

 <p>Medische Biobank Noord Nederland BV Chamber of Commerce number 59133708</p>	<h2>MATERIAL TRANSFER AND/OR DATA ACCESS AGREEMENT</h2> <p>OV18_xxxx 00-00-2018</p>	 <p>iDocs: 22863 Version date: 1-8-2017</p>
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Aim

The aim of this material transfer agreement and/ or data access agreement (MTA/DAA) is to:

- describe the partners involved in the data and/or sample release for the research project proposed in the granted research proposal and their relations;
- warrant the privacy of the Lifelines participants;
- warrant transparency of the proposed research project and the researchers ;
- specify that Lifelines is the owner of the data and materials of the Lifelines participants;
- clarify the conditions in relation to data and material access.

Context

The material transfer agreement and/or data access agreement MTA/DAA is embedded within the procedure 'Procedure finance and contract for research proposals'. The Lifelines Research Office draws up the MTA/DAA with the parties involved and will get the MTA/DAA formalised.

The MTA/DAA is aimed to aid the collaboration between Lifelines and the researcher. This MTA/DAA does not apply for data and/or material release for consortia like BBMRI, nor for research proposals or for data and/or material that have been gathered under BBMRI-NL and/or Top Institute Food & Nutrition, nor for requests regarding the Lifelines expertise and infrastructure.

Summary

The main points of the agreement are:

- i. Biobank's Research Office must have approved the research proposal before any transfer to Recipient of data and/or material will be performed;
- ii. This contract will give the right to:
 - i. Use the data solely for the purpose defined in the research proposal for a pre-determined period of time: **12 months**. After this period extension can be granted after a written request to Lifelines Biobank.
 - ii. Use materials solely for the purpose defined in the research proposal. Recipient may only use the data and materials for the common good in scientific research.
 - iii (optional). subcontract specific parties to whom the analysis/research activities are outsourced, this will not affect the Recipients obligations regard to the agreements made in this MTA/DAA and the offer (**OV18_xxxx**).
- iii. Recipient guarantees that, as user of the data and/or material, he will act in compliance with all such codes, acts and regulations and that Recipient will, where applicable, obtain

approval from the appropriate medical-ethical committee(s).

- iv. Biobank shall be the sole owner of any and all data and materials and other information as well as any and all intellectual property rights related thereto, including the data obtained from bioanalysis of the materials. The Recipient shall be entitled to any inventions to the extent that these result from his own independent use of the data and/or material. Recipient shall grant Biobank a worldwide non exclusive royalty free irrevocable research licence with respect to any such inventions.
- v. Within 10 days of the date of termination of the agreement, Recipient shall provide Biobank (research@lifelines.nl) with a written report, describing in reasonable detail (i) the activities executed, (ii) the Results obtained in the course of the Research (including any new algorithms developed) and (iii) methodologies used in the Research (the latter to allow Biobank quality control and uniform approached by the users of data and material).
- vi. Recipient will inform Biobank (research@lifelines.nl) of a contemplated publication (abstract, poster or manuscript) at least 14 days prior to the contemplated submission date in order to allow Biobank to verify that such publication does not contain results caused by incorrect use of data, and to verify that data is published on such a level that traceability to individuals is impossible .
- vii. Upon termination, Recipient shall, at the election of Biobank, either return or destroy the data and/or material. If material must be destroyed, a written declaration of destruction will be signed by Recipient and will be sent to Biobank within 2 (two) weeks after destruction. Biobank may give specific instructions as to the return of material.
- viii. Recipient shall not assign or otherwise transfer its rights and obligations under this Agreement, in whole or in part, to any third Party (including affiliates or successors) without the consent of the other Party.
- ix. Lifelines reserves the right to take appropriate measures in case of non-compliance with these contractual provisions.

