Material Transfer Agreement

Dear

Applicant:
Application Reference Number:

UK Biobank Limited ("**UK Biobank**") is pleased to approve your Application to use the UK Biobank Resource. UK Biobank's approval of this Application is valid for 90 days during which time the Applicant must execute this Material Transfer Agreement ("**MTA**") and pay the Access Charges. These are the final steps before access is granted. If these steps are not taken by the Applicant within 90 days, the Applicant will need to re-apply for access.

Parties

This is an agreement between UK Biobank and the Applicant (each a "**party**", together the "**parties**"). The Applicant PI is not a party to the MTA, however, UK Biobank requires the Applicant PI to sign the MTA to acknowledge that the provisions of this MTA have been "read and understood" so that they are fully aware of the Applicant's obligations to both UK Biobank and to UK Biobank's Participants. The Applicant shall be responsible for the conduct of the Applicant PI and any and all Applicant Researchers involved in this Approved Research Project.

Structure of agreement

The MTA shall become effective on the Effective Date. If you have agreed a previous version of the MTA for this Application/Approved Research Project, the previous version shall automatically terminate on the Effective Date and be replaced by this MTA.

The MTA is conditional upon UK Biobank receiving from the Applicant within thirty (30) days of the Effective Date, cleared funds covering the Access Charges and any applicable VAT. The Access Charges are non-refundable.

Standard terms and Annexes

The content of UK Biobank's standard MTA, and the conditions contained within it, are non-negotiable.

This MTA incorporates the attached Applicant Terms and Conditions (including any documents and/or the materials that are referred to in them), the contents of the Application Form (where applicable) and the attached Annexes:

- Annex 1 (Data Processing Description);
- Annex 2 (Security Measures);
- Annex 3 (Annual Project Report Template); and
- Annex 4 (Approved Research Project – which summarises the Materials that will be made available to the Applicant).

Definitions used in this MTA can be found on pages 15-16.

Payment

The Access Charges which are payable are set out in the payment section of your application. This allows you to generate an invoice on which VAT will be included (if appropriate, and as such VAT will not be included if the Applicant is based outside the UK). A summary of these Access Charges is also set out in Annex 4.

Payment should be made via bank transfer or Sage Pay, in cleared funds and in British pounds sterling (GBP) to:
Bank: Barclays Bank PLC
Account name: UK Biobank Limited
Account number: 33069427
Sort code: 20-24-41
IBAN: GB78 BARC 2024 4133 0694 27

Yours sincerely

For and on behalf of UK Biobank
Jonathan Sellors
General Counsel & Company Secretary

Applicant Terms and Conditions

1. Supply of Materials by UK Biobank

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

1.2 UK Biobank warrants to the Applicant that for the purposes of this MTA:

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

1.2.2 consent to take part in UK Biobank has been obtained from the Participants and further, consent under the Human Tissue Act 2004, has been obtained from the relevant Participants; and

1.2.3 the use of the Materials for the Approved Research Project falls within UK Biobank's generic Research Tissue Bank (RTB) approval from the NHS North West REC, available here.

1.3 The Applicant agrees 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 that use of the Materials shall not infringe the rights of any third party. Except as expressly stated in this MTA, all warranties, terms and conditions, whether express or implied by statute, common law or otherwise, are excluded to the fullest extent permitted by law.

2. Usage of Materials by the Applicant

2.1 The Applicant agrees that the Materials shall only be used:

2.1.1 in accordance with the terms and conditions of this MTA;

2.1.2 to conduct the Approved Research Project for the Permitted Purpose only; and

2.1.3 by the Applicant institution and on an individual level within the Applicant, the Applicant PI, the Applicant Researchers and by Third Party Processors (appointed by the Applicant).

2.2 The Applicant shall not share, sub-license, disclose, transfer, sell, gift or supply the Materials to any other person or unauthorised third party.

2.3 Without prejudice to the other provisions of this MTA, any actual or anticipatory breach of any provision of clause 2.1 or 2.2 shall entitle UK Biobank to terminate this Agreement with immediate effect, and require the immediate return or destruction of any Materials provided by UK Biobank.

2.4 The Applicant shall and shall procure that the Applicant PI, the Applicant Researchers and any Third Party Processors are made aware of, and shall comply with, the terms and conditions of this MTA and the Data Protection Legislation. Any act or omission of the Applicant PI or any Applicant Researcher or any Third Party Processor shall be deemed to be an act of the relevant Applicant for which the relevant Applicant is fully responsible and liable.

2.5 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 shall prevent UK Biobank from supplying the same Materials (or other data and/or samples in the UK Biobank Resource) to another third party, in line with the access procedures (available here and as may be updated by UK Biobank from time to time) or for UK Biobank's other operational purposes.

2.6 In relation to the Materials supplied to the Applicant:

2.6.1 UK Biobank is the owner of the Materials, and UK Biobank is the owner of the Intellectual Property Rights in the Materials; and

2.6.2 UK Biobank hereby grants to the Applicant a revocable, worldwide, royalty-free, non-exclusive, non-transferable licence (but not any ownership rights) during the Term to use the Materials for the Permitted Purpose, subject to the terms and conditions of this MTA.

3. Generation of data by the Applicant

Generation of data by or on behalf of the Applicant during the Approved Research Project

3.1 The data generated by the Applicant in the performance of the Approved Research Project shall be deemed to fall into the following categories:

3.1.1 **Results Data**: data and methodology (for example, the SAS/R/Stata scripts) which underlie the Findings and which would enable another competent researcher to generate the Findings;

3.1.2 **Findings**: the findings generated by the Applicant as a result of the Approved Research Project; and/or

3.1.3 **Other Data**: all other data generated by the Applicant which is not in one of the above two categories.

Ownership of generated data

3.2 Except as provided in clause 3.3, the Applicant shall own the IPRs in their Findings, the Results Data and the Other Data. The Applicant hereby grants a perpetual, irrevocable, worldwide, fully paid up, royalty free, fully sub-licensable non-exclusive licence to UK Biobank to use, reproduce, distribute, publish, store and otherwise disseminate the Findings, the Results Data and the Other Data.

3.3 Nothing in this MTA shall operate to assign to the Applicant any IPRs in the Materials. To the extent that the Findings, the Results Data or the Other Data incorporate any Materials, the IPRs in those Materials shall remain the property of UK Biobank and shall not belong to the Applicant.

3.4 The Applicant warrants to UK Biobank that UK Biobank's receipt of and use of the Applicant's Findings and Results Data shall not infringe the rights, including any IPRs, of any third party.

Rights to inventions/developments made by the Applicant

3.5 Subject always to the restriction in clause 3.7, UK Biobank confirms that it shall have no rights or licence to the IPRs in relation to any inventions made by the Applicant as a result of using the Materials, Results Data, Findings or Other Data ("**Applicant-Generated Inventions**").

