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| 1. **Dated**: 2018
2. **[Name of the supplier]**
3. **UK Biobank Limited**
 |
| **TERMS AND CONDITIONS FOR WHOLE GENOME SEQUENCING**  |
|  |

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**THIS AGREEMENT** is made on [INSERT DATE] 2018 (the “**Agreement**”).

1. **BETWEEN**
2. [NAME OF COMPANY], incorporated and registered in [INSERT] (registered number [COMPANY NUMBER]) with a registered office at [ADDRESS] (the **“Supplier*”***); and
3. UK Biobank Limited, incorporated and registered in England and Wales (company number 04978912) with a registered office at Units 1-2, Spectrum Way, Adswood, Stockport, SK3 0SA (the **“UK Biobank”**).

**BACKGROUND**

1. UK Biobank invited potential service providers (including the Supplier) to tender for the provision of whole genome sequencing services in respect of human DNA samples.
2. On the basis of the Supplier's tender, UK Biobank selected the Supplier to enter into an Agreement to provide whole genome sequencing services to UK Biobank.
3. UK Biobank requires the Supplier to supply the sequenced data to UK Biobank.
4. The Supplier agrees to provide the Services (as defined below) to UK Biobank on the terms and conditions set out in this Agreement.
5. The Supplier and UK Biobank agree to reasonably co-operate in connection with the performance of the Services and to act in good faith in respect of this cooperation.
6. **AGREED TERMS**
7. DEFINITIONS AND INTERPRETATION

In this Agreement:

* 1. the following words and expressions have the following meanings unless the context otherwise requires:

|  |  |
| --- | --- |
| 1. **“Agreement Personal Data”**
 | 1. Personal Data which is to be Processed under this Agreement, as more particularly described in Schedule 3
 |
| 1. **“Applicable Law”**
 | 1. any:
	1. law including any statute, statutory instrument, bye‑law, order, regulation, directive, treaty, decree, decision (as referred to in Article 288 of the Treaty on the Functioning of the European Union) (including any judgment, order or decision of any court, regulator or tribunal);
	2. rule, policy, guidance or recommendation issued by any governmental, statutory or regulatory body; and/or
	3. industry code of conduct or guideline
2. in force from time to time which relates to this Agreement and/or the Services and/or the activities which are comprised in all or some of the Services or the use or application of the output from the Services
 |
| 1. **“Bribery Act”**
 | 1. the Bribery Act 2010
 |
| 1. **“Business Day”**
 | 1. a day that is not a Saturday, Sunday or public or bank holiday in England and/or Wales
 |
| 1. **“Confidential Information”**
 | 1. means information that is confidential (however it is conveyed, or on whatever media it is stored) and may include information where disclosure would, or would be likely to, prejudice the commercial interests, trade secrets, Intellectual Property Rights and Know-How of either party but excludes information that is already, or becomes, publicly known, through no action or inaction of the recipient, information independently developed by a recipient without use of any Confidential Information, information that is received from a third party that is not in breach of any confidentiality obligations of such third party
 |
| 1. **“UK Biobank Data”**
 | 1. all data in any medium which the UK Biobank permits or requests (whether expressly or by implication) the Supplier to access, store, transmit, distribute or otherwise process as part of the Services (including Agreement Personal Data)
 |
| 1. **“Data Protection Laws”**
 | 1. all Applicable Laws relating to data protection, the processing of personal data and privacy, including:
	1. the Data Protection Act 1998;
	2. (with effect from 25 May 2018) the General Data Protection Regulation (EU) 2016/679; and
