

Data Contribution Agreement

COVER PAGE

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HDR:	Health Data Research UK, a charity incorporated and registered in England with company number 10887014 and registered charity number 1194431, whose registered office is at 215 Euston Road, London, England, NW1 2BE. E-mail: [Note to HDR: add e-mail address] (for notices) [Principal point of contact: [Note to HDR: add if applicable]]
Data Contributor:	[insert name and address details of Data Contributor] E-mail: [insert e-mail address] (for notices) Principal point of contact: [insert name, position and e-mail address]
Commencement Date:	[insert date on which the obligations in this Agreement are to start]
Term:	[insert term of this Agreement]
[Trusted Research Environment] OR [Databank][delete as applicable]:	[insert details of repository to which Data will be transferred, e.g., Trusted Research Environment (TRE), and/or Databank]
Data Delivery Date:	Each of [insert event(s) on which the Data is to be transferred from Data Contributor to the Data Repository, e.g., Commencement Date and the last day of each calendar month thereafter]
Data:	[include details of the Data collected by, or on behalf of, Data Contributor, cross-referencing to the completed Due Diligence Questionnaire at Appendix I]

Introduction

HDR is the convener of the International COVID-19 Data Research Alliance (ICODA), which seeks to build a research partnership to support a rapid response to the COVID-19 pandemic, and a long-term alliance for making data accessible to health researchers and scientists globally.

Data Contributor wishes to submit Data in a De-personalised form to a Data Repository for the purpose of making such Data available to life science, philanthropic and research organisations to harness the power of health data to respond to COVID-19, and any other future pandemic, significant outbreak of disease or

other global health initiative or health challenge, including research into prevention, transmission, symptoms, treatments and vaccinations.

This Agreement sets out the terms applicable to a transfer of Data from Data Contributor to a Data Repository, on the basis of direct obligations to HDR, which is coordinating such transfers.

Signed by duly authorised representatives of the Parties:

[Data Contributor]

HEALTH DATA RESEARCH UK

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

AGREED TERMS

1. DEFINITIONS AND INTERPRETATION

The following definitions and rules of interpretation apply in this Agreement.

a. Definitions:

“**Agreement**” means this agreement, including the cover page;

“**Applicable Law**” means all laws, regulations, regulatory requirements and authorisations, decisions and guidance and codes of regulatory authorities or other requirements applicable in the context of this Agreement in any jurisdiction;

“**Approved Researcher**” means any researcher authorised by HDR to access Data;

“**Attribution Policy**” means the then-current attribution policy of HDR as available from time to time at <https://www.hdruk.ac.uk/wp-content/uploads/2019/07/QPC33-Attribution-policy.pdf>;

“**Commencement Date**” has the meaning provided on the cover page to this Agreement;

“**Data**” means the dataset(s), collected by, or on behalf of, Data Contributor that are processed under this Agreement, as specified on the cover page to this Agreement;

“**Data Contributor**” has the meaning provided on the cover page to this Agreement;

“**Data Delivery Date**” has the meaning provided on the cover page to this Agreement;

“**Data Inventory**” has the meaning given in clause ff;

“**Data Protection Law**” means any and all Applicable Law with respect to data protection and privacy, including the GDPR, the UK GDPR (as defined in the UK Data Protection Act 2018) and/or the UK Data Protection Act 2018, as applicable to either Party and/or the activities under this Agreement;

“**Data Repository**” means a Databank and/or a Trusted Research Environment (TRE);

“**Databank**” means, if specified, the databank identified on the cover page to this Agreement;

“**De-personalisation**” means the Processing of personal data in such a manner that data can no longer be attributed to a specific individual without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to prevent reattribution. Without limiting the foregoing, “De-personalisation” shall include the removal of the identifiers listed in Appendix 2. “De-personalise” and “De-personalised” shall be interpreted accordingly.

