

**DATA TRANSFER AGREEMENT**

**BETWEEN**

**Ziekenhuis Oost-Limburg AV**, with offices at Synaps Park 1, 3600 Genk, Belgium and Registered with the Crossroads Bank for Enterprises under number 0256.543.917, duly represented by Mr. Tom Arts, chairman, Mr. Erwin Bormans, general director and Dr. Griet Vander Velpen, medical director (“**Institution”**)

and

insert name investigator, with registered office at insert address with registration number insert insert registration number and represented by its legal representative, Insert name (“**Investigator**”)

**Institution** and **Investigator** hereinafter jointly referred to as **“the Provider” or “First Data Controller”**

**AND**

name of recipient, with offices at address of recipient with registration number registration number and represented by its legal representative, name legal representative

Hereinafter referred to as **“the Recipient” or “Secundary Data Controller”.**

Hereinafter jointly referred to as “Parties” and individually as “Party”;

**PREAMBLE**

**WHEREAS** the Recipient has requested the “Provider to provide Recipient with description of data for use in accordance with the purpose of the Protocol (the “Study”);

**WHEREAS** the Provider is willing to provide the Data to the Recipient following the terms and conditions of this Agreement.

**THEREFORE THE PARTIES AGREE AS FOLLOWS**

1. **Definitions**

**Recipient** or **Secundary Data Controller:** the Party defined in this Agreement receiving the Data from the Provider who determines, alone or with others, the purposes and means of the processing of personal data, and who is subject to the rights and obligations as ‘data controller’ set forth under the General Data Protection Regulation 2016/679 (“GDPR”), and other applicable laws with respect to the protection of personal data and/or privacy that are equivalent to or that are intended to implement the GDPR and/or laws that are identified in this definition (“Applicable Law”), in relation to the processing of personal data and this Agreement.

**Provider** or **First Data Controller**: the Party defined in this Agreement responsible for providing the Data to Recipient who is data Controller of the data contained in its patients’ medical records for the purposes of providing medical care to its patients and for academic research

**Data**: means any information relating to an identified or identifiable natural person (‘Data Subject’), including without limitation pseudonymized information, as defined under Applicable Law and as specified in the Protocol, and which is being transferred under this Agreement.

**Protocol**: The document that describes the Data and the objective(s), design, methodology and/or statistical considerations for which the Data will be used and attached hereto as Appendix A.

**Invention**: any invention, discovery, improvement, material, signal, process, formula, know-how or other innovation arising from the use of the Data and/or Confidential Information, whether patentable or not arising from the performance of the Protocol.

**Confidential** **Information**: All information, procedures, Results, know-how, data, developments, technologies, inventions and experience of the Provider regarding the Data, its characteristics, Provider’s research concerning the Data, whether of a scientific, technical, engineering, operational, or economic nature, disclosed to or obtained by the Recipient in written or in intangible form such as electronically, orally or by visual inspection.

**Results**: The processed and analyzed Data arising from the performance of the Study.

**Study Report**: The final written study report after completion of the Protocol which contains the clinical and statistical description, presentations and analyses of the Results.

1. **Terms and Conditions**

1. The Data and any Confidential Information provided to the Recipient is and remains the property of the Provider and is made available pursuant to the terms and conditions of this Agreement.

2. In its use of the Data, Recipient agrees to comply with Applicable Law and the obligations of the General Data Protection Regulation 2016/679 (“GDPR”), and other applicable laws with respect to the protection of personal data and/or privacy that are equivalent to or that are intended to implement the GDPR and/or laws that are identified in this definition (“Applicable Law”), in relation to the processing of personal data and this Agreement.

3. The Recipient agrees that the Data: (a) is to be used only for the purposes as described in the Protocol; (b) will not be used for commercial purposes and (c) will not be transferred to a third party. Recipient shall not carry out the performance of the Protocol with any third party or entity without the prior written approval of the Provider.

4. Recipient shall restrict disclosure of the Data solely to individuals as permitted by the Protocol and the notification or informed consent form -if any- and who require the Data for the performance of the Protocol. Recipient shall require those individuals to comply with the obligations as set forth in this Agreement.

5. Data will be provided to the Recipient by Provider in a format to be agreed mutually between Recipient and Provider.

6. The Recipient as ‘data controller’ shall provide sufficient safeguards in respect of the administrative, technical and organizational measures for processing patient data and take all necessary measures to protect the confidentiality, privacy and prevention from accidental or unauthorized destruction, accidental loss, as well as from alteration, access and any other unauthorized processing of the Data.

7. Recipient shall inform Provider of all Results and Recipient shall provide an update of such Results, when requested. Within […] after completion of the Study or early termination of the Study, whichever occurs first, Recipient shall provide the Provider with the Study Report.