	3. the Privacy and Electronic Communications (EC Directive) Regulations 2003
2. and references to **“Data Processor”**, **“Data Subjects”**, **“Personal Data”**, **“Process”**, **“Processed”**, **“Processing”**, **“Processor”** and **“Supervisory Authority”** have the meanings set out in, and will be interpreted in accordance with, such laws
 |
| 1. **“Data Security Incident”**
 | 1. a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, Agreement Personal Data transmitted, stored or otherwise Processed
 |
| 1. **“Deliverables”**
 | 1. means the data to be delivered to UK Biobank in accordance with Schedule 1 and all materials developed by the Supplier or its agents, subcontractors, consultants and employees for the purpose of performing the Services, but excluding any information or data developed by the Supplier that constitute Supplier’s trade secrets, or Supplier’s standard operating process or any technical information relating to Supplier’s proprietary formulations, structures or product designs
 |
| 1. “Good Industry Practice”
 | 1. the level of skill, care, quality control and quality management generally used in the provision of services in the nature of the Services by a supplier of such services
 |
| 1. **“Insolvent”**
 | 1. a party that:
	1. has a receiver, administrator or provisional liquidator appointed;
	2. is subject to a notice of intention to appoint an administrator;
	3. passes a resolution for its winding-up (save for the purpose of a solvent restructuring);
	4. has a winding up order made by a court in respect of it;
	5. enters into any composition or arrangement with creditors (other than relating to a solvent restructuring previously approved in writing by the other party);
	6. ceases to carry on business; or
	7. has any steps or actions taken in connection with any of these procedures; or
	8. is the subject of anything analogous to the foregoing under the laws of any applicable jurisdiction; or
	9. is the subject of any proceeding in any Member State of the European Union which is capable of recognition under the EC Regulation on Insolvency Proceedings (EC 1346/2000) or the EU Regulation on Insolvency Proceedings (Recast) (EU 2015/848); or
	10. is the subject of an application for the recognition of a foreign insolvency proceeding under the Cross-Border Insolvency Regulations 2006 (SI 2006/1030);
 |
| 1. **“International Transfer”**
 | 1. a transfer to a country outside the European Economic Area (as it is made up from time to time) of Agreement Personal Data which is undergoing Processing or which is intended to be Processed after transfer
 |
| 1. **“Know-How”**
 | 1. formulae, methods, plans, inventions, discoveries, improvements, processes, performance methodologies, techniques, specifications, technical information, tests, results, reports, component lists, manuals and instructions
 |
| 1. **“Liability”**
 | 1. liability arising out of or in connection with this Agreement, whether in contract, tort, misrepresentation, restitution, under statute or otherwise, including any liability under an indemnity contained in this Agreement and/or 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 Agreement, in each case howsoever caused including if caused by negligence or a deliberate and/or repudiatory breach by that party
 |
| **“Recipient”**1. **“Records”**
2. **Services”**
 | 1. has the meaning in clause 18
2. has the meaning in clause 18
3. means the services provided by the Supplier as set out in Schedule 1
 |
| 1. **“Effective Date”**
 | 1. the date at the head of this Agreement
 |
| 1. **“Sub-Processor”**
 | 1. any third party appointed by the Supplier to Process Agreement Personal Data
 |
| 1. **“Term”**
 | 1. the period starting on the Effective Date and ending on the Termination Date
 |
| 1. **“Termination Date”**
 | 1. the date on which this Agreement expires or terminates for whatever reason
 |
| 1. **“VAT”**
 | 1. value added tax
 |

