

	<p><b>SUBLICENSE OF OVYY_XXXXX</b>          (Material Transfer Agreement and/or Data Access Agreement”          between Medische Biobank Noord Nederland (Roden , the          Netherlands) and .....(Recipient)</p> <p>15-10-2019</p>	
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This “Sublicense” is entered into as of .... (the “Effective Date of OV...”) by and between....., organized and duly existing under the laws of the Netherlands, with its principal office at ....., hereby legally represented by .....hereafter referred to as **“Recipient”**, on the one part,  
 and

**....., organized and duly existing under the laws of the....., with its principal office at ....., hereby legally represented by “Sublicensor”);**

**Definitions**

- Sublicense: means this Sublicense comprising its clauses, schedules and any appendices attached to it, including the clauses made in **OVYY\_XXXXX**
- All clauses of this Sublicense, nor the main Sublicense cannot be terminated by either Party.
- The sublicense will not affect the Sublicensors obligations regard to the Sublicenses made in **OV 20\_xxxx**
- Effective Date: The date on which **OVYY\_XXXXX** takes effect.
- Material: the human tissue, blood, urine, or other biomaterial specified in the research proposal included in Annex A.
- **Research: samples used for analysis on the ...**
- Biobank: Lifelines as the provider of the samples.

## **Representations**

1. Recipient and Sublicensor represent to each other that they are duly authorized to enter into this Sublicense;
2. Recipient and Sublicensor represent to each other that this Sublicense does not and will not conflict with any other right or obligation provided under any other Sublicense or obligation that it has with any third party.
3. Biobank represents to Sublicensor that the Consent Form allows for the transfer of the data and/or material to a Sublicensor whose definition embraces Sublicensor, for the purposes of and in accordance with the terms and conditions of this Sublicense, including genetic characterization of the data and/or material.
4. Sublicensor represents to Recipient that he has the capacity to carry out the specified analyses of the data and/or material set forth in the research proposal.

## **Conditions precedent**

1. This contract will give the right to use materials solely for the purpose defined in the research proposal. After the research has been completed the Sublicensor will declare to the Biobank that the materials have been destroyed.
2. The Recipient will not transfer the Material to any other body, or permit its use within the Recipient other than by the Recipient Scientist's research group, without (in each case) prior written consent from the Biobank.
3. Sublicensor and Recipient agree that the data and/or material will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the participants from whom data and/or material were obtained or derived.
4. Recipient will provide at the end of the experiment the outcome of the analysis of all individual samples (cases and controls) to Lifelines.

## Grant of Access and Restrictions of Use

1. Biobank shall grant Sublicensor access to the data and/or material as soon as reasonable possible after the Effective Date. Any service in addition to giving mere access that may be requested by Sublicensor to Biobank, including but not limited to assays, whether or not in connection with this Sublicense, shall be governed by a separate Sublicense.
2. Sublicensor ensures that material (and Results) will be kept separate from other material and that they will be clearly labelled as Biobank material.
3. Sublicensor acknowledges that the material may carry viruses, and other infectious agents. Sublicensor agrees to treat the material as if they were not free of contamination and affirms that material will be handled by trained persons under laboratory conditions that incorporate adequate biohazard containment and that the material should be used with prudence and appropriate caution.
4. Each of the Parties shall forthwith inform the other Party of any inconsistencies found in the data and/or material.
5. Biobank grants Sublicensor a non-exclusive license to use the data and material for the sole purpose of outsourced activities by Recipient. Sublicensor is not entitled to use the data and/or material for any other research and in no event for any commercial purposes. Sublicensor may not use the data and material in research with third parties. Sublicensor will not use the material in humans. Biobank/Recipient may instruct Sublicensor to conduct the Research in accordance with certain methodologies indicated by Biobank/Recipient in order to harmonize methodologies of research using data and/or material of Biobank/ Recipient. Sublicensor shall adhere to such instructions as long as such methodologies do not jeopardize the scientific integrity of the Research. Sublicensor may only use the biomaterial for the common good in scientific research.
6. Sublicensor agrees not to transform the material confidentiality of all items or types of unpublished information on the data and/or material. Nothing in this Sublicense shall be constituted as granting any right and/or license with respect to the data and/or material, or any part thereof, other than as specifically allowed under this Sublicense or OVVY\_XXXXX.
7. Sublicensor acknowledges that the data and material should be kept confidential to the highest degree and agrees to take all care necessary to prevent any disclosure or supply of any data and/or material to any person other than employees of Sublicensor that are members of the Research Group listed in Application, that work under the supervision of the Investigator and that need to know about or need to use the data and/or material to execute the Research.
8. Sublicensor acknowledges that Biobank is under strict regulations and codes of conduct with regard to the collection of the source data and/or material and the storage, management and use thereof, including but not limited to the requirements under the EU General Data Protection Regulation (GDPR; Algemene Verordening Gegevensbescherming; AVG), Dutch Act on Medical Treatment (Wet op de geneeskundige behandelingsovereenkomst; WGBO), EU Tissues and Cells Directive and Dutch law on quality of material (Wet Kwaliteit Lichaamsmateriaal), Dutch Act on scientific experiments on humans (Wet medisch-wetenschappelijk onderzoek; WMO) and the Code Appropriate Use of Body Materials (Code Goed Gebruik Lichaamsmateriaal). Recipient guarantees that, as user of the data and the material, he will act in compliance with all such codes (i.e. Good Clinical Practices (GCP), Research Code), acts and regulations and that Recipient will, where applicable, obtain approval from the appropriate medical-ethical committee(s).
9. Sublicensor shall respect the privacy rights of the donors and shall not attempt in any way to determine the identity of the donors of the material and/or data.

