

**WHO TB-IPD PLATFORM  
DATA SHARING AGREEMENT**

This Data Sharing Agreement (**DSA**) is made on **[INSERT DATE]** (“**Effective Date**”).

This Agreement is written in English and other languages, the different versions being equally authentic. Should there be any discrepancies between the versions of this Agreement, the English version shall prevail.

**BETWEEN:**

(1) **UNIVERSITY COLLEGE LONDON**, a body corporate established by Royal Charter with company number RC000631 and whose principal place of business is Gower Street, London WC1E 6BT (**Data Curator**);

AND

(2) **[INSERT]** whose principal place of business is at **[INSERT]** (**Data Contributor**).

**BACKGROUND**

- A. The Data Curator has entered into an arrangement with the WHO under which the Data Curator has agreed to act as the data curator of a global anonymised individual patient data platform for tuberculosis treatment (**TB-IPD Platform**) for and on behalf of the WHO. The Data Curator’s role includes setting up, hosting and managing the TB-IPD Platform for and on behalf of the WHO. The Data Curator will also be responsible for checking that no Personal Data has been included within the data submitted to it by the Data Contributor. If Personal Data is found, the Data Curator will either: (i) securely delete or return the data to the Data Contributor; or (ii) take steps to ensure that the data is effectively anonymised prior to including the data in the TB-IPD Platform.
- B. The TB-IPD Platform will pool individual patient data which is effectively anonymised. The term ‘effectively anonymised’ refers to data which: (i) does not relate to an identified or identifiable individual; or (ii) has been rendered anonymous in such a way that individuals are not (or are no longer) identifiable. Data held by the Data Curator within the TB-IPD shall also be stored securely so that the risk of indirect re-identification is very low. The patient data to be provided to the Data Curator will come from a range of relevant global resources, including researchers, local and national databases relating to TB and development and public health research and surveillance projects.
- C. The data held in the TB-IPD Platform will be made available to Data Analysts appointed by the WHO for the primary purpose of informing future WHO TB treatment guidelines without requiring the approval of the Data Access Committee. In addition, the data held within the TB-IPD Platform will be made available for analysis by individuals and organisations approved by the Data Access Committee. The Steering Committee will have responsibility for oversight and coordination of the TB-IPD.
- D. The Data Contributor holds Data that it wishes to provide to the Data Curator for assimilation within the TB-IPD Platform.
- E. This DSA sets out the terms and conditions upon which the Data Contributor will provide, and the Data Curator will receive, Data for assimilation within the TB-IPD Platform.

**Signed for and on behalf of the Data Curator**

Signature	
Name of Authorised Signatory	
Date	

**Signed for and on behalf of the Data Contributor**

Signature	
Name of Authorised Signatory	
Date	

## IT IS AGREED:

### 1. DEFINITIONS AND INTERPRETATION

In this DSA (including the Background):

#### 1.1. Definitions

1.1.1. the following words and expressions have the following meanings:

<b>Business Day</b>	a day other than a Saturday or Sunday or a bank holiday or public holiday in England and Wales;
<b>Confidential Information</b>	any information or materials (whether in writing, electronic form, oral or otherwise) concerning the affairs of one Party that the other Party obtains or receives as a result of the discussions leading up to or the entering into or the performance of this DSA that is confidential in nature or is marked or identified as confidential at the time of disclosure. Data provided by the Data Contributor to the Data Curator for inclusion within the TB-IPD Platform shall not constitute Confidential Information;
<b>Controller</b>	means a person which, alone or jointly with others, determines the purposes and means of the Processing of Personal Data;
<b>Data</b>	effectively anonymised individual patient data intended to be submitted to the TB-IPD Platform derived from studies of patients with TB;
<b>Data Access Agreement</b>	a data access agreement to be entered into by Data Analysts before accessing Relevant Data;
<b>Data Access Committee</b>	the committee with responsibility for reviewing and accepting or rejecting applications for data access. It will be comprised of a combination of Data Contributors, the WHO and UCL, and other stakeholders as deemed appropriate;
<b>Data Analyst</b>	an individual or entity (approved by the Data Access Committee except where the WHO appoints a Data Analyst directly to access and use the Relevant Data for the purpose of informing future WHO TB treatment guidelines) who has permission to access and use the Relevant Data for the Purpose in accordance with the terms of the Data Access Agreement;
<b>Data Protection Laws</b>	means all laws and regulations relating to the Processing of Personal Data as the same may be in force from time to time;
<b>Data Subject</b>	means the individual to which the Personal Data relates;
<b>Derived Data</b>	any data derived from use or analysis of the Relevant Data in the course of the research performed by Data Analysts and any collections of data, datasets and databases housing the foregoing and any database rights in or relating thereto;

