IDDO Data Platform Data Transfer Agreement
(the “Data Transfer Agreement”)

DATA TRANSFER AGREEMENT (DTA) MADE ON THE DATE OF LAST SIGNATURE
(“Effective Date”) TO THIS AGREEMENT IS BETWEEN:

(1) THE CHANCELLOR MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD,
whose administrative office is at University Offices, Wellington Square, Oxford, OX1 2JD, United Kingdom (the “University”) on behalf of; and

(2) The National Institute of Allergy and Infectious Diseases, National Institute of Health
whose principle investigator is Lori E. Dodd, Ph.D., and whose administrative office is at
5601 Fishers Lane, Suite 6D, Rockville, MD 20892 (“the Data Requestor”)

BACKGROUND

(A) The ‘Ebola Data Platform’ is a global data sharing initiative set up to accelerate research work into Ebola Virus Disease (EVD) and set standards for prospective data collection in the event of another outbreak.

The platform receives EVD data from any members of the research, health and humanitarian communities who contributes individual patient level data to the IDDO EVD platform (Data Contributor) and standardises this into a uniform structure, collated on a single platform accessible to the scientific, health and humanitarian communities for pooled analysis, to maximise the scientific potential and statistical power of research.

(B) The University, on behalf of the Ebola Data Platform, wishes to make available the dataset requested by the Data Requestor and approved for release by the Data Access Committee (DAC), and the Data Requestor wishes to access the dataset, on the terms set out below.

(C) The Data Access Committee is an independent group of experts, appointed by Wellcome (Funder of the Platform) to make decisions on applications for platform data access.

2. PURPOSE OF DATA TRANSFER

2.1 The Data Requestor will hold the Data in trust, on the terms of this agreement solely for the purpose of the Research Proposal set out in their approved application, and not use the Data to carry out any other studies without prior written approval from the DAC and the University.

2.2 The Data Requestor shall not use Data for the development and/or regulatory approval of medical or clinical products, diagnostics or for commercial or for profit purposes unless expressly approved through the application process for Data access.
2.3 Any changes to the proposed analysis, collaborators, or other details of the research included in the application should be submitted to the Data Access Committee for approval prior to initiation.

3. **DATA TRANSFER AND RIGHTS GRANTED**

3.1 Data custody/ownership will remain with the Data Contributor. Transfer of data does not create any ownership rights for the recipient and does not alter any custody arrangement.

3.2 This DTA does not restrict the University’s right to distribute the Data to other commercial or non-commercial entities.

3.3 The Data Requestor understands that the University makes no representations and gives no warranties of any kind in relation to the Data: for example, no warranties are given about quality or fitness for a particular purpose; or that the use of the Data will not infringe any intellectual property or other rights. The University will not be liable for any use made of the Data.

4. **UNIVERSITY OBLIGATIONS**

4.1 The Ebola Data Platform must comply with the U.K. laws and regulations, and the European Union legal and regulatory framework, in particular (but not limited to) the rules and regulations governing the protection of personal data, clinical trials, research and the protection of human rights.

4.2 The Ebola Data Platform also abides by the Oxford University policies reflecting these U.K. and European laws and regulations, which can be found on the Oxford’s Central University Research Ethics Committee (CUREC)’s website at www.admin.ox.ac.uk/curec.

5. **DATA REQUESTOR OBLIGATIONS**

5.1 Data requestors and recipients of EVD data from the Platform shall be required, to observe the highest standards of ethics and integrity in the course of their Research using EVD data, to promote the respect of human rights, the protection of human dignity and privacy, and to maximise the public benefit of Research while minimising the risks of adverse effects and ensuring the safety of all those involved directly or indirectly in the Research.

5.2 Data requestors and recipients are expected to comply with their country’s ethical and legal obligations. However, no national ethical, legal or regulatory requirement can be invoked to justify reducing or eliminating the level of protection for all involved directly or indirectly in the Research.

If the European Convention on Human Rights and Biomedicine (1997) and its Additional Protocols (together, the Oviedo Convention system – [http://www.coe.int/en/web/bioethics/oviedo-convention](http://www.coe.int/en/web/bioethics/oviedo-convention) ) have not been ratified and implemented into the recipients’ national laws and regulations as minimum ethical and legal standards, and the requestors’ national legal and regulatory framework does not incorporate the principles of the Declaration of Helsinki, the requestors shall be expected to pledge compliance with the provisions of the Oviedo Convention system or the Declaration of Helsinki, Oxford University’s policies or a set of no less morally stringent ethical standards.
5.3 The Data Requestor will not transfer the Data to any other body, or third party(ies) or permit its use other than by by the individuals listed in the approved Application, without (in each case) prior written consent from the DAC and University.