3.6 However, the Applicant acknowledges that the Resource has been (a) produced using a combination of the goodwill and contribution of 500,000 UK participants (b) charitable and public funding (from in particular Wellcome and the Medical Research Council) (c) the use of public resources (such as UK health-record data) and (d) established with the express purpose of promoting the conduct of health-related research which is in the public interest. UK Biobank also acknowledges the contribution which is being made to enhance the Resource by the Applicant (in the form of the generation and availability to other researchers of, inter alia, the Findings and Results Data of the Approved Research Project).

3.7 In terms of specific obligations, taking into account the acknowledgements in clause 3.6 above, the Applicant agrees (and this clause is a material provision of this MTA) that it shall not and shall not attempt to:

3.7.1 file any patents with claims directed to; or

3.7.2 otherwise seek to claim or enforce any IPRs in;

the genotype-phenotype data within the Materials or in the genotype-phenotype data which has been generated by (or on behalf of) the Applicant in the course of the Approved Research Project (whether such genotype-phenotype data is in the form of Results Data, Findings or Other Data). Without limiting the above, the parties agree that this clause 3.7 shall not prohibit the Applicant from patenting, or enforcing IPRs in drugs, therapeutics, diagnostics, other technology or methods of treatment provided this does not limit UK Biobank's ability to allow approved researchers to use the data generated by the Applicant (as defined in clause 3.1), including any biomarker data identified by the Applicant, through its use of the Resource.

Limitation on rights granted

3.8 UK Biobank expressly excludes (directly or indirectly) (i) any right of the Applicant to sub-licence any of the rights granted to the Applicant to the Materials under this MTA and/or (ii) any right of the Applicant to publish or distribute any of the Materials, except for the sole purpose of including a commensurate amount of supporting data (which shall not include any Participant Level Data) in the Applicant's publication of its Findings (which may include commensurate publication of certain of the Results Data, as the same may be reasonably required by the relevant publisher).

3.9 For the avoidance of doubt, the rights granted under this MTA to the Applicant to use the Materials 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 performed by it using the Materials shall be carried out in compliance with all applicable laws, regulations, guidelines and approvals, including without limitation the Human Tissue Act 2004, the Data Protection Legislation 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 shall retain the Materials in a secure network system, at such standard which would be reasonably expected for the storage of valuable and proprietary sensitive/confidential data. Further, the Applicant shall be obliged to implement the appropriate technical and organisational measures as set out in Annex 2 (Security Measures) to protect the Materials from the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to the Materials (a "**Data Security Incident**").

4.3 The Applicant shall notify UK Biobank without undue delay (and in any event no later than 24 hours) after becoming aware of a reasonably suspected "near miss" or actual Data Security Incident which affects the Materials. Such notification must be sent by email to DPO@ukbiobank.ac.uk with a copy to access@ukbiobank.ac.uk.

4.3.1 The Applicant shall not delay such notification on the basis that the information is incomplete or the relevant investigation is ongoing. Further, the Applicant shall not make any external announcement, notifications to a supervisory authority or regulator about any such Data Security Incident without the express prior written consent of UK Biobank, unless required by law to do so.

4.3.2 Both parties shall cooperate and provide reasonable assistance to each other to facilitate the handling of the Data Security Incident.

Withdrawal of consent by participants

4.4 The Applicant confirms that it shall deal promptly and appropriately (in accordance with the Participants option to with withdraw as set out on the UK Biobank website here) with any "no further use" withdrawals by Participants which UK Biobank notifies to the Applicant.

Identification of participants

4.5 The Applicant is expressly prohibited from (or attempting to):

4.5.1 developing, linking or re-engineering the Materials supplied to it so as to render it Personal Data;

4.5.2 identifying any Participant from the Materials provided by UK Biobank; or

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

4.6 In the event that the Applicant inadvertently identifies any Participant then it shall notify UK Biobank immediately setting out (in reasonable detail) the circumstances by which it happened. Such notification must be sent by email to DPO@ukbiobank.ac.uk with a copy to access@ukbiobank.ac.uk.

4.7 Other than for the purposes of clause 4.6, the Applicant shall not:

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

4.7.2 attempt to contact the Participant themselves.

4.8 Without prejudice to the other provisions of this MTA, any actual or anticipatory breach of any provision of clauses 4.1, 4.2 and 4.4 to 4.7 inclusive shall entitle UK Biobank to terminate this Agreement with

immediate effect, and require the immediate return or destruction of any Materials provided by UK Biobank.

5. Return and publication of Findings

Publication of summary on UK Biobank's website

5.1 After the Applicant has received the Materials for the Approved Research Project, UK Biobank shall be entitled to publish on its website:

5.1.1 The lay summary of the Approved Research Project contained in the Application (with the exception of any material that has been agreed by UK Biobank would be kept confidential);

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

Annual Project Report

5.2 During the Term, the Applicant shall provide UK Biobank with:

5.2.1 a summary report setting out in reasonable detail the progress of the Approved Research Project in the form attached as Annex 3 (or in such other format as required by UK Biobank from time to time) on an annual basis (from the Effective Date) which shall include the Findings the Applicant has made which in its reasonable view may be:

(a) published;

(b) disclosed in a published patent; or

(c) otherwise of significance (in the context of medical research); and

5.2.2 a summary (and a copy of the application if requested) of any patents whose claims cover, or are intended to cover, an Applicant-Generated Invention within two (2) months of their publication.

5.3 UK Biobank acknowledge and agree that the Applicant may keep such Findings confidential for a reasonable time in accordance with its reasonable business and research and development practices. For the avoidance of doubt, the Applicant is entitled to retain confidentiality regarding any Finding over which patent protection is being sought (and the patent has not yet been published).

5.4 In relation to the Annual Project Report, UK Biobank:

5.4.1 shall have the ability to make the Annual Project Report public, subject to the Applicant (as referred to in clause 5.3 above) retaining a reasonable period of confidentiality on items where patent rights still need to be filed;

5.4.2 shall have the opportunity to ask the Applicant any reasonable questions arising from the Annual Project Report and the Applicant shall respond to any such questions in a timely manner;

5.4.3 strongly encourages the Applicant to make public in a reasonably timely manner the Findings that they make; and

5.4.4 reserves the rights set out in clause 7.1 in the event that the Annual Project Report is not received by UK Biobank in the timeframe, manner and form prescribed.

5.5 If such Findings are made publicly available, UK Biobank requires that the Results Data underlying such Findings shall be promptly returned or otherwise made available to UK Biobank[1].

