Annex II: Material Transfer Agreement with the Applicant for data and/or samples

Dear _____

UK Biobank is pleased to approve your Application Reference Number _____ to use the UK Biobank Resource. Execution of this Material Transfer Agreement (MTA) and payment of the Access Charges are the final steps before access is granted. UK Biobank's approval of this Application is valid for 90 days, after which the Applicant Principal Investigator (PI) will need to re-apply for access. The content of UK Biobank's standard MTA, and the conditions contained within it, are non-negotiable.

Parties

This is an agreement between UK Biobank Limited on the one hand and the Applicant Institution (_____) on the other hand. The Applicant PI is not a party to the MTA; however, UK Biobank requires that the Applicant PI acknowledges that the provisions of this MTA have been "read and understood" by the Applicant PI so that they are fully aware of their Institution's obligations to both UK Biobank and to UK Biobank's participants.

The Applicant Institution will be responsible for the conduct of any and all of the Applicant Researchers involved in this Research Project. The Applicant Institution shall not be responsible for the conduct of the Collaborating Institution(s), the Collaborating Investigator(s) or the Collaborating Researcher(s).

Structure of agreement

The MTA will become effective on receipt by UK Biobank of:

(i) A copy of this MTA Agreement (and copies of the relevant executed MTAs from all Collaborating Institution(s)) executed by an authorised signatory of the Applicant Institution and confirmed as "read and understood" by the Applicant PI; and
(ii) Cleared funds covering the Access Charges from the Applicant Institution.

UK Biobank will then promptly send a dated confirmatory email.

Provision of samples and/or data

Annex A summarises the data and/or samples that UK Biobank will make available to the Applicant in accordance with their approved Application Reference Number _____. The timeframe and methodology by which the data and/or samples will be dispatched is also set out in Annex A.

Payment

The Access Charges which are payable are set out in Annex B. This also serves as an invoice on which VAT will be included (as appropriate). The derivation of these Access Charges is also set out in Annex B.

This payment should be submitted in cleared funds to Barclays Bank PLC, Account name: UK Biobank Limited, Account number: 33069427 and Sort code: 20-24-09.

Standard terms and schedules

This Agreement incorporates the attached terms and conditions (including any documents and/or materials that are referred to in them), the Annexes and where applicable the contents of the Preliminary and Main Application Forms with Reference Number _____.

Yours faithfully

For and on behalf of UK Biobank/Effective Date
(Jonathan Sellors / Company Solicitor)

Accepted and agreed

For and on behalf of Applicant Institution
(Please sign and print your name and position)

Read and understood by the Applicant Principal Investigator
(Please sign and print your name and position)

Annex II: Material Transfer Agreement with the Collaborator for data and/or samples

Dear _____

UK Biobank is pleased to approve the Application Reference Number _____ to use the UK Biobank Resource. Execution of this Material Transfer Agreement (MTA) and payment of the Access Charges are the final steps before access is granted. UK Biobank's approval of this Application is valid for 90 days, after which the Applicant Principal Investigator (PI) (_____) will need to re-apply for access. The content of UK Biobank's standard MTA, and the conditions contained within it, are non-negotiable.

Parties

This is an agreement between UK Biobank Limited on the one hand and the Collaborating Institution (_____) on the other hand. The Collaborating Investigator is not a party to the MTA; however, UK Biobank requires that the Collaborating Investigator acknowledges that the provisions of this MTA have been "read and understood" by the Collaborating Investigator so that they are fully aware of their Institute's obligations to both UK Biobank and to UK Biobank's participants.

The Collaborating Institution shall be responsible for the conduct of any and all of the Collaborating Researchers involved in this Research Project. The Collaborating Institution shall not be responsible for the obligations and responsible for the conduct of either (a) the Applicant Institution, the Applicant Principal Investigator or the Applicant Researchers or (b) third party Collaborating Institution(s), third party Collaborating Investigator(s) or third party Collaborating Researcher(s).

In the event that the related MTA with the Applicant is terminated (for whatever reason) then UK Biobank shall have the right to terminate this MTA forthwith on the provision of written notice to the Collaborator.

Structure of agreement

The MTA will become effective on receipt by UK Biobank of:

(i) A copy of this MTA Agreement (and a copy of the relevant executed MTA from the Applicant Institution and copy(s) of the relevant executed MTA(s) from third party Collaborating Institutions) executed by an authorised signatory of the Collaborating Institution and confirmed at "read and understood" by the Collaborating Investigator; and

(ii) Cleared funds covering the Access Charges from the Applicant Institution.

UK Biobank will then promptly send a dated confirmatory email.

Provision of samples and/or data

Annex A summarises the data and/or samples that UK Biobank will make available to the Collaborator in accordance with the approved Application Reference Number _____. The timeframe and methodology by which the data and/or samples will be dispatched is also set out in Annex A.

Standard terms and schedules

This Agreement incorporates the attached terms and conditions (including any documents and/or materials that are referred to in them), the Annexes and where applicable the contents of the Preliminary and Main Application Forms with Reference Number _____.

Yours faithfully

For and on behalf of UK Biobank / Effective Date
(Jonathan Sellors / Company Solicitor)

Accepted and agreed

For and on behalf of Collaborating Institution
(Please sign and print your name and position)

Read and Understood by the Collaborating Investigator
(Please sign and print your name and position)

Applicant Terms and Conditions

1 Supply of Materials by UK Biobank

1.1 UK Biobank agrees to supply the Materials set out in Annex A to the Applicant, in the timeframe and manner set out in that Annex, subject to the provisions of this MTA.

1.2 UK Biobank confirms that for the purposes of this MTA:

1.2.1 It is entitled to supply the Materials to the Applicant;

1.2.2 Consent in relation to the Data Protection Act 1998 and (where applicable) the Human Tissue Act 2004 has been obtained from the relevant UK Biobank participants; and

1.2.3 Unless specified in Annex A, the use of the Materials falls within UK Biobank's generic Research Tissue Bank (RTB) approval from the NHS North West REC.

1.3 The Applicant acknowledges that the Materials are provided on an "as is" basis without any warranty of satisfactory quality or fitness for a particular purpose or use or any other warranty, express or implied.

2 Usage of Materials by the Applicant

2.1 The Applicant agrees that the Materials may only be used for the Permitted Purpose, namely:

2.1.1 solely to conduct the Approved Research Project in the manner and timeframe set out in Annex A (namely the Permitted Purpose); and

2.1.2 solely by the Applicant PI and the related Applicant Researchers (and, in particular, are not to be shared with any other person without UK Biobank's explicit written approval).

2.2 The Applicant will ensure that the Applicant Researchers are made aware of, and will be bound by, the terms of this MTA. Any act or omission of any Applicant Researcher will be deemed to be an act of the Applicant for which the Applicant is fully responsible.

2.3 This MTA confers on the Applicant only those rights that are expressly granted to the Applicant. For the avoidance of doubt, nothing in this MTA will prevent UK Biobank from supplying the same Materials (or other data and/or samples in the UK Biobank Resource) to another third party.

3 Grant of rights to the Applicant

Provision of samples

3.1 UK Biobank is the owner of the property in the Samples in the Resource.

3.2 UK Biobank hereby grants the Applicant a limited, revocable, worldwide, royalty-free, non-exclusive licence (but not any ownership rights) to use the Samples for the Permitted Purpose only.

Provision of data

3.3 UK Biobank is the owner of the Intellectual Property Rights in the Data currently in the Resource.

3.4 UK Biobank hereby grants the Applicant a limited, revocable, worldwide, royalty-free, non-exclusive licence (but not any ownership rights) to use the Data for the Permitted Purpose only.

Generation of data during the Approved Research Project

3.5 The following provisions shall apply:

3.5.1 UK Biobank shall be the owner of the Intellectual Property Rights in any and all Assay Data generated during the Approved Research Project;

3.5.2 UK Biobank hereby grants the Applicant a limited, revocable, worldwide, royalty-free, non-exclusive licence (but not any ownership rights) to use the Assay Data for the Permitted Purpose only; and

3.5.3 Subject to the license-back provisions below, the Intellectual Property Rights in the Results Data deriving from use of the Resource for the Permitted Purpose will belong to the Applicant.