<b>Enriched Data</b>	any new or additional data that is collected by Data Analysts for the purpose of their research and which incorporates the Relevant Data (or any part thereof) and any collections of data, datasets and databases housing the foregoing and any database rights in or relating thereto;
<b>Intellectual Property Rights</b>	means any and all patents, copyright, registered designs, design rights, trade marks, database rights, regulatory rights in data exclusivity and market exclusivity, know how and any other intellectual property rights anywhere in the world in each case whether registered or unregistered, including any and all applications for such rights and the right to make such applications 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;
<b>Parties</b>	the Data Curator and the Data Contributor;
<b>Personal Data</b>	any information relating to an identified or identifiable living individual;
<b>Personal Data Breach</b>	means the accidental, unauthorised or unlawful destruction, loss, damage, alteration, use, disclosure or acquisition of, or access to, Personal Data;
<b>Processing</b>	means any operation or set of operations which is performed on Personal Data or on sets of Personal Data, whether or not by automated means, and Process, Processes and Processed shall be construed accordingly;
<b>Processor</b>	means a person which Processes Personal Data on behalf of a Controller;
<b>Purpose</b>	(a) to inform, develop, review and/or update: (i) public health and/or clinical guidance in connection with TB treatment which is or may be published by WHO on its website(s) and/or in its printed, electronic or other publications, including the <i>WHO consolidated guidelines on TB treatment</i> ; (ii) WHO's internal research, scientific or public health prioritisation purposes, and/or (iii) any activities or materials relating to any of the foregoing; and/or  (b) for research and scientific purposes by (i) educational or research institutions, country programmes and/or non-governmental institutions, and/or (ii) other organisations authorised by the Data Access Committee from time to time;
<b>Relevant Data</b>	Data that the Data Contributor provides to the Data Curator for inclusion within the TB-IPD Platform, as further described in Schedule 2;
<b>Research</b>	the research performed by a Data Analyst;
<b>Research Results</b>	the results of the Research using the Relevant Data, including all Intellectual Property Rights, Derived Data and Enriched Data that are generated, or otherwise collected, arising, identified or first reduced to practice, in the course of research (but excluding the Relevant Data itself);

<b>Steering Committee</b>	the committee with responsibility for oversight and coordination of the TB-IPD Platform;
<b>TB</b>	tuberculosis;
<b>TB-IPD Platform</b>	has the meaning given to it in paragraph A of the Background section of this DSA; and
<b>WHO</b>	World Health Organization;

## 1.2. Interpretation

- 1.2.1. words importing the singular shall include the plural and vice versa, words importing a gender shall include all genders and words importing persons shall include bodies corporate, unincorporated associations and partnerships;
- 1.2.2. references to Clauses and Schedules are references to clauses and schedules of this DSA;
- 1.2.3. the Schedules form part of this DSA and shall have full force and effect as if expressly set out in the body of this DSA and any reference to this DSA shall include the Schedules;
- 1.2.4. Clause and Schedule headings are included for convenience only and shall not affect the interpretation of this DSA;
- 1.2.5. any reference to persons includes natural persons, firms, partnerships, companies, corporations, associations, organisations, governments, states, governmental or state agencies, foundations and trusts (in each case whether or not having separate legal personality and irrespective of the jurisdiction in or under the law of which it was incorporated or exists);
- 1.2.6. a reference to a statute or statutory provision is a reference to that statute or statutory provision and to all orders, regulations, instruments or other subordinate legislation made under the relevant statute;
- 1.2.7. any reference to a statute, statutory provision, subordinate legislation, code or guideline (legislation) is a reference to such legislation as amended and in force from time to time and to any legislation which re-enacts or consolidates (with or without modification) any such legislation; and
- 1.2.8. any phrase introduced by the terms including, include, in particular, for example or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms.