Publication of Findings

[1] For the avoidance of doubt, the intention of this provision is not to require the return of irrelevant or extraneous data sets but rather to make summary information available to other researchers (in a comparable form to that which academic journals often require), in particular so that it is not necessary for a researcher (reviewing the Findings) to have to re-create certain derived variable or related metrics. Also, for clarity, Applicants shall have no obligation to provide to UK Biobank or publish, and do not grant UK Biobank any rights in or to, any genotype-phenotype data obtained or generated outside of the Approved Research Project.

5.6 The Applicant shall use All Reasonable Endeavours to publish the Findings (and provide UK Biobank with a link thereto) within six (6) months after the Completion Date for the Approved Research Project:

5.6.1 in an academic journal; or

5.6.2 on an open-source publication site.

5.7 Within six (6) months after the publication of the Findings, the relevant Applicant shall provide to UK Biobank the Results Data in such form and format as UK Biobank shall reasonably require (alternatively UK Biobank and the relevant Applicant may agree that the relevant Applicant retains the Results Data on the basis that they are made publicly available to other Researchers and/or publicly available generally).

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

5.9 The Applicant shall use All Reasonable Endeavours to publish a commensurate level of Findings in relation to the Approved Research Project within the first three (3) years of the Term. Where this is not possible, the Applicant shall provide UK Biobank with a reasonable explanation as to why it is not possible and an estimation of when a publication can be expected.

Notification to UK Biobank

5.10 Unless otherwise stated in Annex 4, the Applicant is not required to obtain UK Biobank's approval to any report of its Findings. The Applicant shall nevertheless provide a copy of any report of its Findings and any press release to UK Biobank at least two (2) weeks before their expected date of first public presentation or publication in any format (e.g. paper journal, on-line report, meeting abstract). The Applicant shall upload such documents to AMS in the first instance. If this is not possible, the Applicant shall email such documents to access@ukbiobank.ac.uk.

5.11 However, and notwithstanding the provisions of clause 5.10 above, the Applicant is required to promptly notify UK Biobank in advance (in writing) if any report of its Findings 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

5.12 UK Biobank requires that any publication of Findings 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 under application number [ ]."

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

6. Charges

6.1 The Applicant agrees to pay the Access Charges as set out in the payment section of the Applicant's Application to UK Biobank via bank transfer or Sage Pay, in cleared funds and in British pounds sterling (GBP). The Access Charges are stated to be exclusive of VAT. The Applicant shall pay any applicable VAT in addition to the Access Charges. The Access Charges are non-refundable.

6.2 When paying the Access Charges, the Applicant shall quote the invoice number and/or Application Reference Number as the payment reference. A remittance note shall also be sent to creditcontrol@ukbiobank.ac.uk.

6.3 The rights granted to the Applicant by UK Biobank under this MTA are conditional on the Access Charges (and applicable VAT) being paid and so, for the avoidance of doubt, no Materials shall be provided to the Applicant until or unless the Access Charges (and applicable VAT) then due are received in full. The Applicant shall pay the Access Charges (and applicable VAT) no later than thirty (30) days from the Effective Date.

6.4 If payment of the Access Charges has not been made within ninety (90) days of receipt of this MTA by the Applicant, the Applicant shall be required to re-apply for access to the Resource and Materials.

7. Self-Certification and Audit

7.1 During the Term, UK Biobank requires the Applicant to self-certify on an annual basis that the provisions of the MTA are being complied with by the Applicant. Specifically, the Applicant shall provide UK Biobank with such self-certification as part of the Annual Project Report in the form attached at Annex 3. In the event that the Annual Project Report is not received by UK Biobank in the timeframe, manner and form prescribed then the Applicant's rights under this MTA are suspended and access to the Materials will be removed until such time as the Annual Project Report has been duly and compliantly provided. If the Annual Project Report is still outstanding, notwithstanding a reminder from UK Biobank, 3 months after the relevant anniversary of the Effective Date, then UK Biobank has, inter alia, the right to terminate the MTA by giving the Applicant written notice of termination and/or prevent the Applicant from applying for or accessing any further Materials from UK Biobank.

7.2 In circumstances where UK Biobank reasonably believes that a Data Security Incident or other serious incident has occurred then on 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:

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

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

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

7.4 UK Biobank confirms that its audit rights shall be exercisable no more than once a year and on the provision of reasonable notice (which may be immediate in the event of a Data Security Incident or other serious incident) to the Applicant and be during normal business hours. As far as practically possible, UK Biobank agrees to coordinate any site visits and audits with the other relevant parties.

8. Confidentiality

8.1 Subject to the exceptions in Clause 8.2, UK Biobank shall keep confidential any information disclosed to it in writing by the Applicant that is marked confidential ("**Applicant's Confidential Information**") and shall not disclose such information to any person.

8.2 UK Biobank may disclose the Applicant's Confidential Information where expressly permitted by this MTA or when:

8.2.1 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

8.2.2 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 such Applicant; or

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

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

8.2.5 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.

9. Data Protection

Relationship of the parties[2]

[2] This clause 9 addresses the requirements of the prevailing data protection legislation in the UK: principally the Data Protection Act 2018 (*https://www.legislation.gov.uk/ukpga/2018/12/contents)* and the UK GDPR and related guidance from the relevant regulators, particularly the ICO (*https://ico.org.uk/).* This clause also addresses the impact, from UK Biobank's perspective, of the United Kingdom leaving the European Union. In relation to identifiable data two factors remain the same as under the original MTA:

- UK Biobank has and will continue to go to significant lengths to de-identify the data it releases to researchers, by removing direct and indirect identifiers, such that (even taking into account publicly available information) it should not be possible for a researcher to re-identify a participant;

9.1 The parties acknowledge that UK Biobank and the Applicant are independent Controllers with respect to the Participant Level Data that is Processed in accordance with this MTA, and that the Applicant shall Process the Participant Level Data strictly for the Permitted Purpose. In no event shall the parties Process the Participant Level Data as joint Controllers.

Compliance with law

9.2 Each party shall be individually and separately responsible for complying with the obligations that apply to it as a Controller under Data Protection Legislation.

Cooperation

9.3 In the event that the Applicant or any Applicant Researcher receives any correspondence, enquiry or complaint from a Participant, regulator or other third party ("**Correspondence**") in connection with the Processing of the Participant Level Data, it shall promptly inform UK Biobank giving full details of the same. In all circumstances, the Applicant or any Applicant Researcher shall: (i) obtain UK Biobank's written approval before responding to the Correspondence, including approval of the contents of any response; and (ii) subject to Data Protection Legislation, permit UK Biobank to respond directly to the Correspondence.