MATERIAL TRANSFER AND/OR DATA ACCESS AGREEMENT

This Data access and Material Transfer Agreement (“Agreement”) is entered into as of the date of the last signature (the “Effective Date”) by and between,

Medische Biobank Noord Nederland B.V. organized and duly existing under the law of the Netherlands, having offices in Groningen, at Bloemsingel 1, 9713 BZ, The Netherlands, hereby legally represented by Dr. Ir. S. Mulder, hereafter referred to as " Biobank", on the one part,

and

Institution ... [, a [fill in type of legal entity, e.g. foundation, charitable trust, corporation (Ltd. Inc.)] incorporated, organized and duly existing under the laws of the [fill in appropriate jurisdiction], with its principal office at [insert address], hereby legally represented by [insert name of legal representative], in the capacity of the authorized signatory of the Principal Investigator [name], hereinafter "Recipient");

and/or

Company Z [fill in official name of legal entity that is authorized to enter into this agreement], a [fill in type of legal entity, e.g. corporation (Ltd., inc.)], incorporated, organized and duly existing under the laws under the laws of the [fill in appropriate jurisdiction], with its principal office at [insert address], hereby legally represented by [insert name of legal representative], in the capacity of the authorized signatory of the Principal Investigator [name] and/or [...] [Add any other Party which is to be a Party to the MTA & DAA],

WHEREAS:

1. Biobank is a populations Biobank established with the aim to facilitate research on its collection of human biological data and/or material;
2. Recipient is the Principal Investigator (represented by the authorized signatory) of a non-profit research institute willing to conduct research on certain data and/or material from Biobank to conduct a (scientific) study (the "Research") as further described in Annex A. Annex A is attached hereto and shall be deemed as an integral part of the Agreement, and may be updated from time to time by mutual agreement of the Parties.
3. Biobank is willing to give acces or transfer certain data and/or material to Recipient;
4. Have agreed to be bound by the provisions set out in this Agreement.

Definitions

Agreement: means this agreement comprising its clauses, schedules and any appendices attached to it, except for the research proposal;

- Research Office: to which the research proposal has been submitted for approval;
- Research Group: Principal Investigator, Investigators and other members selected by Principal Investigator,
- Recipient: hereinafter referred to as “Principal Investigator”
- Subcontractor: party/parties selected by the Principal Investigator to whom analysis/research activities can be outsourced.
- Sublicense: The agreement between Recipient and Subcontractor whereby the sublicense will not affect the Recipient’s obligations in regard to the agreements made in offer **OV18_xxxx**.

- Consent Form: Certificate that a participant of Lifelines has signed, where he/she approves use of the (anonymized) data and material for scientific purposes.
- Effective Date: The date on which this agreement, takes effect.
- Material: the human tissue, blood, urine, or other biomaterial specified in the Research proposal included in Annex A.
- Research proposal: Recipient's research proposal attached hereto as Annex A.
- Offer: Lifelines offer describing the financial agreements attached hereto as Annex B.

Representations

1. Biobank and (formal) Recipient represent to each other that they are duly authorized to enter into this Agreement;
2. Biobank and (formal) Recipient represent to each other that this Agreement does not and will not conflict with any other right or obligation provided under any other agreement or obligation that it has with any third party.
3. Biobank represents to Recipient that the Consent Form allows for the transfer of the data and/or Material to a Recipient whose definition embraces Recipient, for the purposes of and in accordance with the terms and conditions of this Agreement, including genetic characterization of the data and/or Material.
4. Recipient represents to Biobank that it 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 Agreement will give the right to:
 - i. Use the data solely for the purpose defined in the Research proposal for a pre-determined period of time: 12 months. After this period extension can be granted after a written request to Lifelines Biobank.
 - ii. Use data and/or Materials solely for the purpose defined in the Research proposal. After a year the Recipient will declare that the Materials have been destroyed or Recipient will send Materials back to Lifelines.
 - iii. Subcontract specific parties to whom the analysis/research activities are outsourced, whereby the Sublicense will not affect the Recipient's obligations in regard to the agreements made in OV18_xxxx.
2. <<OPTIONAL>>Any request by a third party for data generated by the Recipient in application OV18_xxxx will not be honoured by Lifelines for a period of xx months from the date of release. After the agreed period has ended, Biobank has the right to release data generated by the Recipient to new applicants. Biobank will inform new applicants that the data has been established within the framework of application OV18_xxxx and that the Recipient needs to be informed about contemplated publications with this data prior to submission of the manuscript to a journal. The Recipient shall have the right of two co-authorships.
3. During this period, any other request for data generated by the Recipient, will be sent to the Recipient. In this period, the Recipient may decide (not to) participate in a collaboration with others who want to make use of the generated data of the Recipient. After the agreed period has ended, Lifelines has the right to release data generated by the Recipient to others.