## 2. PROVISION OF DATA

- 2.1. As of the Effective Date , the Data Contributor holds Data that it wishes to provide to the Data Curator for assimilation within the TB-IPD Platform
- 2.2. The Data Curator shall send the Data Contributor instructions on how to format the Data for assimilation within the TB-IPD Platform.
- 2.3. The Data Contributor shall be responsible for ensuring that the Data that it provides to the Data Curator:
  - (a) is provided to the Data Curator in the required format, as per the instructions provided pursuant to Clause 2.2;
  - (b) has been effectively anonymised using at least the measures set out at Schedule 3;
  - (c) does not contain any Personal Data;
  - (d) is transferred to the Data Curator via encrypted secure file transfer; and

- (e) may lawfully be assimilated within the TB-IPD Platform, used and shared on the basis contemplated by this DSA without breaching the rights of any third party.

If the Data Contributor does not have sufficient technical capacity to provide the Data to the Data Curator in the required format then the Data Curator may, at its discretion and where relevant resources are available, assist the Data Contributor with providing the Data to the Data Curator in the required format.

- 2.4. On receipt of Relevant Data, the Data Curator shall check the Relevant Data for compliance with the relevant provisions of this DSA, including the requirements set out at Clause 2.3, and then assimilate the Relevant Data within the TB-IPD Platform. If the Data Curator finds at any time that the Relevant Data does not comply with the provisions of this DSA then the Data Curator shall be entitled:
  - (a) not to assimilate the Relevant Data within the TB-IPD Platform; or
  - (b) where the Relevant Data has already been included within the TB-IPD Platform, to remove the Relevant Data from the TB-IPD Platform.

### 3. DATA PROTECTION

- 3.1. The Parties acknowledge that the TB-IPD Platform is intended to contain only effectively anonymised data and that the Data must not contain any Personal Data.
- 3.2. Without prejudice to Clause 3.1, the Parties agree that upon receipt of the Relevant Data, the Data Curator will review the Relevant Data to check whether it contains any Personal Data. If the Relevant Data contains any Personal Data, the Data Curator will either: (i) securely delete or return the data to the Data Contributor; or (ii) take steps to ensure that the Relevant Data is effectively anonymised prior to including the Relevant Data in the TB-IPD Platform.
- 3.3. The parties acknowledge and agree that:
  - (a) in the course of fulfilling its obligations under Clause 3.2, the Data Curator may Process Personal Data contained within the Relevant Data for and on behalf of the Data Contributor;
  - (b) where the Data Curator Processes Personal Data in order to fulfil its obligations under Clause 3.2, the Data Contributor shall be the Controller and the Data Curator shall be the Data Contributor's Processor in respect of all such Personal Data; and
  - (c) to the extent permitted by law, the Data Curator shall not be liable to the Data Contributor in respect of any Processing carried out by the Data Curator in order to achieve the effective anonymisation of the Relevant Data.
- 3.4. Where, in the course of fulfilling its obligations under Clause 3.2, the Data Curator Processes Personal Data on behalf of the Data Contributor as the Data Contributor's Processor, the description of the Processing activities shall be as set out in Schedule 1.
- 3.5. Where, in the course of fulfilling its obligations under Clause 3.2, the Data Curator Processes Personal Data on behalf of the Data Contributor as the Data Contributor's Processor, the Data Curator shall:
  - (a) Process the Personal Data only:
    - (i) on the written instructions of the Data Contributor and to the extent reasonably necessary for the performance by the Data Curator of its obligations under this Agreement. The Data Curator shall immediately inform the Data Contributor if, in its opinion, Processing the Personal Data in accordance with a written instruction received from the Data Contributor or in the performance of its obligations under this Agreement infringes Data Protection Laws to which either the Data Contributor or the Data Curator (in its capacity as a Processor) is subject; or
    - (ii) as otherwise required by the law of the United Kingdom or a part of the United Kingdom to which the Data Curator is subject, in which case the Data Curator shall

inform the Data Contributor of that legal requirement before Processing the Personal Data (unless that law, on important grounds of public interest, prohibits the Data Curator from informing the Data Contributor);