3.6 The Applicant hereby grants a perpetual, irrevocable, worldwide, fully paid-up, royalty-free, fully sub-licensable licence to UK Biobank to use, reproduce, distribute, publish, store and otherwise disseminate the Results Data.

Rights to inventions/developments made by the Applicant

3.7 Subject to the exception in Clause 3.8, UK Biobank confirms that it will have no rights or licence to the Intellectual Property Rights in relation to any inventions or findings developed by the Applicant as a result of using the Materials ("Applicant-Generated Inventions").

3.8 The exception would apply where Applicant-Generated Inventions are, or are in the process of being, used unreasonably to restrict health-related research and/or access to healthcare anywhere in the world ("Unreasonable Restriction"). If, at its reasonable discretion, UK Biobank considers that an Unreasonable Restriction exists or is likely to exist then it shall promptly notify the Applicant and automatically, on receipt of such notification, the Applicant shall be deemed to grant a perpetual, irrevocable, worldwide, fully paid-up, royalty-free, fully sub-licensable licence to UK Biobank to use such Applicant-Generated Invention in order to remove or mitigate the Unreasonable Restriction.

Limitation on rights granted

3.9 UK Biobank expressly excludes (directly or indirectly) (i) any right of the Applicant to sub-licence any of the rights granted to the Applicant hereunder and/or (ii) any right of the Applicant to re-publish any of the Materials except for the sole purpose of including a commensurate amount of Data in the Applicant's publication of its Results.

3.10 For the avoidance of doubt, the rights granted under this MTA are for the Permitted Purpose only and any other purposes or usages shall require the Applicant to make a further Application.

4 Confirmations from the Applicant

General

4.1 The Applicant hereby confirms to UK Biobank that all work using the Materials will be carried out in compliance with all applicable laws, regulations, guidelines and approvals, including without limitation the Human Tissue Act 2004, the Data Protection Act 1998 and any approvals required from a Research Ethics Committee (or the applicable equivalent in the jurisdiction where the Approved Research Project is to be conducted).

Security

4.2 The Applicant will retain the Materials in a secure location as regards Samples or a secure network system as regards Data at such standard as would be reasonably expected for the storage of valuable and proprietary samples and/or sensitive/confidential data.

Withdrawal

4.3 The Applicant confirms that it will deal promptly and appropriately (within the parameters set out in the withdrawal protocol www.ukbiobank.ac.uk/principles-of-access/) with any withdrawals by Participants which UK Biobank notify to the Applicant.

Identification of participants

4.4 The Applicant shall not attempt:

4.4.1 to identify any Participant from the Materials provided by UK Biobank; or

4.4.2 to contact any Participant, save only as may be permitted under an Approved Research Project involving re-contact by the Applicant.

4.5 In the event that an Applicant inadvertently identifies any Participant then they will notify UK Biobank immediately setting out (in reasonable detail) the circumstances by which it happened.

4.6 Other than for the purposes of clause 4.5, the Applicant will not:

4.6.1 share the identification of that Participant with any other person; or

4.6.2 attempt to contact the Participant themselves.

Provide periodic updates to UK Biobank

4.7 The Applicant will provide UK Biobank with:

4.7.1 a report on the progress of the Research Project in a form as required by UK Biobank on an annual basis (from the date on which the MTA was executed); and

4.7.2 a copy of any patents whose claims cover, or are intended to cover, an Applicant Generated Invention within two months of their publication.

5 Additional provisions for different types of Material or Research Project

Samples

5.1 The Applicant acknowledges that the Samples provided may contain viruses, latent viral genomes or other infectious agents. The Applicant undertakes to treat such Samples as if they are not free from contamination and to ensure that all Samples are handled by appropriately trained personnel under laboratory conditions that incorporate adequate biohazard containment. From the time of receipt, the Applicant is fully responsible for the safe and appropriate handling of the Samples.

5.2 The Applicant confirms that the Samples will be kept on the premises of the Applicant at the address specified in the Application and not transferred (in whole or part) to any other location without the prior written approval of UK Biobank.

5.3 The Applicant confirms that the Approved Research Project has been subject to independent scientific review by a recognised body in the manner described in the Application.

5.4 On the Completion of the Research Project, the Applicant will destroy the Samples and confirm to UK Biobank (in writing) that this has taken place.

Assays

5.5 In the event that the Applicant has requested that certain assays be conducted on selected Samples (and UK Biobank agrees to conduct such assays on behalf of the Applicant):

5.5.1 UK Biobank agrees to conduct such assays, or have them conducted by an appropriately qualified third party, with reasonable skill and care;

5.5.2 UK Biobank shall provide the Applicant with the data from the assays ("UK Biobank Assay Data");

5.5.3 The UK Biobank Assay Data shall be treated in the same manner as other Assay Data (as set out in clauses 3.5.1 and 3.5.2) and subject to clause 5.5.4 below, the UK Biobank Assay Data will be deemed to be incorporated within the Data supplied to the Applicant and inter alia subject to the provisions of this MTA;

5.5.4 the Applicant will have a period of 3 months in which to use this Assay Data before UK Biobank makes them available to other Applicants.

6 Return and publication of Results

Publication of summary on UK Biobank's website

6.1 After the Applicant has received the Data (including any sample assays) agreed for the Research Project, UK Biobank will be entitled to publish on its website:

6.1.1 The summary of the Research Project contained in the Application (with the exception of any material that has been agreed by the parties would be kept confidential);

6.1.2 Summary details of the Applicant (unless it has been agreed by the parties that this information would be kept confidential).

Publication of Results

6.2 The Applicant shall use its best endeavours to publish the Results within 6 months after the Completion Date for the Research Project:

6.2.1 in an academic journal; or

6.2.2 on an open source publication site.

6.3 By the earlier of 6 months after the publication of the Results, or 12 months after the Completion Date, the Applicant will provide to UK Biobank a copy of:

6.3.1 the Results themselves in such form and format as UK Biobank will reasonably require;

6.3.2 the Results Data in such form and format as UK Biobank will reasonably require.

6.4 UK Biobank will consider reasonably any written requests (containing an appropriate explanation) for an extension of the time limits set out in this clause.

Notification to UK Biobank

6.5 The Applicant is not required to obtain UK Biobank's approval to any report of its Results.

6.6 The Applicant shall provide a copy of any report of its Results that derive from use of the Resource to UK Biobank at least 2 weeks before their expected date of first public presentation or publication in any format (e.g. paper journal, on-line report, meeting abstract).

6.7 In addition, the Applicant is required to notify UK Biobank (in writing) if any report of its Results is reasonably likely to provoke controversy or otherwise attract significant public attention. In such circumstances, UK Biobank reserves the right to make such recommendations, reservations or suggestions on the report as it sees fit (and which it may make public) for consideration by the Applicant.

Credit to UK Biobank

6.8 UK Biobank requires that any publication of Results includes the following credit, which credit shall be incorporated within the so-called "abstract" of such publication:

"This research has been conducted using the UK Biobank Resource."

6.9 This acknowledgement to UK Biobank should, when possible, be linked to reference search tools (such as PubMed and MEDLINE).

7 Charges

7.1 The Applicant agrees to pay the Access Charges set out in the invoice (Annex B) to UK Biobank in the manner set out in that invoice. Where VAT is applicable, the Access Charges will include it.

7.2 This MTA is conditional on the Access Charges being paid and so, for the avoidance of doubt, no Materials will be provided to the Applicant until or unless the Access Charges are received in full.

8 Audit

8.1 On reasonable notice to the Applicant, and in order to confirm or investigate compliance with the provisions of this MTA, UK Biobank may itself or via appropriate third parties:

8.1.1 choose to inspect the premises and other relevant facilities of the Applicant, in order to review the security, storage or other arrangements for the Materials;

8.1.2 request such additional information about the Approved Research Project and/or its progress as UK Biobank may, from time to time, reasonably require.

8.2 UK Biobank will bear the costs of such audits unless a material default within the procedures and processes of the Applicant is discovered, in which case the Applicant will be obliged to re-imburse the reasonable costs of UK Biobank and any relevant third parties.

9 Confidentiality

9.1 Subject to the exceptions in Clause 9.2, UK Biobank will keep confidential any information disclosed to it in writing by the Applicant that is marked confidential ("Applicant's Confidential Information") and will not disclose such information to any person.