“**Due Diligence Questionnaire**” means the due diligence questionnaire in relation to Data completed by Data Contributor prior to entering into this Agreement, attached at Appendix 1 to this agreement;

“**GDPR**” means the General Data Protection Regulation ((EU) 2016/679);

“**HDR**” has the meaning provided on the cover page to this Agreement;

“**HDR Purposes**” has the meaning given in clause w;

“**Intellectual Property Rights**” means any and all patents, utility models, rights to inventions, copyright and related rights, moral rights, trade marks and service marks, business names and domain names, database rights, rights to use, and protect the confidentiality of, confidential information (including know-how and trade secrets), and all other intellectual property rights, in each case whether registered or unregistered and including all applications and rights to apply for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world;

“**Publication**” means any abstract, report, external communication, website, presentation or peer-reviewed scientific publication that contains information, data or Research Results that are directly or indirectly related to the Data, and “**Publish**” shall be construed accordingly;

“**Research Results**” means the results of research performed using the Data (but excluding the Data itself);

“**Term**” means the term of this Agreement specified on the cover page to this Agreement;

“**Third Party**” means any entity or person other than the Parties;

“**Trusted Research Environment**” or “**TRE**” means, if specified, the trusted research environment identified on the cover page to this Agreement, within which accredited researchers are able to analyse Data to which they have been provided access, for one or more defined and approved research purpose(s); and

“**Website**” means the website available at <https://icoda-research.org/>.

- b. The terms “**Controller**”, “**Data Subject**”, “**Personal Data**”, “**Personal Data Breach**”, “**Processing**” and “**Processor**” shall be interpreted in accordance with applicable Data Protection Law in the relevant jurisdiction.
- c. Clause and Appendix headings shall not affect the interpretation of this Agreement.
- d. The Appendices form part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to this Agreement includes the Appendices.
- e. Unless the context otherwise requires, words in the singular shall include the plural and in the plural shall include the singular.

- f. A reference to legislation or a legislative provision shall include all subordinate legislation made from time to time under that legislation or legislative provision.
- g. References to clauses are to the clauses of this Agreement.
- h. Any words following the terms “including”, “include”, “in particular” or “for example” or any similar expression shall be construed as illustrative and shall not limit the sense of the words, description, definition, phrase or term preceding those terms.
- i. In the case of any conflict between any provision contained in the body of this Agreement and any provision contained in the Appendix, the provision in the body of this Agreement shall take precedence to the extent of the conflict.
- j. A reference to “writing” or “written” includes e-mail.

2. DATA TRANSFER

- k. Data Contributor shall transfer the Data to a Data Repository, on or around each Data Delivery Date and, unless otherwise expressly stated on the cover page to this Agreement, thereafter on or around the first business day of each calendar month during the Term.
- l. Data Contributor shall not transfer any of the Data to a Data Repository under this Agreement that is not De-personalised.

3. RIGHT OF VERIFICATION

- m. Without limiting any obligation on Data Contributor under this Agreement, HDR shall have the right (itself and/or using a contractor) to verify that any of the Data provided by Data Contributor to a Data Repository is in compliance with the terms of this Agreement, including ensuring that any such Data is De-personalised. Where such verification reveals non-compliance by Data Contributor, HDR may, at its sole discretion, either (i) require Data Contributor to promptly rectify such non-compliance to a standard acceptable to HDR, or (ii) terminate this Agreement under clause oo.

4. DATA PROTECTION

- n. To the extent that the Data transferred from Data Contributor under this Agreement contains Personal Data, then (i) each Party shall be considered a Controller for the purposes of Data Protection Law in respect of such Personal Data, and (ii) the terms of this clause 4 shall apply.
- o. Except to the extent set out otherwise in this clause 4, each Party shall be responsible for complying with Data Protection Law when performing its respective obligations and exercising its rights under this Agreement.