- (b) not disclose the Personal Data to any person except as required or permitted by this Agreement or with the Data Contributor's prior written consent;
- (c) without prejudice to the duties of confidence (contractual or otherwise) owed by the Data Curator to the Data Contributor, ensure that all persons authorised by the Data Curator to Process the Personal Data:
  - (i) Process the Personal Data in accordance with provisions of this Clause 3; and
  - (ii) are under an appropriate contractual or other legal obligation to keep the Personal Data confidential;
- (d) notwithstanding any other provision of this Agreement, and taking into account the state of the art, the nature, scope, context and purposes of the Processing and the risks to Data Subjects, implement appropriate technical and organisational measures to ensure the security of the Personal Data and prevent Personal Data Breaches;
- (e) not engage another Processor to Process the Personal Data on behalf of the Data Contributor (Sub-processor) except with the Data Contributor's prior written consent. The Data Curator shall, prior to engaging a Sub-processor, enter into a written contract with the Sub-processor that imposes on the Sub-processor obligations that are the same as, or more onerous than, the obligations imposed on the Data Curator under this Clause 3. The Data Curator shall remain fully liable and responsible for all acts and omissions of its Sub-processors and the acts and omissions of those employed or engaged by its Sub-processors as if they were its own. An obligation on the Data Curator to do, or to refrain from doing, any act or thing shall include an obligation upon the Data Curator to procure that its employees, staff, agents and its Sub-processors' employees, staff and agents also do, or refrain from doing, such act or thing;
- (f) not transfer or Process the Personal Data outside the United Kingdom, nor disclose the Personal Data to any party located outside the United Kingdom, except with the Data Contributor's prior written consent. Where such consent is given by the Data Contributor, the Data Curator shall take such actions and enter into such written agreements as the Data Contributor may require in order to help ensure that such transfer, disclosure or Processing complies with the Data Protection Laws to which the Data Contributor is subject;
- (g) provide such assistance and co-operation as the Data Contributor may require from time to time in relation to the Personal Data to help the Data Contributor comply with its obligations under the Data Protection Laws to which it is subject, including (without limitation) its obligations in relation to:
  - (i) keeping Personal Data secure;
  - (ii) dealing with Personal Data Breaches;
  - (iii) carrying out data protection impact assessments; and
  - (iv) dealing with requests from Data Subjects to exercise their legal rights in relation to their Personal Data.

This shall include the Data Curator entering into such other written agreements as may be required by the Data Contributor from time to time to enable the Data Contributor to comply with the Data Protection Laws to which the Data Contributor is subject;

- (h) notify the Data Contributor without undue delay after, and in any event within 24 hours of, becoming aware of a Personal Data Breach in respect of the Personal Data;

- (i) at the Data Contributor's option, permanently and securely delete or return to the Data Contributor all the Personal Data promptly on termination of this Agreement, and delete any existing copies of the Personal Data save to the extent that the Data Curator is required to retain copies of the Personal Data by the law of the United Kingdom or a part of the United Kingdom to which the Data Curator is subject; and
- (j) make available to the Data Contributor all information necessary to demonstrate its compliance with its obligations under this Clause 3.

3.6. The Data Contributor reserves the right to audit the Data Curator's compliance with its obligations under this Clause 3, or to appoint a third party to carry out such audits.

#### 4. **DATA CURATOR RESPONSIBILITIES AND WARRANTIES**

4.1. The Data Curator warrants and undertakes that it shall:

- (a) host and maintain the TB-IPD Platform and the Relevant Data held within it;
- (b) inform the Data Contributor of any internal policies that may apply to the receipt and sharing of Relevant Data;
- (c) take appropriate measures to help ensure the security, integrity and confidentiality of Relevant Data held within the TB-IPD Platform, including by holding the Relevant Data in a secure data storage environment with restricted access which is limited to specific named individuals;
- (d) not attempt to re-identify Data Subjects;
- (e) only use the Relevant Data as reasonably necessary in connection with the Purpose and the operation of the TB-IPD Platform, which shall include facilitating remote access to the Relevant Data by WHO and the Data Analysts, subject (in the case of Data Analysts) to the terms of the Data Access Agreement; and
- (f) ensure that each Data Access Agreement obliges the Data Analyst to carry out research using the Relevant Data in accordance with all applicable laws and regulations and with applicable TB-IPD guidelines.