* 1. the Schedules form part of this Agreement and will have the same force and effect as if set out in the body of this Agreement and any reference to this Agreement will include the Schedules;
	2. the background section and all headings are for ease of reference only and will not affect the construction or interpretation of this Agreement;
	3. unless the context otherwise requires:
		1. references to the singular include the plural and vice versa and references to any gender include every gender;
		2. references to a “person” include any individual, body corporate, association, partnership, firm, trust, organisation, joint venture, government, local or municipal authority, governmental or supra-governmental agency or department, state or agency of state or any other entity (in each case whether or not having separate legal personality);
	4. references to any statute or statutory provision will include any subordinate legislation made under it and will be construed as references to such statute, statutory provision and/or subordinate legislation as modified, amended, extended, consolidated, re-enacted and/or replaced and in force from time to time;
	5. any words following the words “include”, “includes”, “including”, “in particular” or any similar words or expressions will be construed without limitation and accordingly will not limit the meaning of the words preceding them;
	6. references to “in writing” or “written” include e-mail.
1. SCOPE OF THIS AGREEMENT
	1. The Supplier will provide the Services and deliver the Deliverables to UK Biobank in accordance with **Schedule 1** and the terms and conditions of this Agreement.
	2. The Supplier will perform the Services on an initial batch of one thousand (1000) DNA samples and subject to its compliance with quality management systems and quality control/performance metrics as outlined in Schedule 1, on further batches of five thousand (5000) DNA samples (or such other number as UK Biobank may reasonably require), at UK Biobank’s option and as requested by UK Biobank from time to time.
	3. In consideration of performing the Services, UK Biobank will pay the Supplier in accordance with **Clause 10** below.
2. TERM
	1. This Agreement will commence on the Effective Date and will continue until the third anniversary of the Effective Date and after that for any extension period agreed by the parties in accordance with clause 3.2.
	2. Without prejudice to the rights of termination set out in this Agreement, the parties may agree in writing to extend the term of this Agreement by a period of up to twelve months from the date on which it would otherwise have expired.
3. CHANGE CONTROL
	1. The Parties shall meet as and when UK Biobank shall reasonably require in order to discuss matters relating to the Services.
	2. If UK Biobank wishes to change the scope or execution of the Services, it shall submit details of the requested change to the Supplier in writing.
	3. If UK Biobank requests a change to the scope or execution of the Services, the Supplier shall, within a reasonable time (and in any event not more than fifteen (15) Business Days after receipt of UK Biobank’s written request), provide a written estimate to UK Biobank of:
		1. the likely time required to implement the change;
		2. any necessary variations to the Supplier's charges arising from the change;
		3. necessary changes to the Services; and
		4. any other impact of the change on the Agreement.
	4. Unless both parties consent to a proposed change, there shall be no change to the Services or the Agreement.
4. DELIVERY OF SERVICES
	1. The Supplier will perform and warrants that it will perform the Services:
		1. using reasonable care and skill and not less than that employed by comparable providers of comparable services and at all times in accordance with Good Industry Practice; and
		2. in accordance with all Applicable Laws.
	2. UK Biobank shall provide DNA samples from time to time during the Term and the Supplier shall, at UK Biobank’s request, provide sequencing Services in respect of such samples.
	3. Once the previous batch of data and/or Deliverables have complied with quality management systems and performance/quality control metrics in Schedule 1, UK Biobank shall take all reasonable endeavours to meet the DNA sample delivery timelines as outlined in Schedule 1. Supplier acknowledges and agrees that all DNA sample delivery timelines, dates and volumes provided by UK Biobank are estimates only and notwithstanding any other clauses within this Agreement may be changed by UK Biobank (acting reasonably) from time to time.
	4. The Supplier shall use all reasonable endeavours to meet UK Biobank’s timelines for delivery of Deliverables, as outlined in Schedule 1. UK Biobank acknowledges delays to the estimated DNA sample delivery timelines dates and volumes may impact on any timelines given by Supplier for the delivery of the Deliverables. In the event of a non-trivial delay, the Supplier shall keep UK Biobank informed in writing at all times.
	5. The provisions of this clause shall survive any performance, acceptance or payment pursuant to this Agreement and shall extend to any substituted or remedial services provided by the Supplier.
5. DELIVERABLES
	1. Supplier warrants that any Deliverables created by the Supplier in the course of performing the Services shall:
		1. conform to any applicable specifications and descriptions set out in Schedule 1; and
		2. be of satisfactory quality; be accurate; be complete and will comply with any relevant quality management systems. There shall be no restrictions or limitations imposed by the Supplier on UK Biobank’s use of the Deliverables.
6. INTELLECTUAL PROPERTY RIGHTS
	1. The Supplier assigns to UK Biobank all patents, rights to inventions, utility models, copyright and related rights, trade-marks, service marks, trade, business and domain names, rights in trade dress or get-up, rights in goodwill or to sue for passing off, unfair competition rights, rights in designs, rights in computer software, database rights, topography rights, rights in confidential information (including Know-How and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications for, and renewals or extensions of, such rights, and all similar or equivalent rights or forms of protection in any part of the world, arising out of the Services and all rights in the Deliverables (the “**Intellectual Property Rights”).**
	2. Notwithstanding the above, UK Biobank recognises that the Supplier has pre-existing intellectual property in certain pre-existing materials, software, spreadsheets and other documents and data (the “**Supplier Background IP**”) which the Supplier may use in performing the Services and which shall remain solely the property of the Supplier.
	3. The parties agree that this Agreement (save to the extent expressly set out herein), will not convey, transfer, assign, license or otherwise convey any rights to UK Biobank in Supplier’s platform (including arrays, probes, reagents, instruments or software), Supplier’s Confidential Information, or Supplier Background IP, nor will UK Biobank make any claim or demand to that effect.
	4. The Supplier further represents and warrants that there are no circumstances where UK Biobank will be required to obtain or make:
		1. Any form of licence, consent, approval or otherwise from the Supplier (or from any related third party); or
		2. Any form of payment or other consideration to the Supplier (or to any related third party);