- p. In the event of a Personal Data Breach or the receipt of any correspondence from a competent regulatory authority or other public authority relating to Personal Data processed under this Agreement, the affected/receiving Party shall notify the other Party without undue delay and in any event within forty eight (48) hours after becoming aware of the same. In the event of a Personal Data Breach each Party shall cooperate and assist the other in promptly investigating, mitigating and remediating any such Personal Data Breach and/or responding to any such complaint or other correspondence from a regulator or other public authority. The Parties shall, following consultation with each other, comply with any applicable obligations under Data Protection Law in relation to any such Personal Data Breach or correspondence from a competent regulatory authority or other public authority, including (where applicable) notification of a Personal Data Breach to any competent regulatory authorities, and/or Data Subjects.
- q. Data Contributor shall be solely responsible for compliance with all obligations under Data Protection Law relating to De-personalisation and transfer of Personal Data, including (i) ensuring it has and maintains a valid legal basis (ii) providing all required information to Data Subjects, (iii) handling requests received from Data Subjects wishing to exercise their rights under Data Protection Law, and (iv) ensuring that any international transfer of Personal Data is conducted in compliance with Data Protection Law.
- r. As between HDR and Data Contributor, HDR shall be solely responsible for (i) ensuring the suitability of the Trusted Research Environment for the processing of any Personal Data contained in the Data and (ii) entering into appropriate agreement(s) with the operator(s) of such Trusted Research Environment(s).
- s. Each Party agrees that, within a reasonable period of the other Party's request, it shall negotiate in good faith with the other Party and seek to agree promptly any such further documents as in each Party's reasonable opinion are required to comply with or take account of (i) any amendment, re-enactment or extension of Data Protection Law and (ii) any relevant guidance issued by a regulatory authority of competent jurisdiction with respect to the activities regarding the Data under this Agreement.

5. REPRESENTATIONS AND WARRANTIES

- t. Each of HDR and Data Contributor represents and warrants that it has the capacity to enter into this Agreement.
- u. Except as specifically and clearly disclosed in the Due Diligence Questionnaire, Data Contributor represents, warrants, and where applicable undertakes to HDR, in relation to all Data, that:

the Data has been collected and transferred in compliance with all Applicable Law (including in those jurisdictions in which the Data was collected or from which the Data otherwise originates), and without limitation, Data Contributor has and shall maintain an appropriate lawful basis (including any required licences, permits and consents) under Applicable Law for the collection, processing, storage and transfer of the Data under clause k;

the collection, transfer and use of the Data as contemplated by this Agreement is and shall be within the scope of regulatory or ethics approvals existing at the time thereof, including the transfer of the Data under clause k;

there are no restrictions applicable to the use of the Data other than those specified in the Due Diligence Questionnaire (if any);

no information or statement provided by Data Contributor in the Due Diligence Questionnaire contains any false, misleading or materially inaccurate statement or fact, and Data Contributor has not omitted any material information or fact necessary to make the statements contained therein, in light of the circumstances in which they are made, misleading, materially incomplete or materially inaccurate;

it has appropriate technical and organisational security measures in place to ensure the integrity of the Data, including with respect to the transfer of the Data under clause k; and

the collection, transfer, use and other processing of the Data as contemplated by this Agreement has not infringed or misused, and shall not infringe or misuse, the Intellectual Property Rights or other rights of any Third Party.

6. HDR OBLIGATIONS

v. HDR shall:

comply with all obligations to which it is subject under Applicable Law; and

take all reasonable steps to ensure that Approved Researchers do not attempt to use the Data to re-identify or contact any individual (living or deceased), associated with the Data.

w. HDR may only access and use the Data for (i) any verification purposes as provided for in clause m, (ii) support and maintenance of a Data Repository and the Data within it, and/or (iii) to perform its obligations or exercise its rights under this Agreement (the purposes in paragraphs (i) to (iii) collectively, the “**HDR Purposes**”).

x. HDR shall not, during the Term or at any time thereafter, disclose the Data to any persons, except that HDR may disclose, or authorise the disclosure of, the Data:

to its officers, employees and other personnel, and to contractors such as those who provide a Data Repository and associated services to HDR, in each case who are under appropriate obligations of confidentiality and need to access the Data for the HDR Purposes;

to Approved Researchers, provided that (i) HDR and the relevant Approved Researcher have signed a data access agreement, and (ii) the research purpose(s) of the relevant Approved Researcher has/have been authorised in advance through the appropriate HDR processes; and/or

as required by an order of any court of competent jurisdiction or any regulatory, judicial, governmental or similar body of competent jurisdiction or as otherwise required by applicable law, provided that

prior to any such disclosure, HDR shall, to the extent permitted by law, use reasonable endeavours to give notice to Data Contributor of this disclosure.