4.2. The Data Curator shall be responsible for obtaining all applicable ethical and regulatory approvals necessary to perform its obligations under this DSA and shall ensure that its use of Relevant Data for the purposes of this DSA complies with all applicable laws and regulations.

#### 5. **DATA CONTRIBUTOR RIGHTS**

5.1. As between the Data Curator and the Data Contributor, the Data Contributor shall remain the owner of the Relevant Data and nothing in this DSA shall prevent or restrict the Data Contributor from using the Data for its own purposes, including but not limited to publication of the Relevant Data or distribution of the Relevant Data to third parties for any purposes.

5.2. The Data Contributor acknowledges and understands that Relevant Data:

- (a) will be assimilated by the Data Curator within the TB-IPD Platform;
- (b) will be used by the Data Curator in its role of setting up, hosting and managing the TB-IPD Platform for and on behalf of the WHO; and
- (c) may be accessed and used by the WHO and the Data Analysts in connection with the Purpose.

5.3. The Data Contributor may request at any time that the Data Curator removes Relevant Data assimilated within the TB-IPD Platform from the TB-IPD Platform. Subject to Clause 5.4, promptly following receipt of any such request, the Data Curator will remove the Relevant Data from the TB-IPD Platform and either destroy or return to the Data Contributor the Relevant Data (as instructed by the Data Contributor).



- 5.4. The Parties agree that where the Data Contributor exercises its right to request the removal of Relevant Data pursuant to Clause 5.3:
- (a) where any Data Access Agreements are in place in respect of the Relevant Data, the Relevant Data will remain within the TB-IPD Platform and may be used by the affected Data Analysts in accordance with the terms of those Data Access Agreements until the termination or expiry of all such Data Access Agreements, as applicable (unless a longer retention period is required in accordance with Clause 5.4(b), in which case that longer retention period shall apply); and
  - (b) where applicable, copies of the Relevant Data may be stored and used:
    - (i) by Data Analysts who have entered into a Data Access Agreement in respect of the Relevant Data; and
    - (ii) by the Data Curator within the TB-IPD,  
  
for the retention periods required by relevant third party funders and host organisations in order to satisfy applicable requirements relating to data integrity and research reproducibility. This includes the Data Curator retaining archived copies of previous versions of the TB-IPD.

## 6. PUBLIC STATEMENTS

The Data Contributor acknowledges that once the Relevant Data has been assimilated within the TB-IPD Platform the Data Contributor may be publicly acknowledged by the Data Curator and the WHO as the attributor of the Relevant Data.

## 7. DATA CONTRIBUTOR RESPONSIBILITIES AND WARRANTIES

7.1. The Data Contributor warrants and undertakes that:

- (a) it has the right, power and authority to provide to the Data Curator the Relevant Data and for the Relevant Data to be used for the purposes contemplated by this DSA, including the Purpose;
- (b) Relevant Data:
  - (i) shall be effectively anonymised in accordance with the standards set out in Schedule 3 so as to avoid possible re-identification of any of the Relevant Data; and
  - (ii) has been collected in compliance with all applicable laws, statutes, rules, regulations and legal, ethical and/or medical standards or requirements;
- (c) it has obtained all approvals, informed consents, licences and permits which are necessary for it to be able to share the Relevant Data, and for the Relevant Data to be used, for the purposes contemplated by this DSA, including the Purpose; and
- (d) where applicable, the study/processes leading to the collection of the Relevant Data have been reviewed by a competent institutional review board.

7.2. The Data Contributor shall indemnify the Data Curator from and against all costs (including the cost of bringing or defending any legal action), damages, losses and expenses suffered or incurred by the Data Curator arising out of or in connection with:

- (a) the Data Curator's use of the Relevant Data in accordance with the provisions of this DSA;
- (b) any claim made or threatened alleging that the use of the Relevant Data as contemplated by this DSA constitutes an infringement or other violation of any rights of any third party.

7.3. Each Party shall indemnify the other Party from and against all costs (including the cost of bringing or defending any legal action), damages, losses and expenses suffered or incurred arising out of or in connection with any breach by the indemnifying Party of its obligations under this DSA.