9.2 UK Biobank may disclose Applicant's Confidential Information where allowed by this MTA or when:

9.2.1 it is required to be disclosed by law, by any governmental or other regulatory authority, by a court or other authority of competent jurisdiction; or

9.2.2 it can be shown by UK Biobank (to the Applicant's reasonable satisfaction) to have been known by UK Biobank before disclosure to it by the Applicant; or

9.2.3 it was lawfully disclosed to UK Biobank by a third party who did not impose any restrictions on its disclosure;

9.2.4 the information was in (or enters into) the public domain other than by reason of a breach of this clause by UK Biobank; or

9.2.5 UK Biobank and the Applicant agree, acting reasonably, that such information is trivial or obvious, or they agree in writing that such disclosure may be permitted.

10 Indemnity

10.1 The Applicant will indemnify UK Biobank against all losses (whether direct or indirect, reasonably foreseeable or specifically contemplated by the parties), damages, costs, expenses (including but not limited to reasonable legal costs and expenses) that it incurs directly as a result of: (i) any material breach of clauses 2, 4, 5 or 6 by the Applicant; or (ii) any negligence or wilful default of the Applicant, provided that UK Biobank agrees to use its reasonable endeavours to mitigate any loss.

11 Term

11.1 The term of this MTA shall commence on the Effective Date and shall end on the later of: (i) twelve (12) months after the Completion Date; or (ii) the date on which UK Biobank receives a copy of the Results Data in accordance with the provisions of clause 6.3.

11.2 This term may be extended by UK Biobank, in its reasonable discretion, on application to UK Biobank by the Applicant setting out (in reasonable detail) the reasons for any delay or extension, (for example where the Applicant seeks to publish further or supplemental Results).

12 Termination

12.1 UK Biobank will be entitled to terminate this MTA forthwith by written notice to the Applicant if:

12.1.1 The Applicant commits any breach of a material provision of this MTA and, in the case of a breach capable of remedy, fails to remedy the same within 10 days after receipt of a written notice giving particulars of the breach and requiring it to be remedied;

12.1.2 The Applicant PI ceases to be employed (or otherwise engaged by) the Applicant Institution; or

12.1.3 The Applicant Institution ceases, is likely to cease, or threatens to cease carrying on business.

12.2 For the purposes of clause 12, a breach will be considered capable of remedy if the Applicant can comply with the provision in question in all respects other than as to the time of performance, provided that time of performance is not of the essence.

12.3 The rights to terminate this MTA given by this clause will be without prejudice to any other right or remedy of either party in respect of the breach concerned, if any, or any other breach.

13 Consequences of termination

13.1 Upon expiry of the MTA pursuant to clause 11 above or termination of this Agreement by UK Biobank pursuant to clause 12:

13.1.1 The grant of rights to the Applicant will be automatically terminated;

13.1.2 The Applicant shall destroy the Data or otherwise render it inaccessible; and

13.1.3 The Applicant shall, at the option of UK Biobank, destroy or return forthwith any unused Samples.

13.2 Without prejudice to the foregoing and to any other rights that UK Biobank may have in relation to termination as a consequence of a material breach, UK Biobank may take the following steps in respect of a breach under clause 12.1:

13.2.1 It may prohibit the Applicant PI and other researchers from the Applicant's Institution from accessing any further materials from within the UK Biobank Resource; and/or

13.2.2 It may inform relevant personnel within the Applicant PI's Institution, funders of the Applicant and/or governing or other relevant regulatory bodies.

13.3 Notwithstanding termination of this MTA for any reason, the provisions of clauses 1, 2, 3, 4, 5, 8, 9, 10, 12, 13, 14, 15, 17 and 18 shall continue in force in accordance with their respective terms.

14 Notices

14.1 Notices required under this MTA will be in writing and will be delivered by email to the addresses set out below or (in the event of a failure to deliver an email) by post to UK Biobank or the Applicant and will be deemed to be given, in the case of delivery by email, upon receipt at the recipient's email server (unless an automatic response indicating an undeliverable message is received) and, in the case of delivery by post, on the date of delivery (or, if not a business day, on the first business day thereafter).

14.2 Notices to UK Biobank will be sent to the Research Access Administration Manager with a copy to access@ukbiobank.ac.uk and marked for the attention of Mrs Lorraine Gillions. Notices to the Applicant will be sent to the Applicant PI with a copy to the Applicant Institution.

15 Assignment and sub-contracting

15.1 Neither party will be entitled to assign this MTA or any of its rights or obligations hereunder without first having received the written approval of the other party, which approval not to be unreasonably withheld or delayed.

15.2 The Applicant will not sub-contract the performance of any of its obligations under the MTA or any part thereof without having first obtained the prior written consent of UK Biobank, such consent not be unreasonably withheld.

15.3 In the event that consent is granted under clause 15.2, the Applicant shall be responsible for the acts, defaults and omissions of its sub-contractors as if they were the Applicant's own, and any consent given will not relieve the Applicant of any of its obligations under this MTA.

16 Force majeure

16.1 If any party is prevented from, hindered or delayed in performing any of its obligations under this MTA by reason of a Force Majeure Event, such party will promptly notify the other of the date of its commencement and the effects of the Force Majeure Event on its ability to perform its obligations under this MTA. If mutually agreed by the parties, then the obligations of the party so affected will thereupon be suspended for so long as the Force Majeure Event may continue.

16.2 The party affected by a Force Majeure Event will not be liable for any failure to perform such of its obligations as are prevented by the Force Majeure Event provided that such party will use every reasonable effort to minimise the effects thereof and will resume performance as soon as possible after the removal of such Force Majeure Event. If the period of non-performance exceeds 28 days from the start of the Force Majeure Event then the non-affected party will have the option, by written notice to the other party, to terminate this MTA.

16.3 For the purpose of this clause, Force Majeure Event means any event beyond the reasonable control of a party including, without limitation, acts of God, war, terrorism, riot, civil commotion, malicious damage, compliance with any law or governmental order, rule, regulation or direction, accident, fire, flood or storm. For the avoidance of doubt, strike, industrial action, failure of technology systems, third party insolvency and failure of UK Biobank or any other third party will not be considered to be Force Majeure Events.

16.4 The provisions of this clause 16 will not affect any other right which either party may have to terminate this MTA.

17 Dispute resolution

17.1 Any party may give the other party written notice of any dispute arising out of or in connection with this MTA ("Notice of Dispute") not resolved in the normal course of business. Within five (5) business days following

delivery of such notice, a UK Biobank representative and an Applicant representative will discuss by telephone or meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve such Dispute.

17.2 If any Dispute raised pursuant to clause 17.1 is not resolved by the respective representatives of the parties within ten (10) business days of the date on which delivery of the Notice of Dispute is deemed to be given then the Dispute will be referred to the UK Biobank Principal Investigator and an appropriate senior member of the Applicant Institution. These senior representatives of the parties will convene as soon as reasonably practicable (in person or by phone) after such referral to discuss the Dispute in an attempt to resolve it.

17.3 If any Dispute remains unresolved ten (10) business days following such referral, either party may initiate non-binding mediation of the Dispute to the London Court of International Arbitration ("LCIA") for mediation in accordance with the LCIA Mediation Procedure. All negotiations related to this referral shall be confidential and treated as compromise and settlement negotiations. The place of such mediation will be London and the language of the mediation shall be English.

17.4 Nothing in this clause 17 will serve to prevent either party from seeking interim relief in the High Court of England and Wales or from terminating this MTA.

18 General

18.1 This MTA governs the relationship between the parties to the exclusion of any other terms and conditions and, together with any other document referred to in this Agreement, constitutes the whole agreement between the parties in relation to the subject matter hereof.

18.2 If there is any conflict between the provisions of this MTA and any of the annexes and related documents (including, but without limitation, the provisions of the Access Procedures) then the provisions of this MTA will apply.

18.3 A waiver, delay or forbearance by either party, whether express or implied, in enforcing or exercising any of its rights or remedies hereunder will not constitute a waiver of such right or remedy.

18.4 No provision of this MTA is intended to be enforceable by any person who is not a party to this Agreement and nor are any rights granted to any third party under statute or otherwise.

18.5 Nothing in this MTA will create a partnership, joint venture or relationship of agency between the parties.

18.6 All variations to this MTA must be agreed, set out in writing and signed on behalf of the parties before they take effect.