5.4 Data Requestors will secure the Data, and shall ensure the Data is not used or stored at any facility which would enable access to anyone not listed on the approved Data Access Application.

6. CONFIDENTIALITY

6.1 Data Requestors shall not attempt to contact or identify any Subject (living or deceased), individual in the Subject’s community, community member, or Data Contributor. If such contact is required to pursue the research, this should be explicitly approved by the relevant research ethics committee(s) and the Data Access Committee.

6.2 Data Requestors must agree not to link the Data provided with any other data unless such link has been clearly declared in the application.

7. PUBLICATION AND TRANSPARENCY

7.1 Data Requestors are expected to submit the results of their research to a peer reviewed publication (“Publication”) within the timescale of the publication plan detailed in the approved application.

7.2 Data Requestors will take reasonable steps to see that all Publications are openly available without cost to the reader, and will use their best efforts not to enter into any copyright agreement that unreasonably restricts access in any way to electronic versions of any Publications, notably in light of potential public health benefits of releasing results immediately and without restrictions. It is understood that proper acknowledgement of the original researchers will be made.

7.3 To the extent permitted by law, any Publication or presentation using Platform Data shall include an acknowledgement using the following text (or a reasonable variation thereof): “This Research includes data provided by the IDDO Ebola Data Platform and the International Severe Acute Respiratory and Emerging Infections Consortium (ISARIC), not otherwise research partners or party to this Research” unless Data Contributor objects to such acknowledgement within 10 business days following receipt by the Data Requestor of the draft Publication.

7.4 Any other reference to names, logos, or any adaptation of Platform or Data Contributor trademarks requires prior authorisation of those entities.

7.5 Data Requestors should provide the Platform with a copy of all Research Output(s) and Publication(s) based on Data within an acceptable timeframe and not later than 1 month after the publication or public release of the Research Output or Publication.

7.6 The University and Data Contributors may, after appropriate discussion and agreement (which shall not be unreasonably withheld) by NIAID, and in compliance with any applicable copyright, reproduce the contents of approved applications and outputs, on their websites or other media with attribution to the Data Requestor(s).

8. INTELLECTUAL PROPERTY

8.1 The primary purpose of Data made available to requestors is to generate evidence that fills knowledge gaps of importance to those affected by or at risk of emerging and poverty-
related diseases. It is not expected that commercial outputs will result from use of Data. Access to Data will be granted on the basis of this assumption.

8.2 Should a Data Requestor wish to pursue intellectual property claims or rights on any output resulting from use of the Data, the DAC has to be notified and the University of Oxford needs to be contacted to discuss relevant conditions and terms in advance of this pursuit.

9. **LIABILITY**

9.1 The liability of either party for any breach of this DTA, or arising in any other way out of the subject matter of this DTA, will not extend to events such as loss of business or profit, or to any indirect or consequential damages or losses incurred by the University or Requestor.

9.2 Without prejudice to paragraph 3.3 to the extent permitted by law, the liability of the University to the NIAID for any breach of this DTA, or arising in any other way out of the subject matter of this DTA, will not exceed the maximum amount of £10,000.

10. **TERMINATION**

10.1 The University has the right to terminate this DTA at any time by means of written notice to the Data Requestor. Otherwise DTA will terminate 18 months after the Effective Date.

10.2 On termination of this DTA, the Data Requestor shall immediately cease all use of the Data and delete the Data from the Data Requestor’s servers and will erase, delete or otherwise destroy all copies of the Data in whatever format and confirm to the University that this has been done.

11. **GENERAL**

11.1 Non-compliance with the DTA by the Data Requestor may result in reporting of non-compliance to the Data Requestor’s institution, relevant ethical committees, and/or journals where any relevant work is published.

11.2 Legal action against non-compliance with the DTA may be pursued by the University of Oxford.

11.3 The University and the Data Requestor have executed this Agreement through their duly authorised representatives.

**Accepted and Agreed on behalf of**

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The Chancellor, Masters and Scholars of the University of Oxford

Name:

Position:
DRAFT
SCHEDULE 1 - DESCRIPTION OF DATA TO BE TRANSFERRED

Open-label, single arm trial to investigate the efficacy of TKM-130803 with a concurrent observational study of Ebolavirus Disease in Sierra Leone”

**IDDO Study ID: EORKWS**

Two files will be transferred:

1. **RAPIDE TKM Data Repository Dictionary V1.2 22Aug2016 (4841KB)**
   
   This file is the data dictionary to accompany the dataset.

2. **TKM All Data 01Aug2016.csv (490KB)**
   
   This data file contains:
   - 55 variables
   - 5912 rows
   - 17 unique patient IDs