7. DATA SECURITY

- y. HDR shall implement appropriate technical and organisational security measures, having regard to the state of the art, to protect the Data held on behalf of HDR under this Agreement from unauthorised access and/or disclosure. Data Contributor acknowledges and agrees that these obligations may be fulfilled through a separate agreement with a Processor.

8. INTELLECTUAL PROPERTY

- z. To the extent that Data Contributor owns or controls Intellectual Property Rights in the Data, nothing in this Agreement transfers, or is intended to transfer, to HDR such Intellectual Property Rights to HDR.
- aa. HDR acknowledges that it shall have no rights in or to the Data other than the right to use it in accordance with the express terms of this Agreement.
- bb. For the avoidance of doubt, nothing in this Agreement shall prevent Data Contributor from being able to use the Data for any purpose, including publication of the Data or distribution of the Data to Third Parties for research purposes.
- cc. Data Contributor acknowledges and agrees that it shall have no and does not acquire any Intellectual Property Rights or other rights in any Research Results.
- dd. Data Contributor hereby grants HDR a non-exclusive, worldwide, sub-licensable (through multiple tiers), royalty-free, fully paid-up licence to use or otherwise exploit howsoever the Data for the sole purposes of performing (or having performed) its obligations and exercising its rights under this Agreement
- ee. Data Contributor hereby grants HDR a non-exclusive licence to use (i) Data Contributor's logo(s) and trade mark(s) for the purposes of publishing and maintaining the Data Inventory under clause ff, and (ii) Data Contributor's name in Publications for the purposes of giving Data Contributor due attribution in accordance with the Attribution Policy.

9. PUBLICATIONS

- ff. Data Contributor acknowledges that HDR:

maintains a publicly-available aggregated listing of the Data made available through Data Repositories ("**Data Inventory**"); and

may publish and otherwise disclose Data Contributor's name and limited summary data concerning the type, volume and source of the Data, within the Data Inventory and otherwise.

- gg. HDR may publish copies of any written reports received from Approved Researchers describing their use of the Data and / or any benefits derived therefrom.
- hh. Data Contributor acknowledges that Approved Researchers may Publish Research Results without the consent of Data Contributor.

10. LIABILITY

- ii. Nothing in this Agreement shall have the effect of excluding or limiting any liability for (i) death or personal injury resulting from negligence, (ii) fraud or fraudulent misrepresentation, or (iii) any other liability that cannot be excluded or limited under Applicable Law.
- jj. Subject to clause ii, neither Party shall have any liability to the other, whether arising in contract, tort (including negligence) or otherwise howsoever, for:
 - loss of profits, sales, business or revenue; or
 - any special, indirect, consequential or pure economic loss, costs damages, charges and expenses, whether or not reasonably foreseeable and even if a Party had been advised of the possibility of the other Party incurring that loss or type of loss.
- kk. Data Contributor shall indemnify HDR against all liabilities, costs, expenses, damages or losses (including any direct or indirect consequential losses, loss of profit, loss of reputation and all interest, penalties, and legal and other costs and expenses) suffered or incurred, to the extent arising out of or in connection with any action, claim or investigation brought by or on behalf of a Third Party against HDR resulting from or arising out of Data Contributor's breach of clause 1, 4 or 0.
- ll. The maximum aggregate liability of Data Contributor under the indemnity in Clause kk shall not exceed one million (1,000,000) pounds sterling.
- mm. Subject to clauses ii to ll (inclusive), above, the maximum liability of each Party to the other Party arising out of or in connection with this Agreement, whether in contract, tort (including negligence) or otherwise, shall not exceed one thousand (1,000) pounds sterling.

11. TERM AND TERMINATION

- nn. This Agreement shall commence on the Commencement Date and shall terminate upon expiry of the Term, unless terminated earlier in accordance with this clause 11.