10. Sublicensor acknowledges that donors of material and/or data may request destruction of the material and/or data donated by them. Upon first request by Biobank, Sublicensor shall destroy or return such material and/or data to Biobank.

### **Ownership and Intellectual Property**

1. Lifelines is and shall remain the sole owner of all Source Data and/or Material and/or Derivate Data (i.e. all existing data (in)directly derived from the original Source Data) and also of all data obtained by the (bio)analysis of Source Data and/or Material and/or Derivate Data, and any other information as well as any and all intellectual property rights related thereto. Sublicensor and/or Recipient, based on the agreements made between Sublicensor and Recipient, shall be entitled to any research findings as well as any and all intellectual property rights related thereto resulting from research for which Source Data, Derivate Data and/or Material was used. In case during the Sublicensors research data is created from the (bio)analysis of Source Data, Derivate Data and/or Material, this Derivate Data will be made available to Lifelines. At the request of Sublicensor and/or Recipient an embargo period can be agreed upon for any Derivate Data resulting from the research of Sublicensor for a maximum period of two years. This embargo period will entail that the concerned Derivate Data will be available for request by others, but requests to access to this Derivate Data shall only be granted after the prior approval of Sublicensor and/or Recipient. The embargo period commences when all derivate data or other at request of recipient collected additional data, is made available to Lifelines. Sublicensor and Recipient acknowledge that Lifelines participants remain the persons that are authorized to decide on the use of the Source Data and/or Material donated by them, including destruction thereof if they so request.

### **Disclaimer /Indemnification**

1. Both the Biobank and the Recipient make no representations and extend no warranties, either express or implied, as to the data and/or material. Data and material are provided "as is".
2. Both the Biobank and the Recipient shall not be liable for any damages, losses and expenses, whether consequential or incidental, as a direct or indirect result or consequence of the use or application of the data and/or material, or any part thereof. Sublicensor shall indemnify Recipient and Biobank, hold Recipient and Biobank harmless and shall not take any recourse actions towards Recipient and Biobank, against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon Recipient and Biobank in connection with any claims, suits, actions, demands or judgments of third parties resulting from the use of the data and/or material or breach of any obligation imposed under this Sublicense and OVVY\_XXXXX.
3. Any material provided pursuant to this Sublicense is understood to be of human origin and may have hazardous properties. The Sublicensor shall indemnify Recipient and Biobank for claims for damages by third parties resulting from the use, storage or disposal of the material.

### **Duration /Termination**

1. This Sublicense will be effective as of the date first written above ("Effective Date") and will remain in full force and effect until completion of the Research or, if earlier, 12 (twelve) months from the Effective Date provided, however, that if the Research is not completed within said 12

months, Sublicensor may request an extension of this Sublicense, substantiating the grounds for such extension. Biobank shall not unreasonably withhold its consent to such extension.