4. The Recipient agrees that 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.
5. It is the Biobank's obligation to give access to data and or Material, is conditional on the fulfilment, to the satisfaction of the Biobank, the following conditions:
 - The Recipient has submitted to the Biobank for assessment by the Biobank's Research Office the Research proposal setting forth the analyses to be performed by the Recipient on the data and/or Material and the justification for its use of the data and/or Material of the Biobank;
 - The Biobank's Research Office has approved of the transfer to the Recipient of the data and/or Material for purposes of the research set out in the Research proposal;
 - The Recipient agrees to supply a duly authorized Purchase Order for the supply of data and/or Material;
 - In consideration for the Biobank's entering into this Agreement, the Recipient agrees to pay Biobank an amount of €... excl. 21% VAT) by wire transfer to Biobank, IBAN: NL77INGB0650769015, BIC: INGBNL2A, Annex B.

Grant of Access and Restrictions of Use

1. The Biobank shall grant the Recipient 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 the Recipient to the Biobank, including but not limited to assays, whether or not in connection with this Agreement, shall be governed by a separate agreement under applicability of Biobank's terms and conditions.
2. The Recipient acknowledges that the data will be made accessible through Biobank on-line access facility (workspace).
3. The Investigator or another member of the research group of the Investigator as listed in Application (the "Research Group") will be provided with a personal log-on key. A tracking and tracing system is included in Biobank's on-line access facility. Recipient shall ensure that all such persons will not give their personal log-on key and/or password to any person without Biobank's prior written approval.
4. The Recipient shall ensure that the person that has access to the data will not download, delete and/or copy the data on any computer without the prior written approval of Biobank.
5. Only in exceptional circumstances where the Recipient can demonstrate that the Research cannot be conducted by on-line access only, may data be made available by other means (i.e. CD-rom / USB stick). In such event, the Recipient shall ensure that the persons within the Research Group that will obtain such data, will not grant any other person access to such data.
6. The Recipient will be responsible for transport of the Material from the Biobank to the Recipient or Subcontractor and for subsequent storage of the Material. The Recipient shall ensure that the Material (and Results as defined below) will be kept separate from other material and that it/they will be clearly labelled as Biobank (Lifelines) material.
7. The Recipient acknowledges that the Material may carry viruses, and other infectious agents. Recipient agrees to treat the Material as if it 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.

8. The Recipient agrees that it is responsible for all actions outsourced to subcontractors. The Recipient agrees to bind subcontractor to (relevant) agreements made in this MTA/DAA (proposal for sublicense Annex C). Where the agreement speaks of the Recipient it also means Subcontractors.
9. Each of the Parties shall forthwith inform the other Party of any inconsistencies found in the data and/or Material.
10. Biobank grants Recipient a non-exclusive license to use the data and Material for the sole purpose of performing the analyses as stated in the proposal. Recipient is not entitled to use the data and/or Material for any other research and in no event for any commercial purposes. Recipient may not use the data and Material in research with third parties. Recipient will not use the Material in humans. Biobank may instruct Recipient to conduct the Research in accordance with certain methodologies indicated by Biobank in order to harmonize methodologies of research using data and/or Material of Biobank. Recipient shall adhere to such instructions as long as such methodologies do not jeopardize the scientific integrity of the Research. Recipient may only use the data and Material for the common good in scientific research.
11. Recipient agrees not to transform the material confidentiality of all items or types of unpublished information on the data and/or Material. Nothing in this Agreement 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 Agreement.
12. Recipient 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 Recipient that are members of the Research Group listed in the Application, that work under the supervision of the Principal Investigator and that need to know about or need to use the data and/or Material to execute the Research.
13. Recipient acknowledges that Biobank is under strict regulations and codes of conduct with regard to the collection of the data and Material and the storage, management and use thereof, including but not limited to the requirements under the EU Data Protection Directive, the Dutch Privacy Act (Wet Bescherming Persoonsgegevens), Dutch Act on Medical Treatment (WGBO), EU Tissues and Cells Directive and Dutch law on quality of material ("Wet Kwaliteit Lichaamsmateriaal"), Dutch Act on scientific experiments on humans ("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 Epidemiological Practices, Research Code), acts and regulations and that Recipient will, where applicable, obtain approval from the appropriate medical-ethical committee(s).
14. Recipient shall respect the privacy rights of the donors and shall not attempt in any way to determine the identity of the donors of the data and/or Material.
15. Recipient acknowledges that donors of data and/or Material may request destruction of the data and/or Material donated by them. Upon first request by Biobank, Recipient shall destroy or return to Biobank such data and/or Material.