for the use any such Intellectual Property Rights.

* 1. The Supplier shall, promptly at UK Biobank’s request, do (or procure to be done) all such further acts and things within Supplier’s control and the execution of all such other documents by Supplier’s employees as UK Biobank may from time to time require for the purpose of securing for UK Biobank the full benefit of this Agreement, including all right, title and interest in and to the Intellectual Property Rights and all other rights assigned or licensed to UK Biobank under this Agreement.
1. REPRESENTATIONS AND WARRANTIES
	1. General Warranties
		1. UK Biobank warrants and represents to the Supplier that it has full power and authority to enter into this Agreement and that it has the right to provide the Input Material to the Supplier for the purposes of this Agreement.
		2. The Supplier warrants and represents to UK Biobank that:
			1. it has full power and authority to enter into this Agreement;
			2. to Supplier’s knowledge, no litigation, arbitration, adjudication, dispute or administrative proceeding has been commenced, is pending or is threatened against the Supplier, and no judgment or award has been given or made or is pending against it, which:
				1. in any way questions its power or authority to enter into or perform its obligations under this Agreement; or
				2. may have a material adverse effect on its ability to perform its obligations under this Agreement; and
			3. all written materials submitted to UK Biobank are true, complete and accurate in all material respects (save to the extent that they have been superseded by subsequent communications in writing to UK Biobank or the relevant agents, advisers or employees).
	2. **Supplier’s Obligations**
		1. The Supplier shall manage and complete the Services, and deliver the Deliverables to UK Biobank, in accordance with UK Biobank’s requirements as set out in **Schedule 1** and shall allocate sufficient resources to the Services to enable it to comply with this obligation.
		2. The Supplier shall, before the date on which the Services are to start, obtain, and at all times maintain, all necessary licences and consents and comply with all relevant legislation in relation to the Services.
		3. The Supplier acknowledges and agrees that:
			1. UK Biobank is entering into this Agreement on the basis that the Supplier’s proposals are accurate and complete in all material respects, and are not misleading; and
			2. Title to all DNA samples and related documents, information and materials provided by UK Biobank relating to the Services (the “**Input Material**”) shall at times remain with UK Biobank. Risk in the Input Material shall pass to the Supplier on receipt by the Supplier save in the case where the Supplier pays for shipping, risk shall pass to the Supplier on receipt of the Input Material by the Supplier’s carrier.
	3. **UK Biobank's Obligations**
		1. UK Biobank shall reasonably co-operate with the Supplier in all matters relating to the Services and will act in compliance with all Applicable Laws.
2. EXCLUSIONS AND LIMITATIONS OF LIABILITY
	1. The Supplier shall indemnify and hold UK Biobank harmless from all third party claims and all direct costs, proceedings, fines, damages and expenses (including legal and other professional fees and expenses) awarded against, or incurred or paid by, UK Biobank as a result of, or in connection with any alleged or actual infringement, whether or not under English law, of any third party's intellectual property rights arising out of (i) the Supplier’s performance of the Services; (ii) Supplier’s delivery of the Deliverables to UK Biobank. UK Biobank shall:
		1. notify the Supplier by written notice of any such claim, specifying the nature of the claim in reasonable detail, as soon as reasonably practicable;
		2. allow the Supplier to conduct all negotiations and proceedings and at the cost and expense of the Supplier provide Supplier with such reasonable assistance as it may require;
		3. not make any admission relating to such claim or attempt to settle or compromise such claim without Supplier’s prior written consent (such consent not to be unreasonably withheld or delayed or given);
		4. use all reasonable endeavours to mitigate the effects of any such claim.
	2. Subject to **clause 9.3**, neither party shall be liable for any indirect, special, or consequential damages or for loss of profits or loss of business, even if that party had notice of the possibility thereof.
	3. Nothing in the Agreement shall limit or exclude the liability of either party for:
		1. death or personal injury resulting from negligence or for fraud or fraudulent misrepresentation; and
		2. any liability which cannot be excluded by applicable law.
	4. Subject to **clauses 9.2** and **9.3**, each party’s total liability under or in connection with:
		1. **clauses 15.1** or **18** shall not exceed the three times the aggregate sum of fees paid or payable under the Agreement; and
		2. this Agreement howsoever arising (including by way of negligence, or breach of statutory duty) shall not exceed the aggregate sum of fees paid or payable under the Agreement.
3. CHARGES AND PAYMENT
	1. In consideration of the supply of the Services by the Supplier and subject to **clause 10.2** (or unless otherwise agreed in writing) UK Biobank shall pay Supplier for batch data deliveries completed and delivered (or otherwise retained by the Supplier in a manner agreed between UK Biobank and the Supplier) which meet the quality management systems and quality control/performance metrics outlined in Schedule 1 at the price set forth in **Schedule 2** within thirty (30) days after receipt of invoice. The invoice may be submitted on completion of a sequenced batch and delivery of all Deliverables for that batch. Each invoice shall include such supporting information required by UK Biobank to verify the accuracy of the invoice, including but not limited to the relevant purchase order number.
	2. All payments required to be made by UK Biobank under the Agreement shall be subject to receipt by UK Biobank of a valid invoice. All invoices must quote the reference number stated on UK Biobanks’ order and shall be sent to purchasing@ukbiobank.ac.uk, regardless of the address to which any Services are supplied. Failure to submit an invoice in accordance with this **clause 10.2** may lead to delay in payment and / or the invoice being returned for amendment.
	3. Payment by UK Biobank of any invoice shall not constitute a waiver of UK Biobank’s rights subsequently to question or contest the amount or correctness of the invoice or to seek reimbursement.
4. **VAT**

All amounts due under this Agreement are exclusive of VAT and if any supply made or referred to in this Agreement is or becomes chargeable to VAT then UK Biobank shall in addition pay the Supplier the amount of that VAT against receipt of a proper VAT invoice in respect of that supply.

1. INTEREST

The parties shall pay interest on any amount payable under this Agreement not paid, save for any amounts which UK Biobank (acting reasonably) has notified the Supplier are queried or in dispute, on the due date, for the period from that date to the date of payment on a daily basis at a rate equal to 2% per annum over the HSBC plc base rate from time to time. The parties agree that this **clause 12** is a substantial remedy for late payment of any sum payable under this agreement in accordance with section 8(2) of the Late Payment of Commercial Debts (Interest) Act 1998.