8. Recipient will report any Inventions to the Provider. Recipient shall promptly provide the Provider with a detailed written description of the Invention and indicate the role, if any, of any of Recipient’s employees in creating the Invention. Determination of inventorship shall be made in accordance with the patent laws of the United States of America (which clearly define inventorship), and if an employee of the Provider is named as an inventor on any patent application filed by Recipient for an Invention, then Provider will use reasonable efforts to have all documents signed that are required for the patent prosecution. In the event the Invention is a joint Invention, both Parties shall make appropriate mutual arrangements concerning the protection and exploitation of such joint Invention.

9. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the Recipient under any intellectual property (IP) rights of the Provider.

10. It is expressly understood that the Provider does not make any warranties regarding the Data and specifically does not warrant or guarantee that the Data will be useful for any particular purpose.

11. Recipient shall treat all Confidential Information as confidential during the term of this Agreement and thereafter for a period of ten (10) years following termination or expiry of this Agreement. Such confidentiality obligation shall not apply to any information which Recipient can demonstrate: (i) is or was generally available to the public through no fault of the Recipient, or (ii) is received by the Recipient from a third party who is in rightful possession of such information and has the legal right to make such disclosure, or (iii) Recipient can show was in its possession prior to disclosure and that such information was legally required and not directly or indirectly from the other Party, or (iv) is developed independently by an employee of the Recipient who has had no access to the Confidential Information or (v) is required by law or court order to be disclosed, provided that Recipient shall notify the Provider of any such disclosure required by law or court order as far as possible in advance.

12. **OPTION 1**

Publication of the Study Report and any information derived from the Study or the Data will be in accordance with the provisions as described in the Protocol and with the accepted scientific practice, academic standards and customs.

OR

**OPTION 2**

The Parties agree that at first they will strive to make a joint publication. If such joint publication has not been made within one year after termination of the Study, Parties shall be allowed to publish the Results as follows:

As a general principle, the Parties agree that prior to submission of a publication or any other dissemination of the Results, including oral presentation, the Provider shall have the right to prior review and comment on the content of the material to be published or presented. Provider shall have the right to request, within thirty (30) days following the receipt of the publication or any other dissemination of the Results, that Provider’s Confidential Information would be deleted before proceeding with the publication or any dissemination of the Results, without such right however constituting in any way a right of editorial control. Authorship and other related publications questions shall be addressed in accordance with the principles of the ‘Uniform Requirements for Manuscripts Submitted to Biomedical Journals’ and in accordance with the requirements of the respective medical journal.

*[All publications using Provider’s Data must include at least one (1) co-author of the Provider, to be named by Provider at a later stage.]*

13. Recipient will pay Provider ZERO or AMOUNT IN EURO EUR in accordance with the financial arrangements (Appendix B) for transfer of the Data.

14. This Agreement will become effective on the Effective Date and will terminate after completion of the Study(unless terminated earlier. Either Party can terminate this Agreement upon one (1) month prior written notice. Any clauses that will be expected or intended by its nature to survive the termination or the expiration of this Agreement, shall survive the termination or the expiration of this Agreement. Upon termination of this Agreement, any further transfer of Data and Confidential Information will automatically end. Recipient will return or destroy all Confidential Information, excluding the Data and Results received from the Provider and at Provider’s choice, and shall provide written confirmation thereof, provided that Recipient may retain in its confidential files one (1) copy of any written materials for purposes of verifying compliance with this Agreement.

15. Each Party shall be responsible towards the other Party for its obligations, representations or warranties under this Agreement and the Protocol.

16. In the event of any inconsistencies between the terms of this Agreement and the terms of the Protocol or the appendices, the terms of this Agreement shall prevail except to the extent that any conflict relates to a clinical or medical issue , in which case the Protocol shall prevail.

17. This Agreement will be construed, governed, interpreted and enforced according to the laws of Belgium. All disputes arising out of or in relation to this Agreement will be brought before the competent courts of Limburg, Belgium.

18. This Agreement including the Protocol and its appendices sets forth the entire understanding among the Parties and supersedes all other understanding or agreement, whether written or oral, including any confidential disclosure agreement, between or among any of the Parties with respect to the same subject matter. No modifications hereof shall be binding unless executed in writing by the Parties hereto.

19. If any portion of this Agreement is in violation of any applicable regulation, or is unenforceable or void for any reason whatsoever, such portion will be considered inoperative without prejudice to the validity of the rest of this Agreement.

20. Both Parties acknowledge that the signatories to this Agreement are authorized representatives of each of the Parties and legally authorized to sign this Agreement.

**IN WITNESS WHEREOF**, the Parties have executed this Agreement, in four originals, as of the Effective Date.

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| For **PROVIDER**,  By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | For **RECIPIENT,**  By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| For Provider’s Investigator  By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | For Recipient's Investigator  By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**APPENDIX A - PROTOCOL**

**APPENDIX B – FINANCIAL ARRANGEMENTS**