Standard terms and conditions

Section 1. Limited user right

1.1 THE RECIPIENT will use the Human Biological Material for non-profit research purposes only, hereunder for the Research Project exclusively. Any and all other direct or indirect use of the Human Biological Material requires the written consent from the PROVIDER.

1.2 The RECIPIENT warrants and represents that the Human Biological Material will not be used for commercial purposes, including but not limited to selling, commercial screening and transferring the Human Biological Material to a third party for any such purpose. The RECIPIENT warrants and represents that the Human Biological Material will not be used by the RECIPIENT in research that grants rights to a commercial party.

1.3 It is prohibited to use the Human Biological Material in humans or for any diagnostic, prognostic, or treatment purposes, and the RECIPIENT shall at all times ensure that this is duly respected.

Section 2. User requirements

2.1 The RECIPIENT will comply with any and all laws, rules, and regulations applicable to the handling and use of the Human Biological Material, hereunder the European General Data Protection Regulations (GDPR) and the Norwegian Act on international transfer of biological material.

2.2 The RECIPIENT will conduct the Research Project by the highest ethical standards.

2.3 The RECIPIENT warrants and represents that it has obtained approval(s), as appropriate, to use the Human Biological Material, and the RECIPIENT shall ensure that such approvals are valid and maintained during the term of the Agreement.

2.4 The RECIPIENT will not contact or make any effort to identify individuals who are or may be the sources of Human Biological Material, without prior written approval from the PROVIDER.

Section 3. Volumes and specific destruction requirements

3.1 The access to the Human Biological Material is subject to availability and the PROVIDER is not obliged to provide access to the agreed volume of the Human Biological Material should the availability be limited. The same will apply if the RECIPIENT finds that the Human Biological Material cannot be provided in a safe and responsible manner, e.g., due to risk of deterioration.

3.2 The RECIPIENT is obliged to promptly and appropriately destructing specific Human Biological Material and data on the PROVIDER`s request, e.g., if an individual decides to withdraw from MoBa.

Section 4. Approved employees and third parties

4.1 The RECIPIENT will only allow access to and use of Human Biological Material by the RECIPIENT`s principal investigator and approved research team (all specified in ANNEX A) that are under the direct supervision of RECIPIENT`s principal investigator and only after they have been informed of and agreed in writing to the provisions and restrictions stated in the Agreement.

4.2 The RECIPIENT will only allow access to and use of the Human Biological Material by third parties approved in ANNEX A, and only after such third parties have been informed of and agreed in writing to the provisions and restrictions stated in the Agreement.

Section 5. Changes

5.1 The RECIPIENT shall notify the PROVIDER about any and all changes in the Research Project, approvals, and/or other matters relevant to the Research Project, save for minor changes of insignificant importance. Depending on the nature of the notified change, the PROVIDER may at its own discretion decide that a new approval for access is required or terminate the Agreement.

Section 6. Confidential Information

6.1 Any information that the Parties exchange or otherwise acquire in connection with the Agreement shall be kept secret and shall not be disclosed to unauthorised parties without the written consent of the other Party, unless the receiving Party can document that the information: i) was publicly accessible when it was received, ii) was already known to the receiving Party when it was received, iii) was received from a third party without any secrecy agreement, iv) was developed by the receiving Party independent of the received information. For the avoidance of doubt, the Human Biological Material shall be considered as Confidential Information. The duty of confidentiality shall not preclude the disclosure of information that is strictly required pursuant to laws or regulations, save that each Party shall to the extent possible seek to keep such information secret to the extent permitted by law. If possible, the other Party must be notified before such information is disclosed.

6.2 The Parties shall at all times take all necessary precautions to prevent unauthorised persons from gaining access to, or knowledge of, confidential information. The duty of confidentiality shall apply to the employees, third parties who act on behalf of the parties in connection with the performance of the Agreement.

6.3 The duty of confidentiality shall continue to apply after the expiration of the Agreement.

6.5 The confidentiality obligation set out in this section 6 shall not hinder the publication of Analytical data in line with section 8 below.

Section 7. Reporting and information requirements

7.1 The RECIPIENT shall provide the PROVIDER with a detailed, analysis report no later than at the expiration of the Agreement. This report shall describe the process and techniques, analytical methods, methodologies, and hardware/system used when analysing the Human Biological Material and when extracting Analytical data, Metadata and Raw data. The report shall include, if applicable:

7.1.1 A list of failed tests, incl. an assessment of what caused or may have caused the failure.

7.1.2 Specification of the units of measurement for each metabolite measure, incl. limit of detection/limit of quantification for each of these as well as information on cases and controls pursuant to the FAIR-principles.

7.2 The RECIPIENT shall provide the PROVIDER with copies of all recorded information or data extracted from the human biological material (raw data, quality-controlled data, analytical data and associated metadata) no later than at the expiration of the Agreement.

7.3 The RECIPIENT will inform the PROVIDER of any known batch effects or variations on the Human Biological Material (intra and inter variation) if applicable.

Section 8. Publication, dissemination, etc.

8.1 The Human Biological Material, and other information and data received under the Agreement and/or extracted from the Human Biological Material may not under any circumstances be uploaded to public repositories or databases.

8.2 The PROVIDER has the right to retain, use, duplicate or disclose the Raw data, Analytical data and Metadata and other information it receives pursuant to section 7, in whole or in part, for research – and development purposes, including the right to make the information available for third parties.