Where the Applicant is located outside of the UK

9.4 Where UK Biobank transfers Participant Level Data to an Applicant outside the UK in a territory that has not been specified as ensuring an adequate level of protection in accordance with Data Protection Legislation, the parties agree that the C2C Model Clauses shall be incorporated into this MTA by reference from the Effective Date as follows:

9.4.1 UK Biobank shall be the data exporter;

9.4.2 the Applicant shall be the data importer;

9.4.3 where the C2C Model Clauses being relied upon are those approved by the European Commission: (i) under the "II Obligations of the data importer" section of the C2C Model Clauses option h (iii) (the data processing principles set forth in Annex A) shall be deemed to have been selected; (ii) the provisions of Annex 1 shall be deemed to be set out in Annex B to the C2C Model Clauses; and (iv) the optional illustrative commercial clauses shall be deemed to have been deleted; and

9.4.4 if there is any conflict between the MTA and the C2C Model Clauses, the C2C Model Clauses shall prevail.

The parties agree to use All Reasonable Endeavours to put in place any additional or supplementary measures that may be required in order to give effect to the C2C Model Clauses.

International transfers by the Applicant

9.5 The Applicant shall not Process any Participant Level Data (nor permit any Participant Level Data to be Processed) in a territory outside of the UK (or where clause 9.4 applies, where Processing occurs in a subsequent territory) unless it has taken such measures as are necessary to ensure the transfer is in compliance with Data Protection Legislation.

10. Limitation of Liability

10.1 The parties agree that:

10.1.1 Subject to clauses 10.2, 10.3 and 10.4, UK Biobank's maximum aggregate Liability under this MTA and/or in relation to the Approved Research Project shall be limited to the Access Charges paid or payable by the Applicant to UK Biobank (whether or not invoiced to the Applicant) in relation to the Approved Research Project; and

10.1.2 Subject to clauses 10.2, 10.3 and 10.5, the Applicant's maximum aggregate Liability under this MTA and/or in relation to the Approved Research Project shall be limited to the Access Charges

- Further, the Applicant is expressly prohibited from actual (and making any attempt to) re-identification any Participant in accordance with clause 4.5 of the MTA.

Nevertheless, UK Biobank considers that it is appropriate for UK Biobank to require researchers to treat the UK Biobank data as if it considered to be Personal Data, and this requires the Applicant (as part of the MTA) to agree to the provisions of this clause. The Applicant will be considered to be a separate and independent data Controller under Data Protection Legislation. The Applicant is not a Processor. Please refer to the Data Protection FAQs (link provided in Annex 1) for more information. As with all other clauses of this MTA, this clause 9 is non-negotiable.

paid or payable by the Applicant to UK Biobank (whether or not invoiced to the Applicant) in relation to the Approved Research Project.

10.2 Notwithstanding clause 10.1 above, UK Biobank shall have no Liability to the Applicant and the Applicant shall have no Liability to UK Biobank for any:

10.2.1 loss of profit (whether direct, indirect or consequential);

10.2.2 loss of use, loss of revenue, loss of production or loss of business (in each case whether direct, indirect or consequential);

10.2.3 loss of goodwill, loss of reputation or loss of opportunity (in each case whether direct, indirect or consequential);

10.2.4 loss of anticipated savings or loss of margin (in each case whether direct, indirect or consequential);

10.2.5 loss of use or value of any data or software (in each case whether direct, indirect or consequential); or

10.2.6 indirect or consequential loss.

10.3 Nothing in this MTA shall operate to exclude or limit any Liability which cannot legally be limited including but not limited to liability for:

10.3.1 death or personal injury caused by negligence;

10.3.2 for its fraud or fraudulent misrepresentation; and

10.3.3 for any matter for which it is not permitted by law to exclude or limit, or to attempt to exclude or limit, its Liability.

10.4 For the avoidance of doubt, UK Biobank shall have no responsibility or Liability (including but without limitation any product-related Liability) for any finding, product, test or treatment developed directly or indirectly by the Applicant using the Materials.

10.5 Nothing in this MTA shall operate to exclude or limit the Applicant's Liability to UK Biobank for any loss, damage, costs or expenses arising from:

10.5.1 the Applicant's failure to comply with clause 9 (Data Protection) and clauses 14.5 to 14.10 inclusive (Third Party Processors);

10.5.2 any breach of clause 2.2 or any circumstance in which the Applicant sub-licenses, distributes or otherwise shares the Materials (including any IPRs) with any unauthorised person or third party;

10.5.3 any circumstance set out in clauses 4.5 and 4.7; and

10.5.4 any Data Security Incident which is caused by the Applicant.

11. Term

11.1 The term of this MTA shall commence on the Effective Date and shall end on the Completion Date unless terminated sooner in accordance with clause 12 or in accordance with law.

11.2 The Term of this MTA may be extended by the Applicant during the final year of the Approved Research Project in the following one (1) year increments:

11.2.1 for a minimum of period of one (1) year;

11.2.2 for a period of two (2) years; or

11.2.3 for a maximum of period three (3) years;

on application to UK Biobank setting out (in reasonable detail) the reasons for the extension request and subject to the payment of the relevant further Access Charges.

11.3 For the avoidance of doubt, the extensions set out in clause 11.2 above can be applied cumulatively (subject to applicable Access Charges) so that, for example, an extension of 3 years may be granted to take the Approved Research Project duration from 3 years to 6 years, and this may then be extended by a further 3 years to 9 years and so on.

12. Termination and consequences of termination

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

12.1.1 commits any breach of a material provision of this MTA or a material breach 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; or

12.1.2 ceases, is likely to cease, or threatens to cease carrying on business or suffers an Insolvency Event, or is subject to a serious, adverse regulatory finding.

12.2 Upon expiry of the MTA pursuant to clause 11.1 above or termination of this MTA by UK Biobank pursuant to clause 12.1 or in accordance with law:

12.2.1 The grant of rights and all licences to the Applicant under this MTA shall be automatically terminated; and

12.2.2 The Applicant shall destroy the Materials or otherwise render them inaccessible. For the avoidance of doubt, the Applicant shall not be required to destroy Results Data or Other Data subject to the provisions of this MTA being complied with.

12.3 Without prejudice to the foregoing and to any other rights or remedies that UK Biobank may have, UK Biobank may take the following steps if there is a breach that entitles UK Biobank to terminate this MTA under clause 12.1:

12.3.1 it may prohibit the Applicant PI, Applicant Researchers and any other researchers from the Applicant from accessing any further Materials from within the UK Biobank Resource for an indefinite period of time; and/or

12.3.2 it may elect to inform the relevant personnel within the defaulting Applicant, funders of the defaulting Applicant and/or governing or other relevant regulatory bodies.

12.4 Notwithstanding termination of this MTA for any reason, the provisions of clauses 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 13, 14, 16 and 17 shall continue in force in accordance with their respective terms.

12.5 Termination or expiry of this MTA shall not affect the rights and obligations of the parties accrued at the date or termination or expiry.