## 8. **CONFIDENTIALITY**

- 8.1. Each Party shall hold in confidence all Confidential Information obtained from the other Party. Neither Party shall disclose to any third party any Confidential Information in relation to the other Party save as expressly permitted by this DSA or with the prior express written permission of the other Party.
- 8.2. The provisions of Clause 8.1 shall not apply to any information which:
- (a) is or becomes public knowledge other than by breach of this Clause 8;
  - (b) is already in the possession of a Party without restriction in relation to disclosure before the date of its receipt from the other Party; or
  - (c) is received from a third party who lawfully acquired or developed it and who is under no obligation restricting its disclosure.
- 8.3. A Party may disclose Confidential Information in relation to the other Party:
- (a) except as otherwise expressly stated in this DSA, to those of its officers, employees, professional advisers, parent or subsidiary companies, or agents or sub-contractors as may be reasonably necessary for the purpose of fulfilling its obligations under this DSA or, in the case of professional advisors, for use in their professional capacity, provided that before any such disclosure that Party shall make such officers, employees, professional advisers, parent or subsidiary companies, or agents or sub-contractors aware of its obligations of confidentiality under this DSA and shall at all times procure compliance by those persons with them; or
  - (b) where such disclosure is required by any law, court order or competent regulatory authority.
- 8.4. Without prejudice to the other rights of the disclosing Party, in the event of unauthorised disclosure or use of its Confidential Information occurring directly or indirectly through disclosure made to the receiving Party, the receiving Party shall (as soon as it becomes aware of the same) notify the disclosing Party of such unauthorised disclosure and use all reasonable endeavours to assist the disclosing Party in recovering and preventing the use of, dissemination, sale or other disposal of such Confidential Information.
- 8.5. Unless required to do so by applicable laws, neither Party shall make public the details of the terms or the operation or circumstances of termination of this DSA without the other Party's prior written consent. For clarity, this Clause shall not prevent the Data Contributor from stating on its website that a particular dataset is no longer included within the TB-IPD.

## 9. **LIABILITY**

- 9.1. To the extent permitted by applicable law, the Data Curator shall not be liable to the Data Contributor for any use of the Relevant Data by any third party save where the Data Curator has knowingly given such third party access to the Relevant Data in breach of its obligations under this DSA.
- 9.2. To the extent permitted by applicable law, neither Party shall be liable to the other Party under or in connection with this DSA for:
- (a) any loss of profit, loss of business opportunity, loss of anticipated revenue or savings, loss of or damage to data and/or loss of or damage to goodwill arising out of or in connection with this DSA; or
  - (b) any indirect or consequential loss or damage arising out of or in connection with this DSA.
- 9.3. To the extent permitted by applicable law, each Party's total liability to the other Party under or in connection with this DSA (whether such liability arises under any statute or in contract, tort (including negligence) or otherwise) shall be limited to £100,000.

## 10. **INTELLECTUAL PROPERTY RIGHTS**

10.1. The Parties acknowledge and agree that the Research Results shall be owned by the Data Analyst creating such rights in accordance with the terms of the Data Access Agreement signed by each Data Analyst.

## 11. PUBLICATIONS

11.1. The Data Curator may publish on its website materials received from Data Analysts including:

- (a) copies of any written reports received from Data Analysts describing their use of the Relevant Data and/or any benefits derived therefrom; and
- (b) any Research Results that are notified to it by Data Analysts in accordance with the terms of the relevant Data Access Agreement.

In such circumstances the Data Curator shall give the Data Contributor due attribution.

11.2. Subject to Clause 11.3, Data Contributor acknowledges that Data Analysts and the WHO may publish the results derived from their use of the Relevant Data (including the Research Results) without the consent of Data Contributor.

11.3. The parties acknowledge that the Data Access Agreement requires that the Data Analyst shall: (a) acknowledge the use of the TB-IPD in all official publications and outputs relating to the Research Results in the manner prescribed by the Data Curator; (b) inform the Data Curator of all official publications and outputs relating to the Research Results; and (c) give the Data Contributor due attribution in all publications relating to the Research Results.

## 12. TERM AND TERMINATION

12.1. This DSA shall commence on the date of this DSA and shall continue until terminated in accordance with the terms and conditions of this DSA.