18.7 This MTA will be governed by and construed in accordance with English law and, subject to clause 17 above, the parties irrevocably agree that the English courts will have exclusive jurisdiction over any suit, action, proceedings or dispute arising out of, or in connection with, this Agreement.

Definitions used in the Material Transfer Agreement (MTA)

Access Charges: the charges payable by the Applicant (which may include VAT) to access the Materials.

Applicant: the Applicant Institution.

Applicant-Generated Invention: an invention developed by the Applicant as a result of carrying out the Approved Research Project.

Applicant Institution: the institution making the Application for access in respect of the Research Project and by which the Applicant PI is employed or otherwise contractually attached.

Applicant Principal Investigator (*PI):* the Principal Investigator of the Research Project.

Applicant Researcher: a researcher who is working with the Applicant PI on the Research Project.

Application: the application by the Applicant to UK Biobank for access to the Materials for use in relation to the Research Project.

Approved Research Project: the Research Project approved by UK Biobank (specifically including any conditions or stipulations made by UK Biobank).

Assay Data: any data generated pursuant to analyses of the Samples or other Materials (including but without limitation any data variables derived from the analysis of combination(s) of any Data or Assay Data), irrespective of whether such Assay Data is generated (a) by or on behalf of UK Biobank (in which case it is UK Biobank Assay Data) (b) by the Applicant or (c) other third party.

Collaborator: the Collaborating Institution.

Collaborating Institution: the institution collaborating with the Applicant in respect of the Application for access (in respect of the Research Project) and by which the Collaborating Investigator is employed or otherwise contractually attached.

Collaborating Investigator: the lead investigator in respect of the Application at the Collaborating Institution.

Collaborating Researcher: a researcher who is working with the Collaborating Investigator at the Collaborating Institution on the Research Project.

Completion Date: the date contained within Annex A on which the Applicant represents that the findings of the Approved Research Project will be published (or as such date may, from time to time, be altered by agreement with UK Biobank).

Consent: the consent provided by each Participant.

Data: the data being supplied to the Applicant by UK Biobank for the Approved Research Project.

Effective Date: the date on which a confirmatory email is sent by UK Biobank to the Applicant confirming receipt of a copy of this MTA executed by the parties and cleared funds covering the Access Charges.

Findings: the findings made by the Applicant pursuant to the Approved Research Project.

Intellectual Property Rights (IPRs): all present and future intellectual property rights including but not limited to patents, trade and service marks, design rights, copyright, database rights, trade secrets and know-how, in all cases whether registered or not or registerable, and including all registrations and applications for registrations of any of these and rights to apply for the same as well as any renewals, extensions, continuations, combinations or divisions thereof, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these anywhere in the world.

Materials: the Data and/or Samples supplied by UK Biobank to the Applicant under this Agreement.

Participants: the individuals who consented to participate in UK Biobank.

Permitted Purpose: to conduct the Approved Research Project in the manner and timeframe set out in Annex A, subject to the provisions of this MTA.

Resource: the collection of Data and Samples within UK Biobank which are accessible by Applicants.

Results: the findings generated by the Applicant pursuant to the Approved Research Project.

Results Data: the data generated and derived by the Applicant, other than any Assay Data, which underlie the Results.

Samples: the samples held by UK Biobank that are being used for the Approved Research Project.

Term: the period starting on the Effective Date and ending at the time and on the basis set out in this Agreement and as may be extended or terminated in accordance with the terms of this Agreement.

Annex III: Conflict of Interest Policy

1 Introduction and Background

1.1 This policy aims to ensure that UK Biobank's decision-making processes for access to the UK Biobank Resource are conducted in accordance with the highest standards of integrity. The key principle guiding access is the promotion of high quality health research for the public benefit.

2 Application of Policy

2.1 This policy applies to UK Biobank's:

- Board of Directors, including its Access Sub-Committee;
- Principal Investigator and UK Biobank staff; and
- Any advisors involved in the access review process.

2.2 Each person covered by this policy (Individual) has an ongoing responsibility to comply with the terms of this policy. In complying with these terms, an interpretation should be taken which ensures adherence to both the spirit and the letter of this policy.

3 Guiding principles

3.1 Decisions concerning applications for access to the Resource should be guided by UK Biobank's Ethics & Governance Framework and its Access Criteria, and made free from external influences (such as related academic interests or positions of responsibility held outside of UK Biobank).

3.2 Individuals must be alert to the risk of a conflict of interest arising, and appreciate that this is an ongoing responsibility. They must not make any academic or financial gain as a result of involvement in UK Biobank's decision-making processes.

3.3 A conflict of interest in this context specifically includes academic, financial or other conflicts which (directly or indirectly) might interfere with, limit or compromise the ability of the Individual to review applications to use the Resource in an objective manner.

4 Managing Conflicts

4.1 If an Individual identifies an actual or potential conflict of interest with any Application under review, they should disclose the nature and extent of this conflict to UK Biobank's Board Secretary immediately. An actual or potential conflict of interest will include any situation which could reasonably be perceived to result in such conflict.

4.2 Individuals should declare all direct and indirect academic interests relating to an Application, including (but without limitation) being involved in the preparation of the Application, being involved in a "competing" research activity, and/or being funded by the same institution as the Applicant.

4.3 If an Individual has a commercial interest in the Applicant Institution and/or funding organisation for the Applicant Institution, this should be disclosed to UK Biobank's Board Secretary. A commercial interest is deemed to exist where that interest is deemed to be worth more than £25,000.

4.4 Disclosures of conflicts of interest may either be specific to a particular Application or may be general with respect to an Applicant PI, Applicant Researcher, Applicant Institution and/or funding organisation. A general disclosure will exempt an Individual from making repeat disclosures in respect of future Applications involving that Individual, Institution and/or funding organisation.

4.5 Any Participant, Applicant, Researcher or other person who considers that a conflict of interest exists should disclose their concern to UK Biobank's Board Secretary.

5 Conflict Action Points

5.1 At the beginning of each meeting of the Access Sub-Committee or the Board, the Board Secretary will request that members declare any potential conflicts of interest related to the Applications that are under consideration.

5.2 In the event that a disclosure is made, it will be for UK Biobank's Board Secretary to determine whether it is a material conflict of interest:

5.2.1 in conjunction with the Chair of the Access Sub-Committee if the conflict relates to a member of the Access Sub-Committee or a member of UK Biobank Staff (including the UK Biobank Principal Investigator) or an advisor to UK Biobank;

5.2.2 in conjunction with the Chair of the Board of UK Biobank if the conflict relates to the Chair of the Access Sub-Committee or a member of UK Biobank's Board; or

5.2.3 in conjunction with the Deputy Chair of the Board of UK Biobank if the conflict relates to the Chair of the Board of UK Biobank.

5.3 In the event of a material conflict of interest, the Individual must not take part in any decisions relating to that Application. In particular, the Individual must not:

5.3.1 be involved in the review of the Preliminary or Main Application, or any Reconsiderations;

5.3.2 be involved in decisions about the Preliminary or Main Application, or any Reconsiderations;

5.3.3 receive any further papers or information concerning the Application; and

5.3.4 attend those parts of any meetings in which the Application is discussed.

6 Conduct

6.1 This policy will be subject to periodic review. Individuals should be familiar with the most recent version of the policy.

6.2 If Individuals have any queries or concerns regarding the application of this policy, they should consult with UK Biobank's Board Secretary.

6.3 Breaches of this policy will be treated seriously and disciplinary action taken in appropriate cases.

Annex IV: Data Protection Policy for the personal data of Applicants

1 Policy statement

1.1 UK Biobank is committed to the fair and lawful processing of personal data, in accordance with the Data Protection Act.

1.2 This data protection policy explains how UK Biobank uses personal information collected about Applicant Principal Investigators and Researchers (collectively Applicants*)* seeking access to the UK Biobank Resource.

1.3 This data protection policy has no application to the personal data of participants, which are dealt with under entirely separate criteria.

2 What information will UK Biobank collect about Applicants?

2.1 All Applicants intending to request access to data and/or samples will be required to provide their personal details before UK Biobank is able to process their Preliminary Applications.

2.2 Applicants will be required to update their personal details before UK Biobank is able to process their Main Applications.