1. TERMINATION
	1. Either party shall be entitled to immediately terminate this Agreement pursuant to **clause 13.2** where:
		1. Either party commits a material breach of any of its obligations under this Agreement and (if such breach is remediable) fails to remedy that breach within a period of thirty (30) days after being requested in writing to do so;
		2. Either party persistently breaches of any of its obligations under this Agreement; or
		3. Either party is Insolvent.
	2. Without prejudice to its other rights in relation to any such event, if any of the events described in **clause 13.1** has occurred and is continuing and the non-defaulting party wishes to terminate this Agreement, it shall serve a termination notice to the other party specifying the type and nature of the relevant event and giving reasonable details thereof and the date on which the termination shall take effect, in which case, with effect from the date specified in the notice:
		1. the obligations of the Supplier to provide the Services shall cease; and
		2. the obligations of UK Biobank to provide any Input Material or to make any further payments (other than for payments already due from UK Biobank to the Supplier) shall cease.
	3. Any termination of this Agreement, howsoever caused, shall not affect the rights or liabilities of either party which have accrued prior to the date of termination and the provisions of this Agreement which are expressly or by implication to come into force on termination or to continue in force notwithstanding termination shall continue in full force and effect.
2. CONSEQUENCES OF EXPIRY OR TERMINATION
	1. Following the Termination Date:
		1. any provisions which expressly or impliedly continue to have effect after expiry or termination of this Agreement will continue in force; and
		2. all other rights and obligations will immediately cease without prejudice to any rights, obligations, claims (including claims for damages for breach) and liabilities which have accrued prior to the Termination Date.
	2. On termination of this Agreement for any reason, the Supplier shall immediately:
		1. deliver to UK Biobank all Input Material and all copies of information and data provided by UK Biobank to the Supplier for the purposes of this Agreement. The Supplier shall certify in writing to UK Biobank that it has not retained any copies of Input Material or other information or data, except that the Supplier may retain one copy of any documents or other information which the Supplier may use, solely to determine its obligations under the Agreement; and
		2. deliver to UK Biobank all specifications, data and other relevant documentation and/or materials comprised in the Deliverables and existing at the date of such termination, whether or not then complete. The Supplier shall certify in writing to UK Biobank that it has not retained any copies of such materials. All rights, including Intellectual Property Rights, in such materials shall automatically pass to UK Biobank (to the extent that they have not already done so by virtue of **clause 7**), who shall be entitled to enter the premises of the Supplier to take possession of them within sixty (60) days of termination; and
		3. on UK Biobank’s request, destroy all DNA samples, data, and all copies of the same, generated under, or in connection with, the provision of the Services or otherwise derived from the Input Material. The Supplier shall certify in writing to UK Biobank that it has destroyed such data.
3. RESTRICTIONS ON USE OF MATERIALS
	1. The Supplier shall not transfer any Input Materials provided to it by UK Biobank or any derivatives to any third party for any purpose and shall not use them for any purpose other than the provision of the Services.
	2. The Supplier shall keep all Input Material in accordance with UK Biobank’s specifications in **Schedule 1**; at a secure location; and other related data on a secure network system, at such standard as would be reasonably expected for the storage of valuable and proprietary materials and/or sensitive and confidential data, and in accordance with Good Industry Practice.
	3. Any DNA samples that are no longer required for the provision of the Services shall be returned to UK Biobank, or if requested in writing by UK Biobank, destroyed by the Supplier and in such event the Supplier shall confirm in writing the same has been done.
	4. The Supplier shall not attempt:
		1. to identify any individual whose DNA is to be analysed pursuant to this Agreement, from the Input Material, from the products of the Services (including the Deliverables, and other related data) or in any other way; or
		2. to contact any individual whose materials have been used.
	5. In the event that the Supplier inadvertently identifies any individual whose DNA is to be analysed pursuant to this Agreement then it shall notify UK Biobank immediately setting out (in reasonable detail) the circumstances by which it happened.
	6. Other than for the purposes of **clause 15.5**, the Supplier shall not:
		1. share the identification of that individual with any other person; or
		2. attempt to contact that individual.
	7. All Input Material and other related data are the property of UK Biobank (or shall become the property of UK Biobank pursuant to **clause 15.1**) and shall remain the property of UK Biobank at all times. The Supplier shall not use, reproduce or retain such material or data for any purpose other than the provision of the Services. On request by UK Biobank, the Supplier shall delete all UK Biobank Data and/or Deliverables that it has in its possession or control.
4. SUSPENSION OF SERVICES BY UK BIOBANK

UK Biobank shall be entitled at any time to suspend the provision of the Services for a specified period of time (not exceeding twelve months) and by providing not less than thirty (30) Business Days written notice to the Supplier. During the period of such suspension the Supplier shall not be obliged to provide the Services and UK Biobank shall not be obliged to pay any payments for the Services. At the end of the suspension period, the parties’ obligations shall re-commence.