13. Notices

13.1 Notices required under this MTA shall be in writing and shall be:

13.1.1 sent by email to the addresses set out below; or

13.1.2 (in the event of failure to deliver an email) by post to UK Biobank or to the Applicant.

13.2 Any notice shall be deemed to be received:

13.2.1 if sent by email, upon receipt at the recipient's email server, (or, if this time falls outside business hours in the place of receipt, when business hours resume); or

13.2.2 if sent by post, on the date of delivery if a business day in the place of receipt (or, if not a business day, on the first business day thereafter).

13.3 Notices to UK Biobank shall be sent to the access team at access@ukbiobank.ac.uk. Notices to the Applicant shall be sent by email to the relevant Applicant and the Applicant PI.

14. Affiliates, assignment and sub-contracting

Affiliates

14.1 The rights granted to the Applicant under this MTA include the Affiliates of the Applicant, subject to the Applicant remaining fully liable and responsible for the conduct of its Affiliate(s) and for ensuring that it's Affiliate(s) comply with the terms and conditions of this MTA.

Assignment

14.2 Neither UK Biobank nor the Applicant shall 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, such approval not to be unreasonably withheld or delayed.

Subcontracting

14.3 Other than in the circumstances set out in clause 14.5, the Applicant shall 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 to be unreasonably withheld.

14.4 In the event that consent is granted under clause 14.3, the relevant 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 shall not relieve such relevant Applicant of any of its obligations under this MTA.

Third party processors

14.5 UK Biobank acknowledges and agrees that the Applicant may subcontract to third party Processors to Process the Materials strictly for the Permitted Purpose and only in relation to discrete elements of data computation and analysis (such Processors being, "**Third Party Processors**"). The Applicant must comply with, and only engage Third Party Processors strictly in accordance with the terms set out in clauses 14.6 to 14.10 inclusive.

14.6 The Applicant warrants that the Third Party Processor is not a Collaborator and shall only be engaged for the purposes of discrete elements of data computation and analysis in relation to the Permitted Purpose (the "**Processor Task**").

14.7 Prior to engaging a Third Party Processor, the Applicant shall conduct and document the following assessment:

14.7.1 whether the Third Party Processor is necessary for the progress of the research aims of the Approved Research Project;

14.7.2 whether the Third Party Processor is a suitable recipient for the data in terms of both its provenance on past data security and past data usage / activities (for example Cambridge Analytica would not qualify); and

14.7.3 whether the Third Party Processor is able to provide sufficient assurance(s) that it shall Process the Materials in a manner that will meet the requirements of Data Protection Legislation.

14.8 The Applicant shall:

14.8.1 remain fully responsible to UK Biobank for all acts, defaults and omissions of the Third Party Processor as if they were the Applicant's own;

14.8.2 provide only such Materials to the Third Party Processor as is strictly necessary for the Third Party Processor to perform the Processor Task;

14.8.3 provide details of each Third Party Processor and the Processor Task in the Annual Project Report submitted to UK Biobank on an annual basis in accordance with clause 7.1 of the MTA; and

14.8.4 only engage the Third Party Processor on the basis that a written agreement with the Third Party Processor is executed prior to any data transfer or Processing of Materials taking place. Such agreement must include inter alia:

(a) a clear definition and scope of the Processor Task, including an agreement only to Process the data in accordance with the Applicant's documented instructions;

(b) to authorise the Third Party Processor to only undertake the Processor Task and not to perform any other act, unless expressly authorised to do so;

(c) to store, process and use the Materials to the security standards set out in the MTA (as a minimum) and implements appropriate technical and organisational security measures to protect the Materials against a Data Security Incident;

(d) to delete the Materials (and any data generated as a result of the Processor Task) once the Processor Task has been completed;

(e) to confirm that the Third Party Processor has no rights (directly or indirectly) in either any Materials (or data derived therefrom) or from anything which the Applicant has created or done as part of the Approved Research Project (which is covered by the MTA between UK Biobank and the Applicant);

(f) to confirm that the Third Party Processor is bound by the provisions which are equivalent to the relevant provisions in the MTA, including, but not limited to: a) not to transfer the Materials (or data derived therefrom) to any third party and b) not to make any attempt to re-identify any Participant;

(g) that the Third Party Processor provides sufficient assurance(s) that it shall Process the Materials in a manner that will meet the requirement of Data Protection Legislation; and

(h) that the Applicant has an unfettered unilateral right to terminate its agreement with the Third Party Processor immediately if a material problem arises (including a breach by the Third Party Processor of any of the above provisions).

14.9 The Applicant must keep the activities of the Third Party Processor under reasonable review in order to ensure compliance with clauses 14.5 to 14.10 inclusive.

14.10 In the event that UK Biobank raises any concern regarding the identity of the Third Party Processor or the activities of a Third Party Processor the Applicant shall investigate and report on the matter promptly. UK Biobank may require, if reasonably necessary (and subject to a dialogue with the Applicant), the Applicant to:

14.10.1 to audit the Third Party Processor; and / or

14.10.2 terminate the agreement with the Third Party Processor.

15. Force majeure

15.1 If a 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 shall 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 shall thereupon be suspended for so long as the Force Majeure Event may continue.

15.2 The party affected by a Force Majeure Event shall not be liable for any failure to perform or delay in performing such of its obligations as are prevented, hindered or delayed by the Force Majeure Event provided that such party shall use every reasonable effort to minimise the effects thereof and shall resume performance as soon as possible after the removal of such Force Majeure Event. If the period of non-performance exceeds 90 days from the start of the Force Majeure Event then the non-affected party shall have the option, by written notice to the other party, to terminate this MTA by giving thirty (30) days' written notice to the other party.

15.3 The provisions of this clause 15 shall not affect any other right which any party may have to terminate this MTA.

16. Dispute resolution

16.1 If a Dispute arises, the parties shall follow the procedure set out in this clause 16.

16.2 Either party may give the other party written notice of a Dispute, setting out its nature and full particulars ("**Notice of Dispute**"), together with relevant supporting documents. Within five (5) business days of service of the Notice of Dispute, a UK Biobank representative and a representative from the Applicant shall attempt in good faith to resolve such Dispute.

16.3 If for any reason the respective representatives of the parties are unable to resolve the Dispute within ten (10) business days of the Notice of Dispute, then any of the parties involved in the respective Dispute may refer it for discussion by UK Biobank's Principal Investigator and appropriate senior officer(s) of the

Applicant. These senior representatives of the parties (or their respective nominees) shall seek to arrange a meeting or telephone or videoconference call promptly with a view to resolving the Dispute.