2.3 UK Biobank will retain a record of all correspondence/contact with Applicants.

3 How will UK Biobank use information about Applicants?

3.1 During the course of UK Biobank's activities, it will collect, store, and process personal information about Applicants. Information that the Applicants supply will be treated in accordance with the principles of the Data Protection Act.

3.2 Information collected will be used to verify the identities of individuals requesting access to the Resource, and will be retained so that UK Biobank has a record for all Applications.

3.3 In reviewing Applications, UK Biobank may need to disclose Applicants' personal data to its Access Sub-Committee, Ethics & Governance Council, International Scientific Advisory Board and/or others (as it deems reasonably necessary).

3.4 UK Biobank seeks to keep the wider public informed of research findings deriving from access to the Resource. For this reason, unless agreed otherwise, details of approved Research Projects identifying the Principal Investigator will be made available on UK Biobank's website. Periodic updates of research that has been conducted, and publications that derive from use of the Resource, will be linked to UK Biobank's website.

3.5 UK Biobank may contact Registered Researchers by e-mail and/or by post, with updates on the Resource. For example, it may inform them when the Resource is likely to be sufficiently mature to establish case-control collections for various conditions; when linkage to health outcomes data has been introduced; and when research yields material extra data that are added to the Resource.

3.6 From time to time, UK Biobank may seek views from Applicants concerning the access procedures that are in place. Responses to such enquiries will be voluntary and any feedback used solely for evaluation purposes.

4 Data protection principles

4.1 In processing Applicants' personal information, UK Biobank is guided by the following principles (as contained in the UK's 1998 Data Protection Act):

4.1.1 Information will be processed fairly and lawfully;

4.1.2 Information will be processed for the purposes outlined in this policy;

4.1.3 Information collected will be relevant and not excessive for these purposes;

4.1.4 Information stored will be kept up to date;

4.1.5 Information stored will not be kept for longer than is necessary;

4.1.6 Information will be processed in accordance with Applicants' rights;

4.1.7 Appropriate organisational and technical measures will be in place to help ensure that information is kept secure; and

4.1.8 Information will not be transferred to people or organisations situated abroad without adequate protection.

5 Applicants' rights

5.1 Applicants have the right to ask for a copy of information that UK Biobank holds about them and to have any inaccuracies in information about them corrected (and UK Biobank may charge a small fee). Any such requests should be made to UK Biobank in writing at: UK Biobank Coordinating Centre, 1 & 2 Spectrum Way, Adswood, Stockport, Cheshire SK3 0SA.

5.2 If Applicants have questions about their rights under the Data Protection Act, or require any further information, they should e-mail dataprotection@ukbiobank.ac.uk or write to the Data Protection Officer, UK Biobank Limited, Units 1&2 Spectrum Way, Adswood, Stockport, Cheshire SK3 0SA.

Collaborator Terms and Conditions

The obligations imposed on the Collaborator contained in this Agreement shall be discharged by the Collaborator to the extent that they, in whole or part, (a) directly apply to the Collaborator and/or (b) have not been discharged by the Applicant.

The rights conferred on the Collaborator contained in this Agreement shall be for the benefit of the Collaborator to the extent that they, in whole or part, (a) directly apply to the Collaborator and/or (b) are not for the benefit of the Applicant.

1. Supply of Materials by UK Biobank/Intentionally deleted

2. Usage of Materials by the Collaborator

2.1 The Collaborator agrees that the Materials may only be used for the Permitted Purpose, namely:

2.1.1 solely to conduct the Approved Research Project in the manner and timeframe set out in Annex A (namely the Permitted Purpose); and

2.1.2 solely by the Collaborator and the related Collaborating Researchers (and, in particular, are not to be shared with any other person without UK Biobank's explicit written approval).

2.2 The Collaborator will ensure that the Collaborating Researchers are made aware of, and will be bound by, the terms of this MTA. Any act or omission of any Collaborating Researcher will be deemed to be an act of the Collaborator for which the Collaborator is fully responsible.

2.3 This MTA confers on the Collaborator only those rights that are expressly granted to the Collaborator. For the avoidance of doubt, nothing in this MTA will prevent UK Biobank from supplying the same Materials (or other data and/or samples in the UK Biobank Resource) to another third party.

3. Grant of rights to the Collaborator

Provision of samples

3.1 UK Biobank is the owner of the property in the Samples in the Resource.

3.2 UK Biobank hereby grants the Collaborator a limited, revocable, worldwide, royalty-free, non-exclusive licence (but not any ownership rights) to use the Samples for the Permitted Purpose only.

Provision of data

3.3 UK Biobank is the owner of the Intellectual Property Rights in the Data currently in the Resource.

3.4 UK Biobank hereby grants the Collaborator a limited, revocable, worldwide, royalty-free, non-exclusive licence (but not any ownership rights) to use the Data for the Permitted Purpose only.

Generation of data during the Approved Research Project

3.5 The following provisions shall apply:

3.5.1 UK Biobank shall be the owner of the Intellectual Property Rights in any and all Assay Data generated during the Approved Research Project;

3.5.2 UK Biobank hereby grants the Collaborator a limited, revocable, worldwide, royalty-free, non-exclusive licence (but not any ownership rights) to use the Assay Data for the Permitted Purpose only; and

3.5.3 Subject to the license-back provisions below, the Intellectual Property Rights in the Results Data deriving from use of the Resource for the Permitted Purpose will belong to the Collaborator.

3.6 The Collaborator hereby grants a perpetual, irrevocable, worldwide, fully paid-up, royalty-free, fully sub-licensable licence to UK Biobank to use, reproduce, distribute, publish, store and otherwise disseminate the Results Data.

Rights to inventions/developments made by the Collaborator

3.7 Subject to the exception in Clause 3.8, UK Biobank confirms that it will have no rights or licence to the Intellectual Property Rights in relation to any inventions or findings developed by the Collaborator as a result of using the Materials ("Collaborator-Generated Inventions").

3.8 The exception would apply where Collaborator-Generated Inventions are, or are in the process of being, used unreasonably to restrict health-related research and/or access to healthcare anywhere in the world ("Unreasonable Restriction"). If, at its reasonable discretion, UK Biobank considers that an Unreasonable Restriction exists or is likely to exist then it shall promptly notify the Collaborator and automatically, on receipt of such notification, the Collaborator shall be deemed to grant a perpetual, irrevocable, worldwide, fully paid-up, royalty-free, fully sub-licensable licence to UK Biobank to use such Collaborator-Generated Invention in order to remove or mitigate the Unreasonable Restriction.

Limitation on rights granted

3.9 UK Biobank expressly excludes (directly or indirectly) (i) any right of the Collaborator to sub-licence any of the rights granted to the Collaborator hereunder and/or (ii) any right of the Collaborator to re-publish any of the Materials except for the sole purpose of including a commensurate amount of Data in the Collaborator's publication of its Results.

3.10 For the avoidance of doubt, the rights granted under this MTA are for the Permitted Purpose only and any other purposes or usages shall require the Collaborator to make a further Application.

4. Confirmations from the Collaborator

General

4.1 The Collaborator hereby confirms to UK Biobank that all work using the Materials will be carried out in compliance with all applicable laws, regulations, guidelines and approvals, including without limitation the Human Tissue Act 2004, the Data Protection Act 1998 and any approvals required from a Research Ethics Committee (or the applicable equivalent in the jurisdiction where the Approved Research Project is to be conducted).

Security

4.2 The Collaborator will retain the Materials in a secure location as regards Samples or a secure network system as regards Data at such standard as would be reasonably expected for the storage of valuable and proprietary samples and/or sensitive/confidential data.

Withdrawal

4.3 The Collaborator confirms that it will deal promptly and appropriately (within the parameters set out in the withdrawal protocol www.ukbiobank.ac.uk/principles-of-access/) with any withdrawals by Participants which UK Biobank notify to the Collaborator.

Identification of participants

4.4 The Collaborator shall not attempt:

4.4.1 to identify any Participant from the Materials provided by UK Biobank; or

4.4.2 to contact any Participant, save only as may be permitted under an Approved Research Project involving re-contact by the Collaborator.

4.5 In the event that the Collaborator inadvertently identifies any Participant then they will notify UK Biobank immediately setting out (in reasonable detail) the circumstances by which it happened.