1. CONFIDENTIALITY
	1. Each party undertakes that it shall not at any time disclose to any person any Confidential Information disclosed to it by the other party except as permitted by **clause 17.2** and, in particular, the Supplier shall not disclose any information provided to it in relation to individuals whose DNA is to be analysed pursuant to this Agreement.
	2. Each party may disclose the other party’s Confidential Information:
		1. to its employees and officers, who need to know such information for the purposes of carrying out the party’s obligations under this Agreement, provided that the disclosing party takes all reasonable steps to ensure that such persons comply with the confidentiality obligations equivalent to those contained in **clause** **17.1**; and
		2. as may be required by law, court order or any governmental or regulatory authority.
	3. Each party reserves all rights in its Confidential Information. No rights or obligations in respect of a party’s Confidential Information other than those expressly stated in this Agreement are granted to the other party or to be implied from this Agreement.
2. UK BIOBANK DATA, DATA PROTECTION AND INFORMATION SECURITY
	1. UK Biobank authorises the Supplier, to Process the Agreement Personal Data during the Term as a Data Processor/Processor solely for the purpose and to the extent described in Schedule **3**.
	2. In performing the Services and its other obligations under this Agreement the Supplier will:
		1. comply with the Data Protection Laws;
		2. not cause UK Biobank to breach any obligation under the Data Protection Laws; and
		3. notify UK Biobank without undue delay if it identifies any areas of actual or potential non-compliance with the Data Protection Laws or this **clause 18**, without prejudice to its obligations to comply with, or to any rights or remedies which UK Biobank may have for breach of, the Data Protection Laws or this **clause 18**.
	3. The Supplier will not engage or use any third party for the Processing of Agreement Personal Data or permit any third party to Process Agreement Personal Data without the prior written consent of UK Biobank.
	4. If the Supplier appoints a Sub-Processor, the Supplier will ensure that, prior to the Processing taking place, there is a written contract in place between the Supplier and the Sub-Processor that specifies the Sub-Processor’s Processing activities and imposes on the Sub-Processor the same terms as those imposed on the Supplier in this clause **18**. The Supplier will procure that Sub-Processors will perform all obligations set out in this clause 18 and the Supplier will remain responsible and liable to UK Biobank for all acts and omissions of Sub-Processors as if they were its own.
	5. The Supplier will:
		1. Process the Agreement Personal Data only on documented instructions (including this Agreement) from UK Biobank (unless the Supplier or the relevant Sub-Processor is required to Process Agreement Personal Data to comply with United Kingdom, European Union (as it is made up from time to time) or European Union member state Applicable Laws, in which case the Supplier will notify UK Biobank of such legal requirement prior to such Processing unless such Applicable Laws prohibit notice to UK Biobank on public interest grounds);
		2. without prejudice to clause 18.5.1 ensure that Agreement Personal Data will only be used for the purpose and to the extent described in Schedule 3;
		3. without prejudice to clause 18.5.1, not without the prior written consent of UK Biobank:
			1. convert any Agreement Personal Data into anonymised, pseudonymised, depersonalised, aggregated or statistical data;
			2. use any Agreement Personal Data for “big data” analysis or purposes; or
			3. match or compare any Agreement Personal Data with or against any other Personal Data (whether the Supplier’s or any third party’s);
		4. ensure that any individual authorised to Process Agreement Personal Data accesses such Agreement Personal Data strictly on a need to know basis as necessary to perform their role in the performance of this Agreement, and:
			1. is subject to confidentiality obligations equivalent to those set out in clause 17 or is under an appropriate statutory obligation of confidentiality; and
			2. complies with this clause 18; and
			3. is appropriately reliable, qualified and trained in relation to their Processing of Agreement Personal Data;
		5. keep all Agreement Personal Data confidential in accordance with the provisions of clause 17 provided that in the event and to the extent only of any conflict between this clause 18 and clause 17 this clause 18 will prevail; and
		6. at the option of UK Biobank, securely delete or return to UK Biobank all Agreement Personal Data promptly after the end of the provision of Services relating to Processing or at any time upon request, and securely delete any remaining copies and promptly certify (via a director) when this exercise has been completed.
	6. The Supplier will not make an International Transfer without UK Biobank’s prior written consent. If UK Biobank gives its prior written consent to an International Transfer, before making that International Transfer the Supplier will demonstrate or implement, to UK Biobank’s satisfaction, appropriate safeguards for that International Transfer in accordance with Data Protection Laws and will ensure that enforceable rights and effective legal remedies for Data Subjects are available. Such appropriate safeguards may include:
		1. there is in force a European Commission decision that the country or territory to which the International Transfer is to be made ensures an adequate level of protection for Processing of Personal Data;
		2. the relevant Data Processor/Processor enters into an agreement with UK Biobank in the form of the standard contractual clauses approved by the European Commission decision for the transfer of personal data to processors established in third countries from time to time, completed with such information as UK Biobank may reasonably require; or
		3. the International Transfer is to the United States of America and the relevant Data Processor/Processor has and maintains for the duration of the Processing a current registration under the US-EU Privacy Shield.
3. If the appropriate safeguards demonstrated or implemented by the Supplier (or the relevant Data Processor/Processor) in accordance with this clause 18.6 are deemed at any time not to provide an adequate level of protection in relation to Agreement Personal Data, the Supplier will implement such alternative measures as may be required by UK Biobank to ensure that the relevant International Transfer and all resulting Processing are compliant with Data Protection Laws. The Supplier or the relevant Sub-Processor will not need to comply with the conditions set out in this clause 18.6 if it is required to make an International Transfer to comply with United Kingdom, European Union (as it is made up from time to time) or European Union member state Applicable Laws, in which case the Supplier will notify UK Biobank of such legal requirement prior to such International Transfer unless such Applicable Laws prohibit notice to UK Biobank on public interest grounds.