16.4 If, following escalation of any Dispute as set out in clause 16.3, UK Biobank's Principal Investigator and appropriate senior officer(s) of the Applicant are for any reason unable to resolve the Dispute within thirty (30) business days of it being escalated to them, then the parties agree to enter into mediation in good faith the settle the Dispute in accordance with the Centre for Effective Dispute Resolution (CEDR) Model Mediation Procedure. Unless otherwise agreed between the parties within 20 business days of service of the Notice of Dispute, the mediator shall be nominated by CEDR. To initiate the mediation, a party must serve notice in writing to the other party to the Dispute, referring the Dispute to mediation.

16.5 For avoidance of doubt, Disputes with respect to scientific or technical issues or business decisions, and not legal issues, shall remain with senior representatives to be resolved.

16.6 If the Dispute is not settled by mediation within 10 business days of commencement of mediation or within such further period as the parties may agree in writing, either party may issue court proceedings in accordance with clause 17.10 of this MTA.

16.7 Nothing in this clause 16 shall serve to prevent any of the parties from seeking interim/injunctive relief to protect its rights and interests in any court of England and Wales; provided that such relief shall not prevent or stay any mediation.

17. General

17.1 The parties agree that the Applicant may change the Applicant PI at any time, and from time to time, by written notice to UK Biobank.

17.2 This MTA governs and constitutes the entire agreement between the parties and supersedes, replaces and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them (whether oral or written) relating to the subject matter hereof. Further, each party acknowledges and agrees that it does not rely on, and shall have no remedy in respect of, any statement, promise, assurance, statement, warranty, undertaking or representation made (whether innocently or negligently) by the other party or any other person except as expressly set out in this MTA in respect of which its sole remedy shall be for breach of contract.

17.3 If there is any conflict between the provisions of this MTA and any of the Annexes, then the provisions of the relevant Annex shall apply.

17.4 A waiver, delay or forbearance by any party, whether express or implied, in enforcing or exercising any of its rights or remedies hereunder shall not constitute a waiver of such right or remedy, unless set forth in a writing signed by the waiving party.

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

17.6 Nothing in this MTA shall create a partnership, joint venture or relationship of agency among the parties.

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

17.8 If any provision or part-provision of this MTA is or becomes invalid, illegal or unenforceable, it shall be deemed deleted, but that shall not affect the validity and enforceability of the rest of this MTA.

17.9 If any provision or part-provision of this MTA is deemed deleted under clause 17.8, the parties shall negotiate in good faith to agree a replacement provision that, to the greatest extent possible, achieves the intended commercial result of the original provision.

17.10 This MTA and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation shall be governed by and construed in accordance with the laws of England and Wales. Subject to clause 16 above, the parties irrevocably agree that the English courts shall have exclusive jurisdiction over any suit, action, proceedings or dispute arising out of, or in connection with this MTA or its subject matter or formation.

This MTA is executed by duly authorised representatives of the parties.

For and on behalf of UK Biobank:	**For and on behalf of the Applicant:**
Signature:	**Signature:**
Print name:	**Print name:**
Position:	**Position:**
Date:	**Date:**

I am the Applicant Principal Investigator of this Approved Research Project and by signing below I confirm that I have read and understood the provisions of this MTA.

Signature:

Print name:

Position:

Date:

Definitions

***Access Charges**:* the charges payable by the Applicant (which may include VAT) to access the Materials as summarised in Annex 4 and detailed in the payment section of the Application on AMS.

Affiliate: any company or other entity that is directly or indirectly Controlling, Controlled by or under common Control with an Applicant (which includes if such Applicant is a company, a subsidiary or parent or holding company of such Applicant, or a subsidiary of such parent or holding company) for so long as such Control exists.

***All Reasonable Endeavours**:* in respect of a party obliged to use "All Reasonable Endeavours", the pursuance of a reasonable course of action to achieve the stated outcome which may require reasonable expenditure, but does not require the party to pursue every available course of action to achieve the outcome or act outside its own operational or commercial interests.

***AMS**:* the online Access Management System the Applicant uses to apply for and manage its access to the Resource.

***Applicant**:* an institution, company or other identifiable legal entity, making the Application for access in respect of the Approved Research Project and by which an Applicant PI is employed or otherwise contractually attached.

***Applicant's Confidential Information**:* as defined in clause 8.1 of this MTA.

Applicant-Generated Inventions: as defined in clause 3.5 of this MTA.

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

Applicant Principal Investigator or ***Applicant PI**:* the Applicant's principal investigator of the Approved Research Project.

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

***Approved Research Project**:* the research project approved by UK Biobank (specifically including any conditions or stipulations made by UK Biobank) and as set out in Annex 4.

***C2C Model Clauses*:** the model clauses for the transfer of Personal Data to Controllers established in third countries approved by the European Commission, the approved version, of which, in force at present is that set out in the European Commission's Decision 2004/915/EC of 27 December 2004 (available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004D0915), as such model clauses may be amended or superseded by the Secretary of State or standard data protection clauses specified in a document issued (and not withdrawn) by the UK Information Commissioner;

***Collaborator**:* the institution(s) collaborating with the Applicant on the Approved Research Project.

***Completion Date**:* the date or dates contained within Annex 4 for the end-date of the Approved Research Project, including any extensions.

***Control**:* means the direct or indirect ownership of at least fifty percent (50%) of the outstanding shares or other voting rights of the subject entity having the power to vote on or direct the affairs of the entity (or such lesser percentage which is the maximum allowed to be owned by a foreign company in a particular jurisdiction), and "Controlling" and "Controlled" shall be construed accordingly.

Controller, Processor, Data Subject, Personal Data, Processing *(and* ***Process****) and* ***Special Categories of Personal Data**:* have the meanings given in Data Protection Legislation;

Data Protection Legislation: means all laws applicable (in whole or in part) to a party's Processing of Personal Data under or in connection with this MTA, and including, as applicable: (i) the GDPR as it forms part of UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (the "**UK GDPR**"); (ii) the UK Data Protection Act 2018; (iii) the Privacy and Electronic Communications (EC Directive) Regulations 2003 as they continue to have effect by virtue of section 2 of the European Union (Withdrawal) Act 2018; and (iv) any other laws in force in the UK from time to time applicable (in whole or in part) to the Processing of Personal Data, in each case as amended or superseded from time to time.

Data Security Incident: as defined in clause 4.2 of the MTA.

***Dispute**:* any dispute, controversy, proceeding or claim (including any legal disputes) between UK Biobank, on the one hand, and the Applicant, on the other hand, arising out of or in connection with this MTA or the performance, validity or enforceability of it.

***Effective Date**:* the date on which this MTA is executed by an authorised signatory of UK Biobank, having already been signed by the Applicant and signed as "read and understood" by the relevant Applicant PI.