4.6 Other than for the purposes of clause 4.5, the Collaborator will not:

4.6.1 share the identification of that Participant with any other person; or

4.6.2 attempt to contact the Participant themselves.

Provide periodic updates to UK Biobank

4.7 The Collaborator will provide UK Biobank with:

4.7.1 a report on the progress of the Research Project in a form as required by UK Biobank on an annual basis (from the date on which the MTA was executed); and

4.7.2 a copy of any patents whose claims cover, or are intended to cover, a Collaborator Generated Invention within two months of their publication.

5. Additional provisions for different types of Material or Research Project

Samples

5.1 The Collaborator acknowledges that the Samples provided may contain viruses, latent viral genomes or other infectious agents. The Collaborator undertakes to treat such Samples as if they are not free from contamination and to ensure that all Samples are handled by appropriately trained personnel under laboratory conditions that incorporate adequate biohazard containment. From the time of receipt, the Collaborator is fully responsible for the safe and appropriate handling of the Samples.

5.2 The Collaborator confirms that the Samples will be kept on the premises of the Collaborator at the address specified in the Application and not transferred (in whole or part) to any other location without the prior written approval of UK Biobank.

5.3 The Collaborator confirms that the Approved Research Project has been subject to independent scientific review by a recognised body in the manner described in the Application.

5.4 On the Completion of the Research Project, the Collaborator will destroy the Samples and confirm to UK Biobank (in writing) that this has taken place.

Assays

5.5 In the event that the Collaborator has requested that certain assays be conducted on selected Samples (and UK Biobank agrees to conduct such assays on behalf of the Collaborator):

5.5.1 UK Biobank agrees to conduct such assays, or have them conducted by an appropriately qualified third party, with reasonable skill and care;

5.5.2 UK Biobank shall provide the Collaborator with the data from the assays ("UK Biobank Assay Data");

5.5.3 The UK Biobank Assay Data shall be treated in the same manner as other Assay Data (as set out in clauses 3.5.1 and 3.5.2) and subject to clause 5.5.4 below, the UK Biobank Assay Data will be deemed to be incorporated within the Data supplied to the Collaborator and inter alia subject to the provisions of this MTA;

5.5.4 the Collaborator will have a period of 3 months in which to use this Assay Data before UK Biobank makes them available to other Applicants.

6. Return and publication of Results

Publication of summary on UK Biobank's website

6.1 After the Collaborator has received the Data (including any sample assays) agreed for the Research Project, UK Biobank will be entitled to publish on its website:

6.1.1 The summary of the Research Project contained in the Application (with the exception of any material that has been agreed by the parties would be kept confidential);

6.1.2 Summary details of the Collaborator (unless it has been agreed by the parties that this information would be kept confidential).

Publication of Results

6.2 The Collaborator shall use its best endeavours to ensure that the Results are published within 6 months after the Completion Date for the Research Project:

6.2.1 in an academic journal; or

6.2.2 on an open source publication site.

6.3 By the earlier of 6 months after the publication of the Results, or 12 months after the Completion Date, the Collaborator will provide to UK Biobank a copy of:

6.3.1 the Results themselves in such form and format as UK Biobank will reasonably require;

6.3.2 the Results Data in such form and format as UK Biobank will reasonably require.

6.4 UK Biobank will consider reasonably any written requests (containing an appropriate explanation) for an extension of the time limits set out in this clause.

Notification to UK Biobank

6.5 The Collaborator is not required to obtain UK Biobank's approval to any report of its Results.

6.6 The Collaborator shall provide a copy of any report of its Results that derive from use of the Resource to UK Biobank at least 2 weeks before their expected date of first public presentation or publication in any format (e.g. paper journal, on-line report, meeting abstract).

6.7 In addition, the Collaborator is required to notify UK Biobank (in writing) if any report of its Results is reasonably likely to provoke controversy or otherwise attract significant public attention. In such circumstances, UK Biobank reserves the right to make such recommendations, reservations or suggestions on the report as it sees fit (and which it may make public) for consideration by the Collaborator.

Credit to UK Biobank

6.8 UK Biobank requires that any publication of Results includes the following credit, which credit shall be incorporated within the so-called "abstract" of such publication:

"This research has been conducted using the UK Biobank Resource."

6.9 This acknowledgement to UK Biobank should, when possible, be linked to reference search tools (such as PubMed and MEDLINE).

7. Charges/Intentionally deleted

8. Audit

8.1 On reasonable notice to the Collaborator, and in order to confirm or investigate compliance with the provisions of this MTA, UK Biobank may itself or via appropriate third parties:

8.1.1 choose to inspect the premises and other relevant facilities of the Collaborator, in order to review the security, storage or other arrangements for the Materials;

8.1.2 request such additional information about the Approved Research Project and/or its progress as UK Biobank may, from time to time, reasonably require.

8.2 UK Biobank will bear the costs of such audits unless a material default within the procedures and processes of the Collaborator is discovered, in which case the Collaborator will be obliged to re-imburse the reasonable costs of UK Biobank and any relevant third parties.

9. Confidentiality

9.1 Subject to the exceptions in Clause 9.2, UK Biobank will keep confidential any information disclosed to it in writing by the Collaborator that is marked confidential ("Collaborator's Confidential Information") and will not disclose such information to any person.

9.2 UK Biobank may disclose Collaborator's Confidential Information where allowed by this MTA or when:

9.2.1 it is required to be disclosed by law, by any governmental or other regulatory authority, by a court or other authority of competent jurisdiction; or

9.2.2 it can be shown by UK Biobank (to the Collaborator's reasonable satisfaction) to have been known by UK Biobank before disclosure to it by the Collaborator; or

9.2.3 it was lawfully disclosed to UK Biobank by a third party who did not impose any restrictions on its disclosure;

9.2.4 the information was in (or enters into) the public domain other than by reason of a breach of this clause by UK Biobank; or

9.2.5 UK Biobank and the Collaborator agree, acting reasonably, that such information is trivial or obvious, or they agree in writing that such disclosure may be permitted.

10. Indemnity

The Collaborator will indemnify UK Biobank against all losses (whether direct or indirect, reasonably foreseeable or specifically contemplated by the parties), damages, costs, expenses (including but not limited to reasonable legal costs and expenses) that it incurs directly as a result of: (i) any material breach of clauses 2, 4, 5 or 6 by the Collaborator; or (ii) any negligence or wilful default of the Collaborator, provided that UK Biobank agrees to use its reasonable endeavours to mitigate any loss.

11. Term

11.1 The term of this MTA shall commence on the Effective Date and shall end on the later of: (i) twelve (12) months after the Completion Date; or (ii) the date on which UK Biobank receives a copy of the Results Data in accordance with the provisions of clause 6.3.

11.2 This term may be extended by UK Biobank, in its reasonable discretion, on application to UK Biobank by the Collaborator setting out (in reasonable detail) the reasons for any delay or extension, (for example where the Collaborator seeks to publish further or supplemental Results).

12. Termination

12.1 UK Biobank will be entitled to terminate this MTA forthwith by written notice to the Collaborator if:

12.1.1 The Collaborator commits any breach of a material provision of this MTA and, in the case of a breach capable of remedy, fails to remedy the same within 10 days after receipt of a written notice giving particulars of the breach and requiring it to be remedied;

12.1.2 The Collaborating Investigator ceases to be employed (or otherwise engaged by) the Collaborator Institution; or

12.1.3 The Collaborating Institution ceases, is likely to cease, or threatens to cease carrying on business.

12.2 For the purposes of clause 12, a breach will be considered capable of remedy if the Collaborator can comply with the provision in question in all respects other than as to the time of performance, provided that time of performance is not of the essence.

12.3 The rights to terminate this MTA given by this clause will be without prejudice to any other right or remedy of either party in respect of the breach concerned, if any, or any other breach.