8.3 The RECIPIENT has the right to publish Analytical data obtained from the use of the Human Biological Material in the Research Project in scientific journals, in accordance with the Vancouver Guidelines on authorship and contributorship, and the authors will have the copyrights to such publications.

8.4 The RECIPIENT is responsible for ensuring that the Human Biological Material are described correctly that mandatory references are included, and that the analyses are in accordance with the stated scientific aims

of the Research Project. See the PROVIDER publication guidelines on our webpages for further instructions, and which the RECIPIENT shall ensure to comply with.

8.5 After publication, the PROVIDER shall have a right to reproduce, translate and publish abstracts of the publications.

Section 9. Inventions

9.1 In case inventions (whether patentable or not) are developed when using the Human Biological Material, the rights shall be held by the Party that developed and/or conceived the invention, or that was developed and/or conceived on its behalf. If both Parties jointly invented the invention, then the rights shall be owned jointly.

9.2 The RECIPIENT shall on a confidential basis inform the PROVIDER about all inventions made on its behalf in the Research Project, incl. approved third parties in order to determine ownership and the legal protection of the invention, as applicable.

9.3 Regardless of ownership, the PROVIDER is entitled to a non-exclusive, perpetual, royalty-free license to use any inventions based on the use of the Human Biological Material for internal use and research purposes.

9.4 If the RECIPIENT no longer wants to maintain or does not actively protect an invention, either patented or not, based on the use of the Human Biological Material, the PROVIDER shall be entitled to have such invention, incl. patent applications and patents, assigned at no cost.

Section 10. Termination and discontinuation of Human Biological Material

10.1 The Agreement may be terminated in writing with 30 days' notice by either Party. The Agreement may also be terminated with immediate effect in writing by a non-breaching Part in case of a material breach of the Agreement by the other Party.

10.2 When the Research Project is completed or the Agreement is terminated, whichever comes first, the RECIPIENT and third parties approved in ANNEX A shall discontinue any and all use of the Human Biological Material immediately.

10.3 Upon termination, any unused Biological Human Biological Material shall either be destroyed in compliance with all applicable statutes and regulations or returned to the PROVIDER if requested by the PROVIDER. The Human Biological Material in form of data, including data deduced from the Human Biological Material, will be deleted by both the RECIPIENT and any and all third parties approved in ANNEX A. Upon request, the RECIPIENT shall confirm such destruction in writing, incl. confirm destruction of data used by approved employees and third parties.

Section 11. Compliance with GDPR

11.1 The RECIPIENT is obliged to assist the PROVIDER in fulfilment of obligations following from participants pursuing their rights as data subjects under the General Data Protection Regulation (GDPR), including promptly and appropriately destroying specific Human Biological Material on the PROVIDER`s request if the PROVIDER makes such request based on participants withdrawing from MoBa.

Section 12. Acknowledgments

12.1 In all oral presentations or written publications concerning the use of the Human Biological Material, the RECIPIENT will acknowledge the PROVIDER’s contribution of the Human Biological Material unless requested otherwise by the PROVIDER.

Section 13. Liability and indemnification

13.1 Any Human Biological Material delivered pursuant to the Agreement are understood to be experimental in nature and may have hazardous properties. The PROVIDER makes no representations and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of

merchantability or fitness for a particular purpose, or that the use of the Human Biological Material will not infringe any patent, copyright, trademark, or other proprietary rights.

13.2 The RECIPIENT shall indemnify and hold the PROVIDER harmless for any loss, claim and/or damage for the RECIPIENT`s breach of the terms set out in the Agreement, incl. non-compliance by third parties that the PROVIDER is responsible for. Except to the extent prohibited by law, the RECIPIENT assumes all liability for damages that may arise from RECIPIENT transport, receipt, use, storage, or disposal of Human Biological Material. The RECIPIENT is not responsible for any indirect losses unless the loss has arisen as a result of gross negligence or wilful actions. The RECIPIENT is also responsible for indirect losses in case of RECIPIENT's breach of sections [1, 2 and 4] of this standard terms and conditions.

13.3 The PROVIDER shall not be liable for any loss, harm, illness or other damage or injury arising from the RECIPIENT`s handling, use or disposal of the Human Biological Material. The PROVIDER`s maximum liability for any and all claims under this Agreement shall be limited to the fees paid for the Human Biological Material under the Agreement.

Section 14. Remedies

14.1 The RECIPIENT agrees that damages alone may not be an adequate remedy for breach of any term of the Agreement, and the RECIPIENT therefore agrees that the PROVIDER may file for injunctive relief for the return or destruction of the Human Biological Material without proof of irreparable damage or injury. Such remedy shall not be deemed to be the exclusive remedy for a breach of the Agreement but shall be in addition to all other remedies available at law to the Parties.

Section 15. Notification

15.1 If RECIPIENT becomes aware of the existence of fraud, waste and/or abuse of the Human Biological Material, or if it deems such situation as likely, it shall immediately report such matters to the PROVIDER.

Section 16. Other

16.1 The RECIPIENT shall not be entitled to transfer its rights and obligations under the Agreement in whole or in part.

16.2 Any amendments of the Agreement must be made in writing and signed by both Parties.

Section 17. Governing law and dispute settlement

17.1 The Agreement is governed by Norwegian law.

17.2 The Parties shall seek to solve any dispute amicably. In case the Parties do not come to a mutual agreement, then Oslo District Court shall be the exclusive legal venue to settle any and all disputes arising out of this Agreement.