12.2. This DSA shall automatically terminate on the date that the Data Curator ceases to operate the TB-IPD Platform on behalf of WHO.

12.3. Either Party may terminate this DSA without cause at any time by giving at least 30 days' written notice of such termination to the other Party.

12.4. Either Party may terminate this DSA with immediate effect by giving written notice of such termination to the other Party if the other Party commits a material breach of any of the terms of this DSA and either that breach is not capable of remedy or, if the breach is capable of remedy, the other Party fails to remedy that breach within 14 days of being notified of the breach.

## 13. EFFECTS OF TERMINATION

13.1. The termination of this DSA shall not prejudice or affect any right of action or remedy which shall have accrued up to the date of termination.

13.2. Subject to Clause 13.3, promptly following termination of this DSA, the Data Curator shall remove all Relevant Data assimilated within the TB-IPD Platform from the TB-IPD Platform and then destroy the Relevant Data.

13.3. The Parties agree that Relevant Data may be retained within the TB-IPD Platform after this DSA has terminated in the following circumstances:

- (a) where any Data Access Agreements are in place in respect of the Relevant Data, the Relevant Data will remain within the TB-IPD Platform and may be used by the affected Data Analysts in accordance with the terms of those Data Access Agreements until the termination or expiry of all such Data Access Agreements, as applicable (unless a longer retention period is required in accordance with Clause 13.3(b), in which case that longer retention period shall apply); and

- (b) where applicable, copies of the Relevant Data may be stored and used:
- (i) by Data Analysts who have entered into a Data Access Agreement in respect of the Relevant Data; and
  - (ii) by the Data Curator within the TB-IPD,

for the retention periods required by relevant third party funders and host organisations in order to satisfy applicable requirements relating to data integrity and research reproducibility. This includes the Data Curator retaining archived copies of previous versions of the TB-IPD.

13.4. Clauses 1, 7 to 11 (inclusive) and 13 to 15 (inclusive) shall survive termination of this DSA and shall continue to apply as shall any other provision which by its nature is intended to survive termination.

**14. NOTICES**

14.1. Any notice required by this DSA to be given by either Party to the other shall be in writing and shall be delivered by hand or sent by recorded delivery post or e-mail to the other Party at the address set out below or otherwise notified by the other Party in accordance with this Clause 14 from time to time.

Data Curator	Data Contributor
The Dean, UCL School of Life and Medical Sciences Gower Street London WC1E 6BT Tel: +44 (0) 2076792000 Email: <a href="mailto:fphs.pa@ucl.ac.uk">fphs.pa@ucl.ac.uk</a>	[insert]

14.2. Any notice served under this DSA shall be deemed to have been received (i) if delivered by hand, immediately upon delivery during the other Party's usual business hours; (ii) if sent by recorded delivery post, two Business Days following delivery; or (iii) if sent by e-mail, when it is actually received by the recipient.

**15. GENERAL**

15.1. Neither Party shall assign, novate, sub-contract or otherwise dispose of any or all of its rights and obligations under this DSA without the prior written consent of the other Party.

15.2. A person who is not a party to this DSA shall have no rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this DSA.

15.3. This DSA, together with the documents referred to in it, constitute the entire DSA between the Parties in respect of its subject matter and supersede all previous negotiations, DSAs and commitments with respect thereto.

15.4. This DSA shall not be construed as giving rise to the relationship of principal and agent (save as otherwise expressly provided herein) or partnership or joint venture.

15.5. If any provision of this DSA or the application thereof to any Party or circumstance shall be declared void, illegal or unenforceable, the remainder of this DSA shall be valid and enforceable to the extent permitted by applicable law. In such event, the Parties shall use their best efforts to replace the invalid or unenforceable provision by a provision that, to the extent permitted by applicable law, achieves the purposes intended under the invalid or unenforceable provision.

15.6. No delay or failure by a Party in exercising or enforcing any right or remedy under the terms and conditions of this DSA will be deemed to be a waiver of any such right or remedy, nor will that failure operate to bar the exercise or enforcement of such right or remedy at any future time.