Ownership and Intellectual Property

Biobank shall be the sole owner of any and all data and materials including all data obtained by the bioanalysis of the Material or derivative data (i.e. data derived from the original data), and other information as well as any and all intellectual property rights related thereto. In case the Recipient creates data from the bioanalysis of the Biobank's Material, the data must be returned to the Biobank. Recipient acknowledges that the donors of the data and Material remain the persons that

are authorized to decide on the use of the Material and data donated by them, including destruction thereof if they so request. The Recipient shall be entitled to any inventions to the extent that these result from its own independent use of the data and/or Material. Recipient shall grant Biobank a worldwide non exclusive royalty free irrevocable research licence with respect to any such inventions. If the Recipient elects not to seek any intellectual property protection with respect to such inventions he shall transfer any such rights to Biobank at no cost.

Disclaimer / Indemnification

1. Biobank makes no representations and extends no warranties, either express or implied, as to the data and Material. Data and Material are provided “as is”. Data have been verified by Biobank but not additional validation of the data has taken place (obligation to use one’s best efforts).
2. Biobank 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. Recipient shall indemnify Biobank, hold Biobank harmless and shall not take any recourse actions towards Biobank, against any liability, damage, loss or expense (including reasonable attorneys’ fees and expenses of litigation) incurred by or imposed upon Biobank in connection with any claims, suits, actions, demands or judgments of third parties resulting from the use of the data and/or Material by Recipient or breach by Recipient of any obligation imposed on Recipient under this Agreement.
3. Any Material provided pursuant to this Agreement is understood to be of human origin and may have hazardous properties. The Recipient shall indemnify Biobank for claims for damages by third parties resulting from the use, storage or disposal of the Material.

Reporting

1. Within 10 days of the date of termination of the Agreement, Recipient shall provide Biobank (research@lifelines.nl) with a written report, describing in reasonable detail (i) the activities executed, (ii) the Results obtained in the course of the Research (including any new algorithms developed) and (iii) the methodologies used in the Research (the latter to allow Biobank quality control and uniform approach by the users of data and Material). The new algorithms will become part of the database of Lifelines, and can be used for future research.

Publication

1. Recipient is entitled to publish the Results subject to the terms of this paragraph in a scientific journal or printed scientific meeting.
2. Recipient will inform Biobank (research@lifelines.nl) of a contemplated publication (abstract or poster or manuscript) at least **14 days** prior to the contemplated submission date in order to allow Biobank to verify that such publication does not contain results caused by incorrect use of data, to verify that data is published on such a level that traceability to individuals is impossible, and that the publication is in accordance with the communication guidelines of Lifelines .
3. If so, reasonable comments by Biobank given **within 7 days** will be addressed in the publication.
4. Forthwith upon publication of the Results by Recipient, Biobank will publish such publication on its website, clearly labelled as Results of the Research with a unique project code for unambiguous identification linking it to the Research and under acknowledgement of the

Investigator and other relevant members of the Research Group.

In the event that Recipient has not published the Results within 12 months after completion of the Research, Biobank is, in view of its policy to make results of research by use of data and Material in the Biobank publicly available, nevertheless entitled to publish the Results on its website, again clearly labeled as Results of the Research with a unique project code for unambiguous identification linking it to the Research and under acknowledgement of the Investigator and other relevant members of the Research Group.