2. This Sublicense may be terminated earlier by either Party, with or without cause, upon thirty (30) days written notice to the other Party, or immediately by Recipient and Biobank upon notice that Sublicensor has breached the Sublicense. Termination or expiration of this Sublicense shall, however, not affect the Sublicensors obligations with regard to maintaining strict confidentiality of the data and material.
3. Upon termination, Sublicensor shall, at the election of Biobank, either return or destroy the material and data (or, in the event of on-line access only, return any log-in key). If material must be destroyed, a written declaration of destruction will be signed by Sublicensor and will be sent to the Biobank within 2 (two) weeks after destruction. Biobank may give specific instructions as to the return of material.
4. In the event that a party breaches or is in default of its obligations under this Sublicense, the non-breaching or non-defaulting party shall give written notice of the breach and grant the breaching or defaulting party 30 days from the date of receipt of the notice to remedy the breach or default. If the breaching or defaulting party fails to remedy the breach or default within such time period, the non-breaching or non-defaulting party shall have the right to terminate this Sublicense upon written notice to the breaching or defaulting party.
5. Either party shall be entitled forthwith to terminate this Sublicense by written notice to the other if:
  - an encumbrance takes possession or a receiver is appointed over any of the property or assets of that other party;
  - that other party makes any voluntary arrangement with its creditors or becomes subject to an administration order that other party goes into liquidation (except for the purpose of an amalgamation, reconstruction or other reorganisation and in such manner that the entity resulting from the reorganisation effectively agrees to be bound by or to assume the obligations imposed on that other under this Sublicense);
  - or that other party ceases, or threatens to cease, to carry on research or business.
6. Any waiver by either party of a breach of any provision of this Sublicense shall not be considered as a waiver of any subsequent breach of the same or any other provision.
7. The rights to terminate this Sublicense given by this section shall not prejudice any other right or remedy of either party in respect of the breach concerned (in any) or any other breach. Upon the termination of this Sublicense for any reason, subject as otherwise provided in this Sublicense and to any rights or obligations that have accrued prior to termination, neither party shall have any further obligation to the other under this Sublicense.
8. Upon any expiration or termination of this Sublicense:  
Sublicensor shall:
  - immediately cease and refrain from using the data and/or material;
  - promptly submit all data and analyses derived from the data and/or material as described in **OVYY\_XXXXX**; and
  - promptly return all used and unused material.
9. This Sublicense contains the entire Sublicense and **OVYY\_XXXXX** between the parties with respect to the subject matter hereof, and supersedes any prior Sublicenses, negotiations or representations between the parties with respect to the subject matter hereof, whether written or oral. This Sublicense may be modified only by a subsequent written Sublicense signed by the parties. If any provision of this Sublicense is held to be unenforceable, the remaining provisions shall continue unaffected.

10. Neither party shall assign this Sublicense without the prior written consent of the other party, which consent shall be not be unreasonably withheld or delayed.
11. If either party is affected by failure or delay due to natural disasters, war, acts of terrorism or any other cause beyond the reasonable control of a party (“Force Majeure”), it shall promptly notify the other party in writing within 48 hours of the affected party first having notice of the event and such notice shall as far as practicable state the nature and the circumstances in question. Notwithstanding any other provision of this Sublicense, neither party shall be deemed to be in breach of this Sublicense, or otherwise be liable to the other, for any delay in performance or the non-performance of any of its obligations under the Sublicense, the delay or non-performance is due to any Force Majeure of which it has notified the other party.

### **Applicable Law and jurisdiction**

1. This Sublicense will be governed and interpreted in accordance with the laws of the Netherlands. Any disputes arising out or in connection with this Agreement shall be referred to arbitration in accordance with the Arbitration Rules of the Netherlands Arbitration Institute (Nederlands Arbitrage Instituut; NAI). The arbitral tribunal shall be composed of one arbitrator and shall make its decision in accordance with the rules of law (regelen des rechts). The place of arbitration shall be Groningen, the Netherlands. The arbitral proceeding shall be conducted in Dutch. Arbitration will not prevent Biobank from seeking provisional measures by any competent court or through the NAI against any threatened breach of this Sublicense or the continuation of such breach, without the necessity of proving actual damages.

### **Other provisions**

1. Sublicensor shall not assign or otherwise transfer its rights and obligations under this Sublicense, in whole or in part, to any third party (including affiliates or successors) without the consent of the other Party.
2. This Sublicense can only be amended, supplemented or changed in writing by means of a document to be undersigned by both of the Parties hereto.

IN WITNESS WHEREOF, the Parties have caused this Sublicense to be executed as of the day and year first written above.

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Name: ...

Title: .....

\_\_\_\_\_

Name:

Title:

Annex A: Research proposal with description of requested data and/or material and a list of Research Group members.

CONCEPT