***Findings**:* as defined in clause 3.1.2 of this MTA and shall mean literally what is found, in terms of conclusions and results, by the Applicant as a result of the Approved Research Project. For clarity, findings do not include Applicant-Generated Inventions and nor do they include findings which result from data which is not UK Biobank Materials.

***Force Majeure Event**:* any cause which arises from or is attributable to acts, events, omissions or accidents beyond the reasonable control of the affected party including without limitation act of God, war, riot, civil commotion, non-performance by sub-contractors or suppliers, compliance with any law or governmental order, rule, regulation or direction, accident, breakdown of plant or machinery, supply failure, epidemic, pandemic, fire, flood or storm.

Insolvency Event: means where a person is unable to pay its debts within the meaning of the Insolvency Act 1986 section 123 (without the need for a determination by a court), has an administrator, receiver, administrative receiver or manager appointed over the whole or any part of its assets, enters into any composition with creditors generally, or has an order made or resolution passed for it to be wound up (unless as part of any scheme for solvent amalgamation or solvent reconstruction) or undergoes any similar or equivalent process in any jurisdiction or undergoes any other arrangement which affects the rights of creditors;

***Intellectual Property Rights** or **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.

Liability: liability arising out of or in connection with this MTA, whether in contract, tort, misrepresentation, restitution, under statute or otherwise, including but not limited to arising from a breach of, or a failure to perform or defect or delay in performance of, any of a party's obligations under this MTA, in each case howsoever caused, including if caused by negligence.

***Materials**:* the data as set out in Annex 4 supplied by UK Biobank to the Applicant under or in connection with this MTA including any Participant Level Data.

MTA: this Material Transfer Agreement, the Applicant Terms and Conditions (including any documents and/or materials that are referred to in them), the Annexes and where applicable the contents of the Applicant's Application Form.

***Notice of Dispute**:* as defined in clause 16.2 of the MTA.

***Other Data**:* as defined in clause 3.1.3 of the MTA.

***Participant(s)**:* the individuals who participate in UK Biobank.

***Participant Level Data**:* the Personal Data contained within the Materials and any applicable generated data (as described in clause 3.1 of the MTA).

***Permitted Purpose**:* to conduct the Approved Research Project in accordance with the approved project scope and the timeframe as set out in the Annex 4, subject to the provisions of this MTA.

***Resource**:* the collection of Materials within UK Biobank which are accessible by Applicant.

***Results Data**:* as defined in clause 3.1.1 of this MTA.

***Term**:* as defined in clause 11.1 of this MTA.

Third Party Processors: as defined in clause 14.5 of this MTA.

VAT: value added tax chargeable under the Value Added Tax Act 1994 (and all amendments and updates thereto) or any similar replacement or additional tax.

Annex 1
Data Processing Description

This Annex 1 forms part of this MTA and describes the types of Participant Level Data disclosed by UK Biobank to the Applicant and Applicant Researchers to process strictly for the Permitted Purpose described in this MTA (or as otherwise agreed in writing by the parties).[3]

Data subjects	The Participants
Categories of data	The Participant Level Data to be Processed concern the following categories of Personal Data: • EIDs – the encoded and unique pseudonymised identifiers which are specific to the Approved Research Project; and • data derived from baseline questionnaire responses and interviews which do not contain special category data, such as birthplace, early life and education, employment history, marital status and number of children.
Special categories of data	The Participant Level Data to be Processed concern the following special categories of data: The UK Biobank Resource contains health, genetic and biometric data. All special categories of data contained in the Materials is de-identified (the direct and indirect identifiers are removed). The types of special category of data may include: • measures of the Participant's phenotype, such as height, weight and blood pressure (approximately 2,000 phenotypes per Participant, as further detailed here http://biobank.ndph.ox.ac.uk/showcase/schema.cgi?id=1) • measures of the Participant's genome, this includes genotype, exome sequence and whole sequence data; • biomarkers created by assay of the Participant's samples, which include common biomarkers (such as cholesterol), infectious disease markers, proteomic and metabolomic markers; • imaging data (on up to 100,000 Participants) as the result of MRI scans of the head, the heart and the body, plus ultrasound and DEXA; and • data derived from health record linkages including hospital records, primary care records, death and cancer registries or any other sources of clinical data; and • special category data derived from baseline questionnaire responses and interviews, such as past illness / disease history, dietary, cognitive and physical measures.
Purpose of the transfer	The transfer is made to allow the Applicant to conduct the Permitted Purpose.
Recipients	The Participant Level Data transferred may be disclosed only to the following recipients or categories of recipients: • Authorised personnel within the Applicant, namely the Applicant Principal Investigator and Applicant Researchers; • Third Party Processors subject to the relevant provisions of the MTA; • Law enforcement agencies acting under Data Protection Legislation; • The relevant data protection authority acting under Data Protection Legislation; and • Auditors (UK Biobank or appropriate third parties).
Processing activities	The Participant Level Data will be subject to the following basic Processing activities: • Access and use of Participant Level Data within the research analysis platform for the Permitted Purpose; • Where approved by UK Biobank the transmission to, making available to and storage on the Researcher's systems/network servers, excluding any WGS (whole genome sequence) or WES (whole exome sequence) files which must not be transmitted or downloaded from the research analysis platform; • research operations, including a Processor Task by a Third Party Processor; and • risk management, compliance, legal and audit functions.
UK Biobank's lawful basis for sharing Personal Data	Personal Data: • Legitimate interests (Article 6(1)(f) UK GDPR) Special Categories of Data: • Scientific research purpose (Article 9(2)(j) UK GDPR)

[3] For further information about this MTA's Data Protection clauses and an explanation of UK Biobank's position in relation to Data Protection, please see the FAQs on the UK Biobank website (which shall be updated by UK Biobank from time to time).

UK Biobank's DPO contact details:	DPO@ukbiobank.ac.uk
Applicant's DPO contact details:	

Annex 2
Security Measures

UK Biobank has a legal obligation under the UK GDPR to ensure that its Materials are stored, retrieved and used securely, with appropriate organisational and technical measures in place. UK Biobank must also take reasonable steps to ensure that Materials it shares continue to be protected with adequate security. This Annex 2 forms part of the MTA and represents the minimum level of security standards for data storage, retrieval and usage that the Applicant must comply with. This Annex 2 may be updated by UK Biobank from time-to-time.

The objective of these security measures is to ensure that Materials provided by UK Biobank are secured and treated as though they are Personal Data, and with particular respect to:

- Confidentiality – data are secured with organisational and technical measures in place to restrict access only to authorised users and protected from unauthorised access by internal and external threats; and
- Integrity – data remains accurate and complete to support high quality research to be undertaken.

1. Information security policy

1.1 The Applicant shall implement and maintain a written information security policy that specifies the security standards it shall apply to protect the Materials it processes in accordance with this MTA.