5. In order to make Biobank visible in PubMed searches, Recipient shall acknowledge the Biobank in the title or abstract of all publications relating to Results, by using the following language: "Lifelines Cohort Study" or "Lifelines". In addition thereto, all publications must contain the following sentences "*Lifelines is a multi-disciplinary prospective population-based cohort study examining in a unique three-generation design the health and health-related behaviours of 167,729 persons living in the North of The Netherlands. It employs a broad range of investigative procedures in assessing the biomedical, socio-demographic, behavioural, physical and psychological factors which contribute to the health and disease of the general population, with a special focus on multi-morbidity and complex genetics*". In the event that one or more references as stated herein are not allowed by the publisher of the scientific article, Biobank can, upon written request by the Investigator, waive one or more of such references to adhere to the publication policies of such publisher.
6. Recipient shall in its publication acknowledge the regional funds that have made the start of Biobank possible by using the following language "*The Lifelines Biobank initiative has been made possible by funds from FES (Fonds Economische Structuurversterking), SNN (Samenwerkingsverband Noord Nederland) and REP (Ruimtelijk Economisch Programma)*".
7. The following reference can be used in scientific papers to refer to the Biobank cohort: "*Stolk RP, Rosmalen JG, Postma DS, et al. Universal risk factors for multifactorial diseases: Lifelines: a three-generation population-based study. European Journal of Epidemiology 2008;23:67-74*" or "*Scholtens S, Smidt N, Swertz MA, et al. Cohort Profile: Lifelines, a three-generation cohort study and Biobank. Int J Epidemiol. 2014 (epub)*".
8. If the authors wish to express their thanks, the following statement may be used under Acknowledgements: "*The authors wish to acknowledge the services of the Lifelines Cohort Study, the contributing research centres delivering data to Lifelines, and all the study participants.*"

Duration / Termination

1. This Agreement 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**, Recipient may request an extension of this Agreement, substantiating the grounds for such extension. Biobank shall not unreasonably withhold its consent to such extension.
2. This Agreement may be terminated earlier by either Party, with or without cause, upon thirty (30) days written notice to the other Party, or immediately by Biobank upon notice that Recipient has breached the Agreement. Termination or expiration of this Agreement shall, however, not affect the Recipients obligations with regard to maintaining strict confidentiality of the data and Material.
3. Upon termination, Recipient 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 login key). If Material must be destroyed, a written declaration of destruction will be signed by Recipient and will be sent to

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 Agreement, 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 Agreement upon written notice to the breaching or defaulting Party.
5. Either Party shall be entitled forthwith to terminate this Agreement 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 Agreement);
 - 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 Agreement shall not be considered as a waiver of any subsequent breach of the same or any other provision.
7. The rights to terminate this Agreement 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 Agreement for any reason, subject as otherwise provided in this Agreement and to any rights or obligations that have accrued prior to termination, neither Party shall have any further obligation to the other under this Agreement.
8. Upon any expiration or termination of this Agreement:
Recipient 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 provided in the Research proposal; and
 - promptly return all used and unused material.
9. This Agreement contains the entire agreement between the Parties with respect to the subject matter hereof, and supersedes any prior agreements, negotiations or representations between the Parties with respect to the subject matter hereof, whether written or oral. This Agreement may be modified only by a subsequent written agreement signed by the Parties. If any provision of this Agreement is held to be unenforceable, the remaining provisions shall continue unaffected.
10. Neither Party shall assign this Agreement without the prior written consent of the other Party, which consent shall 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 Agreement, neither Party shall be deemed to be in breach of this Agreement, or otherwise be liable to the other, for any delay in performance or the non-performance of any of its obligations under the Agreement, 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 Agreement 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 the Dutch. Arbitration will not prevent Biobank from seeking provisional measures by any competent court or through the NAI against any threatened breach of this Agreement or the continuation of such breach, without the necessity of proving actual damages.

Other provisions

1. Recipient shall not assign or otherwise transfer its rights and obligations under this Agreement, in whole or in part, to any third Party (including affiliates or successors) without the consent of the other Party.
2. This Agreement 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 Agreement to be executed as of the day and year first written above.

Biobank

Legal represent Institute

Date:

Date:

Name: Dr. Ir. S. Mulder

Name:

Title: Director

Title:

Read and acknowledged (Principal Investigator)

Date:

Name:

Title:

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

Annex B: Offer related to the research proposal in Annex A.

Annex C: Proposal for sublicense