- oo. Either Party may terminate this Agreement at any time without cause by giving no greater than sixty (60) days' written notice to the other Party, such notice to take effect as specified therein.
- pp. Following termination of this Agreement, at the request of Data Contributor HDR shall procure that all Data is deleted from the TRE within a reasonable period of the request, save for any back-up copies of the Data made by, or on behalf, of HDR, including as required under Applicable Law (provided that HDR shall not make any further use of such back-up copies). Data Contributor acknowledges that HDR is under no obligation to retain, or have retained, any copy of the Data unless as otherwise required under Applicable Law.
- qq. The termination of this Agreement shall not prejudice or affect any accrued rights or liabilities of any of the Parties.
- rr. Upon termination of this Agreement for any reason, the provisions of clauses 1 (Definitions and Interpretation), 2 (Data Transfer), 4 (Data Protection), w (HDR Obligations), 7 (Security), 8 (Intellectual Property), 9 (Publications), 10 (Liability), 11 (Term and Termination), 12 (Further Assurance), 13 (Notices), 14 (General) shall remain in force.

12. FURTHER ASSURANCE

- ss. Each Party shall, and shall use all reasonable endeavours to procure that any necessary Third Party shall promptly execute and deliver such documents and perform such acts as may reasonably be required for the purpose of giving full effect to its obligations under this Agreement.

13. NOTICES

- tt. Any notice given to a Party under or in connection with this Agreement shall be in writing and sent to the other Party's address or by e-mail to the relevant e-mail address, in each case as indicated on the cover sheet.

14. GENERAL

- uu. This Agreement is drafted in the English language. If this Agreement is translated into any other language, the English language version shall prevail.
- vv. Any notice given under or in connection with this Agreement shall be in English. All other documents provided under or in connection with this Agreement shall be in English or accompanied by a certified English translation.
- ww. HDR may assign, transfer, mortgage, charge, subcontract, declare a trust over or deal in any other manner with any of its rights and obligations under this Agreement. Data Contributor may not assign, transfer, mortgage, charge, subcontract, declare a trust over or deal in any other manner with any of its rights and obligations under this Agreement, other than with the prior written consent of HDR.

- xx. No person other than a Party to this Agreement shall have any rights to enforce any term of this Agreement.
- yy. No variation of this Agreement shall be effective unless it is in writing and signed by the Parties (or their authorised representatives).
- zz. No failure or delay by a Party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.
- aaa. If any court or competent authority finds that any provision of this Agreement (or part of any provision) is invalid, illegal, or unenforceable, that provision or part-provision shall, to the extent required, be deemed to be deleted, and the validity and enforceability of the other provisions of this Agreement shall not be affected.
- bbb. Nothing in this Agreement is intended to, or shall be deemed to, establish any partnership or joint venture between any of the Parties, constitute a Party the agent of the other Party, or authorise a Party to make or enter into any commitments for or on behalf of the other Party.
- ccc. This Agreement constitutes the entire agreement between the Parties and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter.
- ddd. This Agreement 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 law of England and Wales.
- eee. Each Party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims), arising out of or in connection with this Agreement or its subject matter or formation.

Appendix 1 – Completed Due Diligence Questionnaire

[to add]

Appendix 2 - De-personalised Data: identifiers that must be removed

(1) Names

[(2) All geographic subdivisions smaller than a region, state, district or province, including street address, city, town, village, county, and geocodes (e.g. post or ZIP) except for the initial digits of a geocode (no more than half) if :

(a) The geographic unit formed by combining all geocodes codes with the same initial digits contains more than 20,000 people; and

(b) The initial three digits of a geocode for all such geographic units containing 20,000 or fewer people is changed to 000

(3) All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

(4) Telephone numbers

(5) Vehicle identifiers and serial numbers, including vehicle registration numbers

(6) Fax numbers

(7) Device identifiers and serial numbers

(8) E-mail addresses

(9) Web Universal Resource Locators (URLs)

(10) Social security numbers

(11) Internet Protocol (IP) addresses

(12) Medical record numbers

(13) Biometric identifiers, including finger and voice prints

(14) Health plan beneficiary numbers

(15) Full-face photographs and any comparable images

(16) Account numbers

[(17) Any other unique identifying number, characteristic, or code; and

(18) Certificate/licence numbers