1.2 The information security policy shall mandate the use of appropriate technical and organisational security measures in the Applicant's organisation to protect Personal Data against unauthorised and unlawful processing and against damage or destruction. It shall further describe the measures to be taken in the event of an actual or suspected data or security breach.

1.3 The Applicant shall appoint a duly skilled employee with responsibility for ensuring the security of the Materials processed by the Applicant in its organisation and for reviewing, maintaining and updating the Applicant's information security policy.

1.4 The Applicant shall ensure duly authorised employees and contractors are properly trained and are aware of their responsibilities for any data they handle including appropriate technical training in order to fulfil their roles. This training programme should include information on current common threats and appropriate actions in response.

1.5 The information security policy shall also set out that:

1.5.1 Information should be stored throughout its existence in an environment suited to its format and sensitivity, to ensure its preservation from physical harm or degradation and its security from unauthorised access;

1.5.2 Data storage devices are appropriately protected via advanced anti-virus software; access should be controlled via directory services;

1.5.3 Servers, client devices and applications used for storing, accessing and analysing UK Biobank Materials are deployed with operating systems, firmware, and software within vendor supported versions and where exceptions are documented with adequate mitigations described and auditable; and

1.5.4 Encryption is in place in transit and at rest where practicable.

2. Access to data

2.1 The Applicant shall implement technical access controls that restrict access to data it processes to duly authorised employees and contractors only. Access logging and monitoring should be put in place.

2.2 The Applicant shall ensure that only duly authorised employees and contractors shall be permitted to access the Materials only to the extent necessary for the performance of their duties.

2.3 The Applicant shall identify and appoint a system administrator with overall responsibility for granting, changing or voiding data access privilege to its data processing systems and access privileged should be periodically reviewed.

2.4 Where an employee or contractor who has access to the Materials either leaves or has their authorisation removed e.g. as a result of a change of role, the Applicant shall ensure that their status is updated within 24 hours e.g. by changing access control lists.

2.5 The Applicant shall ensure that access to server data processing facilities as appropriate shall be restricted on a 24x7 basis to duly authorised employees and contractors by use of keys, biometric readers, or other electronic security measures as practical.

3. User access controls

3.1 The Applicant shall ensure that access to Personal Data shall be controlled through access privileges (described above), usernames and appropriately secure passwords.

3.2 The Applicant shall ensure that employees or contractors should not share or use the same username, and exceptions must be documented with adequate mitigations described and auditable.

3.3 Use of multi-factor authentication should be used to authenticate authorised users of IT systems.

4. Technical controls

4.1 The Applicant shall implement appropriate firewall, anti-virus, anti-spyware and other anti-malware software and technologies on all networks and systems it uses to process the Materials.

4.2 The Applicant shall update its firewall, anti-virus, anti-spyware and other anti-malware software and technologies on a regular basis to ensure that they protect against then-current virus, spyware and other malware threats.

4.3 The Applicant shall ensure that updates and patches of critical software and firmware are applied within a reasonable time period.

4.4 The Applicant shall mitigate external attacks by a number of methods, including the use of Intrusion Prevention and Detection Systems (IPS/IDS) in addition to firewall and anti-virus measures, with appropriate monitoring in place.

4.5 Where remote access is provisioned controls must be implemented to ensure only authorised devices access IT systems.

4.6 The Applicant shall take reasonable measures to ensure that vulnerabilities are discovered and addressed within a reasonable time frame. These measures could include internal vulnerability scanning and use of independent external auditors (penetration testing).

5. Storage and transmission of data

5.1 Where practicable data should be encrypted at rest using strong encryption techniques following best practices for key management.

5.2 Measures should be taken to maintain the integrity of data

5.3 Data should be encrypted during transmission, using best practices. Insecure or obsolete protocols or cipher-suites should not be used.

5.4 Use of portable media should be avoided unless reasonably required to process the data. Where needed data should be encrypted using a strong password or other secret information.

5.5 Any deletion of data should be permanent and deleted data should not be recoverable.

5.6 An information asset register should be maintained so that all UKB data can be removed on request or at the end of the agreement.

Annex 3
Annual Project Report Template

The purpose of this Annex 3 is to provide the Applicant and Applicant PI with a template of the Annual Project Report Form that will need to be completed and submitted to UK Biobank on an annual basis (the annual anniversary of the Effective Date). For the avoidance of doubt, the Applicant is not required to complete this form on execution of the MTA.

UK Biobank reserves the right to update this form from time to time including the manner in which the form is submitted to UK Biobank. The up-to-date version of the form and the instructions for submission are accessible on AMS or the UK Biobank website.

Annual Project Report Template

Every year, as Principal Investigator (PI), there is some information regarding your Research Project that we ask you to provide to us. This is a requirement of all PIs on all research projects. If the information requested is not provided, then this could impact your ability to access the UK Biobank data you need for your research and continued failure to comply could lead to your research project being terminated and future research applications being declined.

Please complete and upload this report template to the Access Management System (AMS). For help, please see our AMS User Guide on the UK Biobank website.

Research Project Number:	
Date report completed:	

1. **Are all Collaborators who are currently accessing UK Biobank data as part of this Research Project named in the Collaborators list in AMS?**

Yes / No	*If no, please ask any unregistered collaborators to submit a registration as soon as possible. After registration approval you can add them to the Collaborator list. Please remove any collaborators who are no longer accessing UK Biobank data.*

2. **Please provide the names of any Third Party Processors who process UK Biobank data as a sub-contractor as part of this Research Project and provide details of the tasks the Third Party Processor conducts on your behalf:**

Third Party Processors:
Third Party Processor tasks:

3. **Please provide a summary update on the progress of your Research Project and your plans for the next 12 months:**

Progress to date:
Plans for the next 12 months:

4. **Please provide details of any research output (e.g. websites, patents[4], GWAS summary statistics location) and list all publications (including pre-prints and peer-reviewed publications) from this Project since your last Annual Project Report. If none, please say so:**

Research Output:
Publications: (*in the format: first author, year, title, journal, PMID, DOI*)

5. **I certify that:**

Please mark with an 'x':

- I am the PI of the Research Project identified above; ☐
- all of the provisions of the Material Transfer Agreement, including but not limited to the Security Measures (Annex 2) are being complied with; ☐
- a GDPR-compliant privacy notice is available on my institution's website in relation to processing participant data for the purposes of this Research Project; and ☐
- all of the information provided in this Annual Project Report is true and accurate. ☐

Note: please save as a .pdf document and upload in AMS

[1]As stated in the Material Transfer Agreement, please provide us with a summary (and a copy of the application if requested) of any patents whose claims cover, or are intended to cover, an Applicant Generated Invention within 2 months of their publication.

PLACEHOLDER

Annex 4
Approved Research Project
(PDF to be added by AMT once generated)