or participants. Describe time period of follow-up. For matched studies, give matching criteria ([RECORD 2019](https://www.record-statement.org/checklist.php)). |
| 1. **Data/statistical analyses (outline the methodology and the statistical tests that will be used as well as the necessary sample size/power calculation)**
 |
| Data/statistical analyses should ([RECORD 2019](https://www.record-statement.org/checklist.php)):* Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
* Describe all statistical methods, including those that will be used to control for confounding. Use the directed acyclic graph approach (DAGs) to identify confounding factors ([dagitty.net/dags.html](https://www.dagitty.net/dags.html)).
* Describe any methods that will be used to examine subgroups and interactions
* Describe any efforts to address potential sources of bias
* Explain how the study size was arrived at
* State whether the study included person-level, implant-level, institutional-level, or other data linkage across two or more databases. The methods of linkage should be described.

Relevant topics regarding methodology for analysing LROI data are described in [this document (in Dutch)](https://www.lroi.nl/media/e1jdbkrs/methodologie-voor-analyse-van-lroi-data.pdf). |
| 1. **Limitations of study design, data sources and analytical methods**
 |
| Limitations should ([RECORD 2019](https://www.record-statement.org/checklist.php)): * Discuss limitations of the study, taking into account sources of potential bias or imprecision.
* Discuss both direction and magnitude of any potential bias.
* Discuss the implications of using data that were not created or collected to answer the specific research question(s).
* Include discussion of misclassification bias, unmeasured confounding, missing data, and changing eligibility over time, as they pertain to the study being reported.
 |
| 1. **Expertise project members**
 |
| Describe the expertise of project members for this particular study. |
| 1. **Time frame of study (max. 12 months)**
 |
| Describe the time frame for:* Linkage of data (if applicable)
* Data cleaning
* Analyses
* Manuscript development
* Co-author review
* Submission
 |
| 1. **Final product**
 |
| Specify intended:* Abstract submission for conference meetings
* Publication in scientific journal
 |
| 1. **Contribution of this study to the quality of orthopaedic care**
 |
| Describe relevance to:* Orthopaedic care, for example:
	+ Insight into…
* Patient perspective, for example:
	+ Relevance of outcome measures to patients
	+ Improvement of quality of life, health and social participation
	+ Fulfillment of patients’ desires and needs
* Orthopaedic research field
	+ Demonstrate associations
	+ Generating hypotheses
	+ Improving knowledge of arthroplasty registry study methods
 |
| 1. **References**
 |
|  |

**Data storage**

|  |
| --- |
| 1. **Please provide information concerning data safety policy, including data storage, security, transfer, and destruction**
 |
| Describe location of data storage, data safety policy, access to data and data protection certificates.  |
| 1. **If you have requested access to patient identifiable data, please give your rationale**
 |
| Describe rationale for necessity to use patient identifiable data. |
| 1. **Does this study involve linkage to patient identifiable data from other sources? If yes, please give details**
 |
| Describe the manner of linkage to patient identifiable data from other sources, variables on which linkage will be based, data quality of the other data sources and previous experience with linkage to the other data sources. |
| 1. **Please provide details of any conflicts of interest**
 |
|  |
| 1. **Have you applied previously to the LROI? If yes, please specify**
 |
|  |
| 1. **Please provide details of the funding available to support this study. Does this funding cover the complete study within one year?**
 |
|  |

**Specification of data application LROI**

|  |  |
| --- | --- |
| **Joint** | **Patient demographics** |
| Hip |  | Gender |  | Charnley score (hip/knee) |  |
| Knee |  | Age at procedure |  | Walch score (shoulder) |  |
| Shoulder |  | ASA score |  | BMI |  |
| Elbow  |  | Diagnosis |  | Smoking |  |
| Ankle |  | Previous operation on affected joint |  |  |  |
| Wrist |  |  |  |  |  |
| Finger/thumb |  |  |  |  |  |
|  |
| **Procedure characteristics** | **Outcome measures** |
|  | **Clinical** | **PROMs** |
| Type of procedure (primary/revision) |  | Overall revision rate |  | Pre PROMs  |  |
| Year of procedure |  | Major (at least one of the fixed components revised) revision rate |  | 3 months / 6 months PROMs |  |
| Side |  | Mortality rate |  | 12 months PROMs |  |
| Type of prosthesis (total, hemi, uni, etc) |  | Other, specify below |  | NRS Pain at rest |  |
| Fixation |  |  |  | NRS Pain during activity |  |
| Approach |  |  |  | HOOS-PS / KOOS-PS |  |
| Articulation |  |  |  | EQ index score |  |
| Femoral head size |  |  |  | EQ thermometer |  |
| Anonymized hospital |  |  |  | OHS / OKS / OSS |  |
| Type of revision |  |  |  | NRS Satisfaction |  |
| Reasons for revision |  |  |  | Anchor question(s) |  |
|  |  |  |  |  |  |
| Specify other data requests:  |

Data is provided on the level of detail needed to answer the research question. Data will not contain any patient identifiable data and is made untraceable to physician(s) and hospital(s). Traceability of data on the level of the physician or hospital will only be performed after approval of the concerning hospital(s) or physician(s).

**Please send this research application form (as a PDF) including Curriculum Vitae of chief investigator to lroi@orthopeden.org.**