- 15.7. A change to this DSA will only be effective if it is recorded in writing and signed by an authorised representative of each of the Parties.
- 15.8. This DSA may be executed in counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.
- 15.9. This DSA and any dispute or claim arising out of or in connection with it or its subject matter or formation (including, without limitation, non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of England and Wales.
- 15.10. Each Party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this DSA and its subject matter or formation (including non-contractual disputes or claims).

## Schedule 1: Data Protection Particulars

<b>The subject matter and duration of the Processing</b>	Personal data is Processed by the Data Curator only in order to review the Relevant Data and: (i) securely delete or return the Relevant Data to the Data Contributor; or (ii) effectively anonymise any Relevant Data which contains Personal Data in accordance with Clause 3.1. The Processing will last for the time required in order to securely delete, return or effectively anonymise (as applicable) the Relevant Data.
<b>The nature and purpose of the Processing</b>	Any Personal Data contained within the Relevant Data will be Processed so that the Data Curator may either: (i) securely delete or return the Relevant Data to the Data Contributor; or (ii) effectively anonymise the Relevant Data prior to the inclusion of the Relevant Data in the TB-IPD, in order to ensure that only effectively anonymised information is included in the TB-IPD.
<b>The type of Personal Data being Processed</b>	The main types of Personal Data being Processed are participant names, contact details and information about participants.
<b>The categories of Data Subjects</b>	Participants in relevant research studies.

## Schedule 2: Description of Relevant Data

**[Note: to be completed by Data Contributor]**

### Acknowledgement of Data Contributor:

1. Name of the Relevant Data: \_\_\_\_\_
2. Names of key personnel to be acknowledged and/or funding acknowledgement for the Data Contributor in any publication by either the Data Curator or the Data Analyst:  
\_\_\_\_\_
3. Any publications that should be cited in association with the Relevant Data:  
\_\_\_\_\_

### Description of the Relevant Data

Data description (type of study, dates, setting etc): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

The number of participants included: \_\_\_\_\_

Relevant Data file format (csv, Excel or other): \_\_\_\_\_

In addition, for clinical trials, where applicable, please include protocol ID number, clinicaltrials.gov record locator and/or equivalent clinical trial registration reference number for all clinical studies being contributed:  
\_\_\_\_\_

### Release of the Relevant Data

All data are available immediately to Data Analysts approved by the WHO for the purpose of informing future WHO TB treatment guidelines. Data are available for onward sharing to Data Access Committee approved Data Analysts:

Immediately

After embargo date: \_\_\_ / \_\_\_ / \_\_\_\_\_

### Supporting documentation

Please indicate any supporting documentation that will be sent with the data:

- data dictionaries/codebooks
- CRFs
- Protocols for data collection
- Other: \_\_\_\_\_

### **Schedule 3: Minimum requirements for effective anonymisation**

This Schedule sets out the minimum measures to be taken by the Data Contributor in order to effectively anonymise Data prior to submitting it to the Data Curator.

#### **1. Removal of identifiers**

The following identifiers of individuals or the individual's relatives, employers, or household members must be removed from the Data prior to submitting it to the Data Curator:

- Names.
- Postal address information, other than town or city, state, and postal code.
- Telephone numbers.
- Fax numbers.
- Electronic mail addresses.
- Social security numbers or other government identification credentials.
- Medical record numbers.
- Health plan beneficiary numbers.
- Account numbers.
- Certificate/license numbers.
- Vehicle identifiers and serial numbers, including license plate numbers.
- Device identifiers and serial numbers.
- Web universal resource locators (URLs).
- Internet protocol (IP) addresses numbers.
- Biometric identifiers, including fingerprints and voiceprints.
- Full-face photographic images and any comparable images.

#### **2. Further issues to consider**

In addition, Data Contributors may consider whether inclusion of the following data are necessary or need to be as granular:

- Geographic subdivisions smaller than a state or province (i.e., county, city, town, precinct).
- 5 or 9-digit ZIP or postal codes.
- All elements of dates directly related to an individual, including birth or death.
- Any other unique identifying number, characteristic or code that could be used by a researcher to identify the individual.

For clinical trial data or observational cohorts data, Data Contributors may also consider replacing date of birth by age at entry in to the study, or dates during follow-up by the number of days from randomisation/enrolment or start of treatment.