	1. The Supplier will:
		1. implement, and assist UK Biobank to implement, technical and organisational measures at a minimum to the standard set out in Schedule 1 UK Biobank Technical Specifications to ensure a level of security appropriate to the risk presented by Processing the Agreement Personal Data, in particular from a Data Security Incident;
		2. notify UK Biobank immediately if at any time the Supplier or a Sub-Processor is, or ought to be, aware of any reason why it is unable to comply with clause 18.7.1, without prejudice to its obligation to comply with, or to any rights or remedies which UK Biobank may have for breach of, clause 18.7.1;
		3. notify UK Biobank immediately after becoming aware of a reasonably suspected, “near miss” or actual Data Security Incident, including the nature of the Data Security Incident, the categories and approximate number of Data Subjects and Agreement Personal Data records concerned, the likely consequences of the Data Security Incident and any measure proposed to be taken to address the Data Security Incident and to mitigate its possible adverse effects. Where, and in so far as, it is not possible to provide all the relevant information at the same time, the information may be provided in phases without undue delay, but the Supplier (and Sub-Processors) may not delay notification under this clause 18.7.3 on the basis that an investigation is incomplete or ongoing;
		4. promptly (and in any event within 72 hours) notify UK Biobank of any request that it receives for exercise of a Data Subject’s rights under the Data Protection Laws or communication or complaint that it receives from a Data Subject or Supervisory Authority or other third party in connection with Agreement Personal Data;
		5. provide reasonable assistance to UK Biobank in responding to requests for exercising Data Subjects’ rights under the Data Protection Laws and communications and complaints from Data Subjects and Supervisory Authorities and other third parties in connection with Agreement Personal Data, including by appropriate technical and organisational measures, insofar as this is possible;
		6. not, without UK Biobank’s prior written consent, make or permit any announcement in respect of a Data Security Incident or respond to any request for exercise of a Data Subject’s rights under the Data Protection Laws or communication or complaint from a Data Subject or Supervisory Authority in connection with Agreement Personal Data;
		7. provide reasonable assistance to UK Biobank in:
			1. documenting any Data Security Incidents and reporting any Data Security Incidents to any Supervisory Authority and/or Data Subjects;
			2. taking measures to address Data Security Incidents, including, where appropriate, measures to mitigate their possible adverse effects; and
			3. conducting privacy impact assessments of any Processing operations and consulting with Supervisory Authorities, Data Subjects and their representatives accordingly.
	2. The Supplier will:
		1. make available to UK Biobank all information necessary to demonstrate compliance with the obligations set out in this clause 18; and
		2. allow for and contribute to audits, including inspections, conducted by UK Biobank or another auditor mandated by UK Biobank.
	3. The Supplier will prepare and securely maintain a record of all categories of Processing activities carried out on behalf of UK Biobank in relation to the Agreement Personal Data, including as a minimum: (i) its name and contact details and details of its Data Protection officer or other person with responsibility for data protection compliance; (ii) the categories of Processing it carries out on behalf of UK Biobank; (iii) International Transfers; (iv) a general description of the technical and organisational security measures referred to in clause 18.7.1; and (v) the same information in relation to any Sub-Processor, together with its name and contact details (together the **“Data Record”**). The Supplier will promptly upon request securely supply a copy of the Data Record to UK Biobank.
	4. The Supplier indemnifies UK Biobank for all loss, damages, liabilities, costs and expenses (including reasonable legal costs, fines and claims for damages) incurred by UK Biobank as a consequence of the Supplier’s breach of its obligations set out in this **clause 18**.
	5. Any breach of this clause 18 by the Supplier or any Sub-Processor will be a material breach of this Agreement irrespective of whether any financial loss or reputational damage arises, and irrespective of the level of any financial loss or deprivation of benefit arising, as a consequence of such breach.
4. ANTI-CORRUPTION
	1. The Supplier shall and shall procure that persons associated with it or other persons who are acting in connection with this Agreement shall:
		1. comply with all applicable laws, statutes, regulations, and binding codes relating to anti-bribery and anti-corruption including but not limited to the Bribery Act 2010;
		2. not engage in any activity, practice or conduct which would constitute an offence under sections 1, 2 or 6 of the Bribery Act 2010 if such activity, practice or conduct had been carried out in the UK;
		3. have and shall maintain in place as long as this Agreement is in force its own policies and procedures, including adequate anti-bribery and anti-corruption procedures, and shall enforce them where appropriate;
		4. promptly report to UK Biobank any request or demand for any undue financial or other advantage of any kind received in connection with the performance of this Agreement; and
		5. if requested, certify to UK Biobank in writing, its compliance with this **clause** **19.1.** The supplier shall provide such supporting evidence of compliance as UK Biobank may reasonably request.
	2. For the purposes of **clause 19.1**, the meaning of adequate procedures and whether a person is associated with another person shall be determined in accordance with section 7(2) of the Bribery Act 2010 (and any guidance issued under section 9 of that Act) and section 8 of that Act respectively. For the purposes of **clause 19.1** a person associated with a party includes any sub-contractor of that party.
5. ASSIGNMENT
	1. Each party will only be entitled to assign, transfer, charge, hold on trust for any person or deal in any other manner with any of its rights under this Agreement if it has obtained the prior written consent of the other party to do so (such consent not to be unreasonably withheld, delayed or made conditional).
6. NOTICES
	1. All notices or other communication under this Agreement to any party to this Agreement shall, subject to **clause 21.2**, be deemed to be duly given or made:
		1. when delivered (in the case of personal delivery or recorded delivery post);
		2. two (2) Business Days after posting (in the case of first class post);
		3. in the case of e-mail, at the time of sending;

