Annex 2: Data Delivery Agreement

Study name: Improving Quality based on the joint registry (IQ Joint study)

Date of Document: 24 October 2018

This Data delivery agreement ("Agreement") is entered into as from 25 September 2018 ("Effective Date") between

Leiden University Medical Centre (LUMC), department of Orthopaedic surgery, an institution organised in accordance with the public law of the Netherlands, located at Albinusdreef 2, 2333 ZA Leiden, the Netherlands, hereinafter referred to as **"IQ Joint Study Group"**

and

[*insert name centre*], an [***describe type of institution***] organised in accordance with the public law of the Netherlands, located at [***insert address***]**, hereinafter referred to as "Centre".**
IQ Joint Study Group and Centre shall be hereinafter individually referred to as "**Party**" and jointly as "**Parties**";

- Whereas the IQ Joint Study Group is a group of researchers involved in the collection and analysis of patient data on total hip arthroplasty ("**THA**") and total knee arthroplasty ("**TKA**") for the purpose of the IQ Joint Study ("**Study**");
- Whereas for the Study, the IQ Joint Study Group intends to collect patient data on THA's and TKA's in a combined database to facilitate health care institutions in defining the variation in performance on different outcomes and will communicate these performance outcomes to the Centre during the trial;
- Whereas Centre is a health care institution performing THA's and TKA's, and as a result collecting anonymized individual patient data relating to such THA's and TKA's;
- Whereas Centre wishes to participate in the Study and agrees to deliver patient data to the IQ Joint Study Group in order for the IQ Joint Study Group to enable data analysis for the Study;

Therefore the Parties agree as follows:

1. Study conduct
1.1 For the purpose and during the Study, the Centre will deliver anonymized data obtained from the Centre's electronic patient file ("**Input Data**") (which requested data is described in annex 1 of this Agreement ("**Annex 1**")) to the IQ Joint Study Group.
1.2 For the performance of the Study, the IQ Joint Study Group shall, in a reasonably timely manner, provide Centre with all necessary information required to perform the Study, or with access thereto and both Parties shall in general cooperate in good faith with each other.

2. Delivery and processing of the Input Data for the Study
2.1 The Centre warrants and undertakes that it shall at all times collect and deliver the Input Data in accordance with this Agreement, the Study protocol, all reasonable instructions from the IQ Joint Study Group, generally accepted professional standards of the health care industry, including but not limited to those regarding clinical research (to the extent such are applicable) and all applicable laws and regulations, including but not limited to the applicable data protection legislation.
2.2 The Centre warrants that the Input Data are the result of careful extraction of data from the electronic patient file. In case of questions raised by the IQ Joint Study Group after the submission of the Input Data by Centre to the IQ Joint Study Group, Centre shall promptly answer questions of the IQ Joint Study Group about the Input Data, and if requested by the IQ Joint Study Group, correct and complete such Input Data.

2.3 In case of a conflict between the instructions in the Study protocol and this Agreement, the Study protocol will prevail for matters related to the Study conduct, except for the description of which data shall be collected, which is described in Annex 1 of this Agreement.
2.4 The Centre acknowledges that Input Data will be integrated with the same type of data provided by other participating centres in the Study in order to enable the IQ Joint Study Group to conduct research in accordance with this Agreement and the Study protocol and to create a database through analysis and processing of the Input Data ("**Output Data**").
2.5 The IQ Joint Study Group will process the Input Data for the purpose of the Study and in accordance with this Agreement. The IQ Joint Study Group will ensure that it has in place and will maintain appropriate technical and organisational measures against unauthorised or unlawful processing of the Input Data and against accidental loss or destruction of or damage to the Input Data.

3. Delivery Output data to Centre

3.1 Monthly, the IQ Joint Study group will sent an email to all orthopaedic surgeons performing THA and/or TKA. The email contains a performance report with both individual outcomes and a composite performance outcome. The results are compared with the other participating centres.

4. IPR

4.1 All patents, trademarks, trade names, service marks, domain names, copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilisation of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature, or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered, and including applications for registration of any of them ("**IPR**") on the Input Data is and will remain with the Centre. All IPR on the Output Data is and will remain the exclusive property of the IQ Joint Study Group. Neither Party will make any claim against the IPR of the other Party. Communication on the Output Data by the Centre is only possible with the prior authorisation of the IQ Joint Study Group.
4.2 The Centre grants the IQ Joint Study Group a royalty-free, non-exclusive licence in respect of Input Data to import and include such Input Data in the Study database. The Input Data may be used by the IQ Joint Study Group to enable statistical and research analysis for the Purpose of the Study, to answer the research questions as described in **Annex 1**.

5. Further obligations

5.1 Each Party warrants it has general and professional liability insurance in place to sufficiently cover its obligations hereunder.
5.2 The Centre shall indemnify and hold the IQ Joint Study Group harmless against any and all loss, claim or expense suffered by the IQ Joint Study Group as a result of the Centre's breach of its obligations hereunder.

