DATA/MATERIAL TRANSFER AGREEMENT

This Agreement, effective as of _____(date), is entered into between

1. Parties

"Cohort" shall be _____ (institution), and contact person _____ (name), _____(address),

and "Recipient" shall be _____ (institution),and Principal Investigator _____ (name).

This Agreement governs the transfer of Material to the Recipient to be used in the Recipient's project, which has been described in Appendix 2.

The Material to be transferred and the logistics of this transfer is described in Appendix 3. Other applicable agreements are specified in Appendix 5.

For the sake of clarity, these terms apply both to Principal Investigator and its affiliation institution, and they shall ensure that any person dealing with the Material adheres to these Terms and the entire Agreement at all times.

2. Definitions

"BBMRI-LPC" –transfer is a material transfer subject to the terms of EU-funded Project BBMRI-LPC, Grant Agreement nr 313000, and subject to the terms and conditions laid down in the Grant Agreement and Consortium Agreement between the Parties, signed in May 2013

"Cohort" means _____(specify here)

"Decision" means the decision of the Cohort to grant access to the Material.

"Material" means personal data (whether anonymous, or coded; specific or raw data), screening results, etc.), biological specimens, images, research tools or other _____ that the Cohort transfers to Recipient for the research purposes as specified in Appendix 2.

"Project" means the research as specified in Appendix 2.

3. Term and Timelines
This Agreement is valid from the signature date until the end date defined in Appendix 2.

The Recipient shall provide progress reports to the Cohort at 12 months intervals during the active project period.

The Recipient shall provide Cohort with the research results, such as assay and analysis data ("raw data") within _____ after termination of the Project as defined in Appendix 2.

The Recipient is encouraged to publish research results in a scientific peer reviewed journal _____(specify) within _____ after termination of the project.

At the Recipient's request, Cohort may, at its discretion, extend the term and timelines by a new decision sent to the Recipient.

4. Services

In addition to the services necessary to transfer the Material (such as sample collection, preparation and coding), the Cohort will provide the Recipient with the services, including data and samples, as listed in Appendix 3

5. Permitted uses and protection of privacy

The Recipient may use the Material for the Research as specified in Appendix 2. Material shall be not used in human subjects. The Recipient shall comply with all applicable laws, the terms of this Agreement, and relevant existing or future decisions or statements by authorities (e.g., data protection) or research ethics boards.

The Recipient may not use the Material for any other purposes than described in the Appendix 2, or share it with any other party without a written approval of Cohort. The Recipient shall notify Cohort of any access requests from any public authorities.

The Recipient is not allowed in its own right to disclose the Material or research project results in Open Access portals, such as public databases or Open Access Journals, if that would mean sharing the individual-level Material. However, it should be noted, that many high quality scientific journals do require some sort of access to raw data/materials and restricting this may prevent the publication of the results. The Cohort contact person will let the Recipient to know about its policy in this matter before the signing of this Agreement, if so requested by the Recipient. Any further policy changes in this topic in the Cohort will be told by the Cohort contact person to the Recipient as soon as possible in case of such occurrence. The Recipient will follow the Cohort policy in this regard for the Cohort data. The Cohort will have a veto right for data sharing by the Recipient, even if this would prevent the publication of the results, in case the data sharing would be against the Cohort policy. The Recipient will let the Cohort contact person know about any data release of the Cohort data at least four weeks before the release.

Secure data access, such as passwords, firewalls, etc., must be in place to ensure that the data are kept secure. Recipient shall access the provided dataset by using a network drive set up by the organisation where they work, and avoid keeping datasets on their own PC/laptop, unless it is highly encrypted. (*More specified, if needed)*.

The Material will be provided without individual identifiers such as names, addresses, contact information and the like. Additionally, extra restrictions have been applied to the data released to external Recipient:

(1) Sample donors are identified using a secondary ID that will be different for each Cohort resource sharing project.

(2) All datasets will be stripped off specific variables that can create a risk of sample donor identification (such as complete date of birth and death), which could potentially enable the identification of subjects.

It will be the responsibility of the Recipient to ensure that no sample donor's identity is disclosed under any circumstances. Recipient must also preserve the confidentiality of the data in outputs and publications. It is forbidden to match or attempt to match or link individual records to any other data not belonging to this project.

The Recipient is responsible to inform all research group members about the terms and conditions of this agreement.

6. No warranty

The Cohort provides the Material on an "as is" basis, without any representations and warranties, whether express or implied. However, if the Material send is not exploitable for quality reasons, the Cohort should be in measure to proceed to a new shipping.

7. Ownership and Intellectual property

The Ownership of the Material remains at the Cohort, and it claims no ownership to new intellectual property invented or developed solely by or for the Recipient in connection with the project. The Recipient covenants not to assert its intellectual property rights arisen from the Project and Material against the Cohort, its owners or successors, in any court or administrative agency. This covenant applies only to not-for-profit activities, research and development.

Terms in EU Agreements, as specified in Appendix 5, are applied within the BBMRI-LPC transfer. Annex-I to EU Grant Agreement, Section B3.2.2 states that the IP management will be implemented in accordance with the IMI Intellectual Property Policy.