in each case to the representative of such party addressed to it at the address specified below or to the following e-mail address:

|  |  |
| --- | --- |
| 1. The Supplier:
 | 1. The UK Biobank:
 |
| 1. [ADDRESS]
 | 1. [ADDRESS]
 |
| 1. [E-MAIL ADDRESS]
 | 1. [E-MAIL ADDRESS]
 |
| 1. For the attention of: [JOB TITLE]
 | 1. For the attention of: [JOB TITLE]
 |

* 1. Notices given by e-mail:
		1. which emanate (or reasonably appear to emanate) from a party’s representative shall be deemed to have been sent by such representative, even if the relevant e-mail in fact emanated from another member of staff or anyone else who may have had access to the e-mail systems of the representative of the party from whom the notice is sent; and
		2. shall only be validly given if they are actually received by the relevant representative and a reply or a read receipt shall (in the absence of evidence to the contrary) be deemed to confirm actual receipt.
	2. A notice or other communication otherwise deemed to be duly given or made under **clause 21** on a day that is not a Business Day or after 5:30pm in the place of receipt shall be deemed to be duly given or made on the next following Business Day in such place.
1. ENTIRE AGREEMENT
	1. This Agreement constitutes the entire agreement between the parties and supersedes any prior agreement or arrangement in respect of its subject matter.
	2. Neither party has entered into this Agreement in reliance upon, and it will have no remedy in respect of, any misrepresentation, representation or statement (whether made by the other party or any other person and whether made to the first party or any other person) which is not expressly set out in this Agreement;
	3. The only remedies available for any misrepresentation or breach of any representation or statement which was made prior to entry into this Agreement and which is expressly set out in this Agreement will be for breach of contract.
	4. Nothing in this clause 22.2 will be interpreted or construed as limiting or excluding the liability of any person for fraud or fraudulent misrepresentation.
2. NO WAIVER

A delay in exercising or failure to exercise a right or remedy under or in connection with this Agreement will not constitute a waiver of, or prevent or restrict future exercise of, that or any other right or remedy, nor will the single or partial exercise of a right or remedy prevent or restrict the further exercise of that or any other right or remedy. A waiver of any right, remedy, breach or default will only be valid if it is in writing and signed by the party giving it and only in the circumstances and for the purpose for which it was given and will not constitute a waiver of any other right, remedy, breach or default.

1. SEVERANCE

If any term of this Agreement is found by any court or body or authority of competent jurisdiction to be illegal, unlawful, void or unenforceable, such term will be deemed to be severed from this Agreement and this will not affect the remainder of this Agreement which will continue in full force and effect.

1. VARIATION

Save as otherwise expressly provided in this Agreement, no variation to this Agreement will be effective unless:

* 1. In the event of a change to the scope of Services it is agreed and executed in accordance with **clause 4**; and
	2. in the case of any other variation to the terms of this Agreement, it is in writing and signed by a duly authorised representative on behalf of each of the parties.
1. NO PARTNERSHIP OR AGENCY

Nothing in this Agreement and no action taken by the parties in connection with it will create a partnership or joint venture or relationship of employer and employee between the parties or, save as expressly provided otherwise in this Agreement, give either party authority to act as the agent of or in the name of or on behalf of the other party or to bind the other party or to hold itself out as being entitled to do so.

1. INDEPENDENT CONTRACTORS

Each party agrees that it is an independent contractor and is entering into this Agreement as principal and not as agent for or for the benefit of any other person.

1. RIGHTS OF THIRD PARTIES
	1. The parties may vary or rescind this Agreement without the consent of the Supplier’s employees, agents or sub-contractors.
	2. The parties do not intend that any term of this Agreement will be enforceable under the Contracts (Rights of Third Parties) Act 1999 by any person.
2. SET-OFF

Save as otherwise expressly provided in this Agreement or required by law, all payments to be made by the UK Biobank to the Supplier under this Agreement will be made in full and without any set-off or any deduction or withholding including on account of any counter-claim.

1. DISPUTE RESOLUTION
	1. In the event of any dispute arising in connection with this Agreement, the parties shall use reasonable endeavours to resolve such dispute within fifteen (15) Business Days. If the parties are unable to do so, either party may refer the dispute to mediation in accordance with the CEDR Model Mediation Procedure. If the matter is not referred to mediation or if the parties fail to resolve the dispute in this way, either party shall be entitled to pursue the dispute through the courts.
	2. Nothing in this **clause 30** shall prevent the parties from seeking from any court or competent jurisdiction an interim order restraining or compelling the other party from doing or not doing any act.
2. GOVERNING LAW AND JURISDICTION
	1. This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims), shall be governed by, and construed in all respects in accordance with, the laws of England and Wales.
	2. Subject to **clause 30**, the parties irrevocably submit to the exclusive jurisdiction of the courts of England and Wales.
3. **SIGNED BY** or on behalf of the parties on the date stated at the beginning of this Agreement.
4. SCHEDULE 1

Part A – SERVICES SPECIFICATION

*UK Biobank’s technical specifications to be included here, including the turnaround times for delivering Input Materials to Supplier and delivery timelines for the Deliverables. This will also include the QC metrics.*

Part B – DELIVERABLES

*This will be taken directly from the specification.*

1. SCHEDULE 2

Part A – BATCH CALL OFF

*This will follow from the relevant deliverables schedule.*

Part B – DELIVERY AND PAYMENT

*This will be linked directly to the relevant deliverables schedule.*

1. SCHEDULE 3
2. AGREEMENT PERSONAL DATA
3. Agreement Personal Data

|  |  |
| --- | --- |
| 1. **Subject matter of Processing**
 | As contemplated by the Agreement.  |
| 1. **Duration of Processing**
 | During the term of the Agreement. |
| 1. **Nature of Processing and Purpose of processing**
 | For the performance for the Services as defined in the Agreement. |
| 1. **Type of Personal Data**
 | * DNA
* Base sequence
* Health records
* Sequenced Data
* Input Materials
* Results Data
 |
| 1. **Categories of Data Subject**
 | UK Biobank Participants  |

Signed by )
**[NAME OF DIRECTOR/OFFICER]** )
for and on behalf of )
**[NAME OF SUPPLIER]** )

Signature of director/officer

Signed by )
**[NAME OF DIRECTOR/OFFICER]** )
for and on behalf of )
**UK BIOBANK LIMITED**

Signature of director/officer