6. Term and termination

6.1 This Agreement shall become effective as of the Effective Date and shall remain in force until completion of the Study or termination in accordance with this clause, whichever comes first.
6.2 Either Party may terminate this Agreement with immediate effect by giving notice in writing to the other Party upon the occurrence of any of the following events:
a.) If the defaulting Party commits a material breach of its obligations under this Agreement and (if the breach is capable of remedy) fails to remedy the breach within thirty (30)

days of being specifically required to do so in writing by the non-defaulting Party.
b.) If any distress, execution, sequestration or other similar process is levied or enforced upon or against property of the defaulting Party which is not discharged within thirty days, or an encumbrancer takes possession of, or an administrator, an administrative receiver, a receiver, a trustee or a liquidator is appointed over the whole or any substantial part of the defaulting Party's undertaking, property or assets, or an order is made or a resolution is passed for the winding-up or analogous proceedings in any jurisdiction of the defaulting Party.

6.3 The IQ Joint Study Group will have the right to terminate this Agreement for any reason upon a thirty (30) days written notice to the Centre or in the event that the IQ Joint Study Group identifies serious and/or persistent non-compliance with the obligations outlined in clause 1 and 2 of this Agreement regarding the collection and delivery of Input Data, the IQ Joint Study Group will have the right to terminate the Agreement with immediate effect and to remove the Input Data from the Study database.

6.4 In the event of termination, Input Data that have already been analysed and used to generate Output Data will be kept available by the Centre for the IQ Joint Study Group for monitoring and/or auditing purposes for a period of fifteen (15) years after termination.

6.5 The rights and obligations of the Parties under clauses 3, 4, 5.5, 7, 8.3 shall survive termination or expiration of this Agreement.

7. Authorship and publication

7.1 The IQ Joint Study Group intends to publish the results of the analyses of the Input Data in reputable scientific and medical journals and at scientific conferences.

7.2 Authorship and acknowledgements follow the criteria established by the International Committee of Medical Journal Editors ("ICMJE").

8. Notices

8.1 Any notices which are required to be given or which shall be given under this Agreement shall be in either in writing and delivered personally or delivered via a reputable delivery services or via e-mail addressed to the Parties as follows:

To the IQ Joint Study Group: Prof.dr. R.G.H.H. Nelissen (e-mail:R.G.H.H.Nelissen@lumc.nl)

To the Centre: [insert name and address (including e-mail)]

9. Miscellaneous

9.1 Assignment. This Agreement shall not be assignable by either Party without the prior written consent of the other Party.

9.2 Independent contractor. For the purposes of this Agreement and all services to be provided hereunder, each Party shall be, and shall be deemed to be, an independent contractor and not an agent or employee of the other Party. Neither Party shall have the authority to make any statements, representations or commitments of any kind or to take any action which shall be binding on the other Party, except as may be explicitly authorised by the other Party in writing.

9.3 Governing law and jurisdiction. The validity and interpretation of this Agreement and the legal relationship of the Parties to it shall, in all respects, be governed by the laws of the Netherlands. Any and all disputes between the Parties that cannot be settled amicably shall be subject to the exclusive jurisdiction of the court having competence in any such matter at Leiden, the Netherlands.

9.4 Entire agreement including annexes and modifications. Unless otherwise specified, this Agreement (including the annexes thereto) embodies the entire understanding between the Parties, and any prior or contemporaneous representations, either oral or written, are hereby

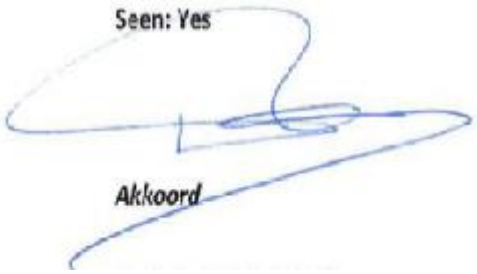
superseded. No amendments or changes to this Agreement shall be effective unless made in writing and signed by authorised representatives of the Parties.

AGREED AND SIGNED BY BOTH PARTIES:

IQ Joint Study Group

Name: Prof. dr. R.G.H.H Nelissen

Date: 17-12-2018



Orthopaedic surgeon in participating centre:

Name: _____

Date: _____

Research questions *IQ Joint* Study Group relating to part 2 of the IQ Joint study:

1. Defining the variation in Dutch hospitals performing THA and/or TKA in participating hospitals and to what extent this variation is explained by patient mix, fixation of the prosthesis, surgical approach, pre-and postoperative processes.
2. Combine the outcomes in a hospital performance profile (textbook outcome).
3. Testing whether an intervention consisting of frequently feedback of performance data leads to better outcomes, more effective use of joint registry and more activities with the aim of improving quality.

Provided data by Centre:

Following data will be sent monthly to the *IQ Joint* study group for all patients undergoing a total hip or total knee replacement.

LROI data + additive variables, namely:

- Length of stay in days (defined as discharge date – admission date)

- Readmission (Yes/No) and
    - Number of days after operation date
    - Number of days after discharge date

- Reoperation other than revisions (Yes/No) and
    - Number of reoperations
    - Number of days after operation date of first reoperation
    - Number of days after discharge date of first reoperation

- Wound infections related to the operation (Yes/No) and
    - Number of infections
    - Number of days after operation date of first wound infection
    - Number of days after discharge date of first wound infection