8. Publications

The most important purpose of the data and sample access is scientific research and the results shall be published. The Recipient shall aim to publish the results in a scientific journal or otherwise in a peer-reviewed, publically available way] without a delay and within 12 months from the completion of the Project or before the date set in forth in [the Appendix 2]. If there are delays to the publication, the Cohort contact person shall be notified of this in the 12 month reports with a plan for time schedule.

Authorship and contributions will be determined in accordance with scientific standards (International Committee of Medical Journal Editors). In general, it is of good scientific practice to include author(s) from the Cohort in the publication(s). If there is foreseen a deviation from this practice and the Recipient's plans are not to include authors from the Cohort, the Cohort contact person will be notified of this at least one month before the first submission of the scientific manuscript or similar publication.

A suitable note of acknowledgement should be included in the publication/s, such as: *"The samples/data used for the research were obtained from "Cohort" –specify". We thank all study participants for their generous participation in the Cohort-study."* If a BRIF-ID has been assigned to the sample collection, this should be mentioned in the Methods section of the publication.

If applicable, the Publication shall include an acknowledgement to the EU Grant as follows: "*This research has received funding from the European Union 7th Framework Programme (FP7/2007-2013) under Grant Agreement no 313010".*

9. Completion of project and returning of research results

On completion of the Project, the Recipient must return any remaining usable samples to the Cohort, unless otherwise agreed. Unusable samples must be destroyed, and the Cohort must be notified of destruction. The data and other Material provided by the Cohort must not be used anymore. All electronic copies of the data must be deleted; excluding copies that are needed for backing up the results. The Recipient shall notify which copies it maintains, and for how long.

The Recipient must offer to the Cohort all research project results, such as assay and analysis data ("raw data"), supplied with appropriate documentation. These research results will be available from the Cohort also for other

researchers according to the Cohort's general access policy after a 12 months after the termination of the project as specified ion the Appendix 2 A certain embargo regarding this obligation can be negotiated on a case-by- case basis.

10. Liability

Parties shall not be liable towards each other for indirect damages,for example a data breach at the other party, followed by a claim from a data subject or a data authority The limitations shall not apply to gross negligence or intentional misconduct of the other party.

11. Indemnification

The Recipient agrees to indemnify the Cohort and its employees and hold them harmless from any third party action, claim, or liability, arising directly or indirectly from the Recipient's use of Material, unless the claim or liability is caused by a gross negligence or intentional misconduct on the Cohort's side.

12. Law and jurisdiction

The Agreement shall be construed, interpreted and governed by the laws of Belgium (*or select primarily the country of the Cohort*). *EU funded project, GA and CA define laws of Belgium, and arbitration in Belgium.* For the sake of clarity, nothing in this Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be Brussels unless otherwise agreed upon. The language to be used in the mediation shall be English unless otherwise agreed upon.

If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within 60 days of the commencement of the mediation, it shall, upon filing of a request for arbitration by either party, be referred to and finally settled by arbitration in accordance of the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The place of arbitration shall be Brussels unless otherwise agreed upon.

The language to be used in the arbitration proceedings shall be English unless otherwise agreed upon.

13. Other Terms

Additional terms (if necessary):_____

Other relevant agreements affecting this Agreement and their priority shall be specified and/or enclosed as Appendix 5. Deviations from Appendix 5 (if necessary):_____

Any amendments to this Agreement shall be made in written and signed by all parties.

14. Payment

Under BBMRI-LPC, transfers are paid by EU FP7 funds budgeted for the BBMRI-LPC access costs. according to the incurred cost. For the access costs to be eligible for BBMRI-LPC reimbursement, the access must be provided by the end of BBMRI-LPC EU funding period. If the Cohort is not eligible for the reimbursement or if it decides to wave the reimbursement, no payment will be done.

Service prices are defined in Appendix 4, if applicable. The Recipient will be invoiced and payment made before delivery of Material.

15. Citation of bioresources

If the bioresource requires to be cited according to the CoBRA (Citation of BioResource in journal Articles) guideline in publications referring to it, the citation format for the specific resource object of the MTA (i.e. name, ID etc.) is specified here (if necessary):

_____

Checklist at: http://www.equator-network.org/reporting-guidelines/cobra/
Full guideline at http://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-015-0266-y

16. Contacts and notifications

Contractual notices are to be provided for the

For Cohort
For Recipient

Contact persons for scientific and practical matters related to the research project:

For Cohort
For Recipient

17. The entire agreement

The entire Material Transfer Agreement between the Parties is composed of this body text and the following appendices:

- Appendix 1: Specification of the Decision granting access to Material.
- Appendix 2: Research plan / application, *as valid and updated* based on the Decision.
- Appendix 3: Specification of the Material and logistics.
- Appendix 4: Payments
- Appendix 5: Other directly relevant and applicable agreements, or a list of them (such as already existing agreements with the parties, EU Consortium and Grant Agreements), and their PRIORITY.
- Appendix 6: List of relevant other decisions or statements by authorities (e.g., data protection) or research ethics review with dates and period of validity / and/or copies of the same.

Acknowledged, accepted and agreed. This agreement can be executed electronically.

Signatures & dates

Appendix 1: Specification of the decision granting access to Material.
Appendix 2: Research plan / application.
Appendix 3: Specification of the Material and Logistics.

Appendix 4: Payments
Appendix 5: Other directly relevant and applicable agreements, or a list of them (such as already existing agreements with the parties, EU Consortium and Grant Agreements), and their PRIORITY.
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