13. Consequences of termination

13.1 Upon expiry of the MTA pursuant to clause 11 above or termination of this Agreement by UK Biobank pursuant to clause 12:

13.1.1 The grant of rights to the Collaborator will be automatically terminated;

13.1.2 The Collaborator shall destroy the Data or otherwise render it inaccessible; and

13.1.3 The Collaborator shall, at the option of UK Biobank, destroy or return forthwith any unused Samples.

13.2 Without prejudice to the foregoing and to any other rights that UK Biobank may have in relation to termination as a consequence of a material breach, UK Biobank may take the following steps in respect of a breach under clause 12.1:

13.2.1 It may prohibit the Collaborating Investigator and other researchers from the Collaborating Institution from accessing any further materials from within the UK Biobank Resource; and/or

13.2.2 It may inform relevant personnel within the Collaborating Institution, funders of the Collaborator and/or governing or other relevant regulatory bodies.

13.3 Notwithstanding termination of this MTA for any reason, the provisions of clauses 1, 2, 3, 4, 5, 8, 9, 10, 12, 13, 14, 15, 17 and 18 shall continue in force in accordance with their respective terms.

14. Notices

14.1 Notices required under this MTA will be in writing and will be delivered by email to the addresses set out below or (in the event of a failure to deliver an email) by post to UK Biobank or the Collaborator and will be deemed to be given, in the case of delivery by email, upon receipt at the recipient's email server (unless an automatic response indicating an undeliverable message is received) and, in the case of delivery by post, on the date of delivery (or, if not a business day, on the first business day thereafter).

14.2 Notices to UK Biobank will be sent to the Research Access Administration Manager with a copy to access@ukbiobank.ac.uk and marked for the attention of Mrs Lorraine Gillions. Notices to the Collaborator will be sent to the Collaborating Investigator with a copy to the Collaborating Institution.

15. Assignment and sub-contracting

15.1 Neither party will be entitled to assign this MTA or any of its rights or obligations hereunder without first having received the written approval of the other party, which approval not to be unreasonably withheld or delayed.

15.2 The Collaborator will not sub-contract the performance of any of its obligations under the MTA or any part thereof without having first obtained the prior written consent of UK Biobank, such consent not be unreasonably withheld.

15.3 In the event that consent is granted under clause 15.2, the Collaborator shall be responsible for the acts, defaults and omissions of its sub-contractors as if they were the Collaborator's own, and any consent given will not relieve the Collaborator of any of its obligations under this MTA.

16. Force majeure

16.1 If any party is prevented from, hindered or delayed in performing any of its obligations under this MTA by reason of a Force Majeure Event, such party will promptly notify the other of the date of its commencement and the effects of the Force Majeure Event on its ability to perform its obligations under this MTA. If mutually agreed by the parties, then the obligations of the party so affected will thereupon be suspended for so long as the Force Majeure Event may continue.

16.2 The party affected by a Force Majeure Event will not be liable for any failure to perform such of its obligations as are prevented by the Force Majeure Event provided that such party will use every reasonable effort to minimise the effects thereof and will resume performance as soon as possible after the removal of such Force Majeure Event. If the period of non-performance exceeds 28 days from the start of the Force Majeure Event then the non-affected party will have the option, by written notice to the other party, to terminate this MTA.

16.3 For the purpose of this clause, Force Majeure Event means any event beyond the reasonable control of a party including, without limitation, acts of God, war, terrorism, riot, civil commotion, malicious damage, compliance with any law or governmental order, rule, regulation or direction, accident, fire, flood or storm. For the avoidance of doubt, strike, industrial action, failure of technology systems, third party insolvency and failure of UK Biobank or any other third party will not be considered to be Force Majeure Events.

16.4 The provisions of this clause 16 will not affect any other right which either party may have to terminate this MTA.

17. Dispute resolution

17.1 Any party may give the other party written notice of any dispute arising out of or in connection with this MTA ("Notice of Dispute") not resolved in the normal course of business. Within five (5) business days following delivery of such notice, a UK Biobank representative and a Collaborator representative will discuss by telephone or meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve such Dispute.

17.2 If any Dispute raised pursuant to clause 17.1 is not resolved by the respective representatives of the parties within ten (10) business days of the date on which delivery of the Notice of Dispute is deemed to be given then the Dispute will be referred to the UK Biobank Principal Investigator and an appropriate senior member of the Collaborating Institution. These senior representatives of the parties will convene as soon as reasonably practicable (in person or by phone) after such referral to discuss the Dispute in an attempt to resolve it.

17.3 If any Dispute remains unresolved ten (10) business days following such referral, either party may initiate non-binding mediation of the Dispute to the London Court of International Arbitration ("LCIA") for mediation in accordance with the LCIA Mediation Procedure. All negotiations related to this referral shall be confidential and treated as compromise and settlement negotiations. The place of such mediation will be London and the language of the mediation shall be English.

17.4 Nothing in this clause 17 will serve to prevent either party from seeking interim relief in the High Court of England and Wales or from terminating this MTA.

18. **General**

18.1 This MTA governs the relationship between the parties to the exclusion of any other terms and conditions and, together with any other document referred to in this Agreement, constitutes the whole agreement between the parties in relation to the subject matter hereof.

18.2 If there is any conflict between the provisions of this MTA and any of the annexes and related documents (including, but without limitation, the provisions of the Access Procedures) then the provisions of this MTA will apply.

18.3 A waiver, delay or forbearance by either party, whether express or implied, in enforcing or exercising any of its rights or remedies hereunder will not constitute a waiver of such right or remedy.

18.4 No provision of this MTA is intended to be enforceable by any person who is not a party to this Agreement and nor are any rights granted to any third party under statute or otherwise.

18.5 Nothing in this MTA will create a partnership, joint venture or relationship of agency between the parties.

18.6 All variations to this MTA must be agreed, set out in writing and signed on behalf of the parties before they take effect.

18.7 This MTA will be governed by and construed in accordance with English law and, subject to clause 17 above, the parties irrevocably agree that the English courts will have exclusive jurisdiction over any suit, action, proceedings or dispute arising out of, or in connection with, this Agreement.

Definitions used in the Material Transfer Agreement (MTA)

Access Charges: the charges payable by the Applicant (which may include VAT) to access the Materials.

Applicant: the Applicant Institution.

Applicant-Generated Invention: an invention developed by the Applicant as a result of carrying out the Approved Research Project.

Applicant Institution: the institution making the Application for access in respect of the Research Project and by which the Applicant PI is employed or otherwise contractually attached.

Applicant Principal Investigator (PI): the Principal Investigator of the Research Project.

Applicant Researcher: a researcher who is working with the Applicant PI on the Research Project.

Application: the application by the Applicant to UK Biobank for access to the Materials for use in relation to the Research Project.

Approved Research Project: the Research Project approved by UK Biobank (specifically including any conditions or stipulations made by UK Biobank).

Assay Data: any data generated pursuant to analyses of the Samples or other Materials (including but without limitation any data variables derived from the analysis of combination(s) of any Data or Assay Data), irrespective of whether such Assay Data is generated (a) by or on behalf of UK Biobank (in which case it is UK Biobank Assay Data) (b) by the Applicant or (c) other third party.

Collaborator: the Collaborating Institution.

Collaborating Institution: the institution collaborating with the Applicant in respect of the Application for access (in respect of the Research Project) and by which the Collaborating Investigator is employed or otherwise contractually attached.

Collaborating Investigator: the lead investigator in respect of the Application at the Collaborating Institution.

Collaborating Researcher: a researcher who is working with the Collaborating Investigator at the Collaborating Institution on the Research Project.

Completion Date: the date contained within Annex A on which the Applicant represents that the findings of the Approved Research Project will be published (or as such date may, from time to time, be altered by agreement with UK Biobank).

Consent: the consent provided by each Participant.

Data: the data being supplied to the Applicant by UK Biobank for the Approved Research Project.

Effective Date: the date on which a confirmatory email is sent by UK Biobank to the Applicant confirming receipt of a copy of this MTA executed by the parties and cleared funds covering the Access Charges.

Findings: the findings made by the Applicant pursuant to the Approved Research Project.

Intellectual Property Rights (IPRs): all present and future intellectual property rights including but not limited to patents, trade and service marks, design rights, copyright, database rights, trade secrets and know-how, in all cases whether registered or not or registerable, and including all registrations and applications for registrations of any of these and rights to apply for the same as well as any renewals, extensions, continuations, combinations or divisions thereof, and all rights and forms of protection of a similar nature or having equivalent or similar effect to any of these anywhere in the world.

Materials: the Data and/or Samples supplied by UK Biobank to the Applicant under this Agreement.

Participants: the individuals who consented to participate in UK Biobank.

Permitted Purpose: to conduct the Approved Research Project in the manner and timeframe set out in Annex A, subject to the provisions of this MTA.

Resource: the collection of Data and Samples within UK Biobank which are accessible by Applicants.

Results: the findings generated by the Applicant pursuant to the Approved Research Project.

Results Data: the data generated and derived by the Applicant, other than any Assay Data, which underlie the Results.

Samples: the samples held by UK Biobank that are being used for the Approved Research Project.

Term: the period starting on the Effective Date and ending at the time and on the basis set out in this Agreement and as may be extended or terminated in accordance with the terms of this Agreement.

Annex III: Conflict of Interest Policy

1 Introduction and Background

1.1 This policy aims to ensure that UK Biobank's decision-making processes for access to the UK Biobank Resource are conducted in accordance with the highest standards of integrity. The key principle guiding access is the promotion of high quality health research for the public benefit.

2 Application of Policy

2.1 This policy applies to UK Biobank's:

- Board of Directors, including its Access Sub-Committee;
- Principal Investigator and UK Biobank staff; and
- Any advisors involved in the access review process.

2.2 Each person covered by this policy (Individual) has an ongoing responsibility to comply with the terms of this policy. In complying with these terms, an interpretation should be taken which ensures adherence to both the spirit and the letter of this policy.

3 Guiding principles

3.1 Decisions concerning applications for access to the Resource should be guided by UK Biobank's Ethics & Governance Framework and its Access Criteria, and made free from external influences (such as related academic interests or positions of responsibility held outside of UK Biobank).

3.2 Individuals must be alert to the risk of a conflict of interest arising, and appreciate that this is an ongoing responsibility. They must not make any academic or financial gain as a result of involvement in UK Biobank's decision-making processes.

3.3 A conflict of interest in this context specifically includes academic, financial or other conflicts which (directly or indirectly) might interfere with, limit or compromise the ability of the Individual to review applications to use the Resource in an objective manner.

4 Managing Conflicts

4.1 If an Individual identifies an actual or potential conflict of interest with any Application under review, they should disclose the nature and extent of this conflict to UK Biobank's Board Secretary immediately. An actual or potential conflict of interest will include any situation which could reasonably be perceived to result in such conflict.

4.2 Individuals should declare all direct and indirect academic interests relating to an Application, including (but without limitation) being involved in the preparation of the Application, being involved in a "competing" research activity, and/or being funded by the same institution as the Applicant.

4.3 If an Individual has a commercial interest in the Applicant Institution and/or funding organisation for the Applicant Institution, this should be disclosed to UK Biobank's Board Secretary. A commercial interest is deemed to exist where that interest is deemed to be worth more than £25,000.

4.4 Disclosures of conflicts of interest may either be specific to a particular Application or may be general with respect to a Collaborating Investigator, Collaborating Researcher, Collaborating Institution and/or funding organisation. A general disclosure will exempt an Individual from making repeat disclosures in respect of future Applications involving that Individual, Institution and/or funding organisation.

4.5 Any Participant, Applicant, Researcher or other person who considers that a conflict of interest exists should disclose their concern to UK Biobank's Board Secretary.

5 Conflict Action Points

5.1 At the beginning of each meeting of the Access Sub-Committee or the Board, the Board Secretary will request that members declare any potential conflicts of interest related to the Applications that are under consideration.

5.2 In the event that a disclosure is made, it will be for UK Biobank's Board Secretary to determine whether it is a material conflict of interest:

5.2.1 in conjunction with the Chair of the Access Sub-Committee if the conflict relates to a member of the Access Sub-Committee or a member of UK Biobank Staff (including the UK Biobank Principal Investigator) or an advisor to UK Biobank;

5.2.2 in conjunction with the Chair of the Board of UK Biobank if the conflict relates to the Chair of the Access Sub-Committee or a member of UK Biobank's Board; or

5.2.3 in conjunction with the Deputy Chair of the Board of UK Biobank if the conflict relates to the Chair of the Board of UK Biobank.

5.3 In the event of a material conflict of interest, the Individual must not take part in any decisions relating to that Application. In particular, the Individual must not:

5.3.1 be involved in the review of the Preliminary or Main Application, or any Reconsiderations;

5.3.2 be involved in decisions about the Preliminary or Main Application, or any Reconsiderations;

5.3.3 receive any further papers or information concerning the Application; and

5.3.4 attend those parts of any meetings in which the Application is discussed.

6 Conduct

6.1 This policy will be subject to periodic review. Individuals should be familiar with the most recent version of the policy.

6.2 If Individuals have any queries or concerns regarding the application of this policy, they should consult with UK Biobank's Board Secretary.

6.3 Breaches of this policy will be treated seriously and disciplinary action taken in appropriate cases.

Annex IV: Data Protection Policy for the personal data of Collaborators

1 Policy statement

1.1 UK Biobank is committed to the fair and lawful processing of personal data, in accordance with the Data Protection Act.

1.2 This data protection policy explains how UK Biobank uses personal information collected about Collaborating Investigators and Researchers (collectively Collaborators) seeking access to the UK Biobank Resource.

1.3 This data protection policy has no application to the personal data of participants, which are dealt with under entirely separate criteria.

2 What information will UK Biobank collect about Collaborators?

2.1 All Collaborators intending to request access to data and/or samples will be required to provide their personal details before UK Biobank is able to process Preliminary Applications on which they are named.

2.2 Collaborators will be required to update their personal details before UK Biobank is able to process Main Applications on which they are named.

2.3 UK Biobank will retain a record of all correspondence/contact with Collaborators.

3 How will UK Biobank use information about Collaborators?

3.1 During the course of UK Biobank's activities, it will collect, store, and process personal information about Collaborators. Information that the Collaborators supply will be treated in accordance with the principles of the Data Protection Act.

3.2 Information collected will be used to verify the identities of individuals requesting access to the Resource, and will be retained so that UK Biobank has a record for all Applications.

3.3 In reviewing Applications, UK Biobank may need to disclose Collaborators personal data to its Access Sub-Committee, Ethics & Governance Council, International Scientific Advisory Board and/or others (as it deems reasonably necessary).

3.4 UK Biobank seeks to keep the wider public informed of research findings deriving from access to the Resource. For this reason, unless agreed otherwise, details of approved Research Projects identifying the Principal Investigator (which may also identify Collaborators) will be made available on UK Biobank's website. Periodic updates of research that has been conducted, and publications that derive from use of the Resource, will be linked to UK Biobank's website.

3.5 UK Biobank may contact Registered Researchers by e-mail and/or by post, with updates on the Resource. For example, it may inform them when the Resource is likely to be sufficiently mature to establish case-control collections for various conditions; when linkage to health outcomes data has been introduced; and when research yields material extra data that are added to the Resource.

3.6 From time to time, UK Biobank may seek views from Collaborators concerning the access procedures that are in place. Responses to such enquiries will be voluntary and any feedback used solely for evaluation purposes.

4 Data protection principles

4.1 In processing Collaborators personal information, UK Biobank is guided by the following principles (as contained in the UK's 1998 Data Protection Act):

4.1.1 Information will be processed fairly and lawfully;

4.1.2 Information will be processed for the purposes outlined in this policy;

4.1.3 Information collected will be relevant and not excessive for these purposes;

4.1.4 Information stored will be kept up to date;

4.1.5 Information stored will not be kept for longer than is necessary;

4.1.6 Information will be processed in accordance with Collaborators rights;

4.1.7 Appropriate organisational and technical measures will be in place to help ensure that information is kept secure; and

4.1.8 Information will not be transferred to people or organisations situated abroad without adequate protection.

5 Collaborators rights

5.1 Collaborators have the right to ask for a copy of information that UK Biobank holds about them and to have any inaccuracies in information about them corrected (and UK Biobank may charge a small fee). Any such requests should be made to UK Biobank in writing at: UK Biobank Coordinating Centre, 1 & 2 Spectrum Way, Adswood, Stockport, Cheshire SK3 0SA.

5.2 If Collaborators have questions about their rights under the Data Protection Act, or require any further information, they should e-mail dataprotection@ukbiobank.ac.uk or write to the Data Protection Officer, UK Biobank Limited, Units 1&2 Spectrum Way, Adswood, Stockport, Cheshire SK3 0SA.